CR 85-132

CERTIFICATE

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

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Linda Reivitz, Secretary of the Department of Health and Social Services and custodian of the official records of said Department, do hereby certify that the annexed rules relating to criteria for the review of applications to purchase a magnetic resonance imaging device or an extracorporeal shock wave lithotriptor for use in medical diagnosis or treatment were duly approved and adopted by this Department on January 30, 1986.

I further certify that this copy has been compared by me with the original on file in this Department and that the same is a true copy thereof, and of the whole of such 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 30th day of January, 1986.

SEAL:

Linda Reivitz, Secretary
Department of Health and Social Services

4-1-86

ORDER OF THE

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
REPEALING, RENUMBERING, AMENDING AND CREATING RULES

To repeal HSS 123.05(6)(a)1 and 2 and (d), and 123.08(10)(b)2; to renumber and amend HSS 123.08(10)(b)1; to amend HSS 123.22(1) and (4); and to create HSS 123.24 and 123.25, relating to criteria for the review of applications to purchase a magnetic resonance imaging device or an extracorporeal shock wave lithotriptor for use in medical diagnosis or treatment.

Analysis Prepared by the Department of Health and Social Services

Under s. 150.61(3), 1983 Stats., no one may enter into an obligation for the purchase by or on behalf of a hospital, independent practitioner, partnership, unincorporated medical group or a service corporation as defined in s. 180.99, Stats., of medical equipment costing more than $624,000. That approval threshold will be raised to $1 million effective January 1, 1986, pursuant to the amendment of the statute by 1985 Wisconsin Act 29 and 72.

In this rule-making order, the Department is adding two sections to its rules for implementation of subch. III of ch. 150, Stats., the capital expenditure review program, in order to provide specialized criteria for review of applications to purchase two very expensive types of medical equipment, the magnetic resonance imaging (MRI) device and

the extracorporeal shock wave lithotriptor (ESWL). The criteria are intended to help the Department restrain increases in health care costs.

A magnetic resonance imaging device is a diagnostic tool that employs magnetic and radio frequency fields to produce images of body structures and organs. The cost of such a device currently ranges between $1 million and $2 million. An extracorporeal shock wave lithotriptor is a treatment-assisting device that generates shock waves which break up urinary stones. The cost of this device is currently $1.75 million.

Section HSS 123.24 identifies the criteria that the Department will employ in its review of MRI applications, and s. HSS 123.25 identifies the criteria the Department will employ in its review of ESWL applications. The criteria in both areas are shown under the headings of need for the service, the requisite resources to provide it, and demonstration of financial feasibility. In the case of the extracorporeal shock wave lithotriptor, no more than 2 will be approved in the state, they cannot be in the same health planning area, and a service must have a volume of at least 800 procedures a year within 3 years after being started.

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, renumbers, amends and creates rules interpreting ss. 150.01 to 150.15 and 150.61 to 150.75, Stats., as follows:

SECTION 1. HSS 123.05(6)(a)1 and 2 and (d) are repealed.

SECTION 2. HSS 123.08(10)(b)1 is renumbered 123.08(10)(b) and, as renumbered, is amended to read:

HSS 123.08(10)(b). ~~Except as provided in subd. 2, the~~ The department shall base concurrent review on a comparative analysis of the applications under all applicable review criteria set forth in this chapter. If, after removing from consideration all applications which fail to meet one or more applicable review criteria, there remain more applications than can be approved under applicable need criteria, the department shall rank the remaining applications according to how each meets each applicable review criterion, assigning the lowest number to the application which best meets each criterion. Applications shall be approved in order beginning with the lowest total score, until all need is met. If there is a tie between applications for the last available approval, the department shall rank the applications according to their scores on review criteria under s. 150.69(5), Stats.

SECTION 3. HSS 123.08(10)(b)2 is repealed.

SECTION 4. HSS 123.22(1) and (4) are amended to read:

HSS 123.22 NEW MEDICAL TECHNOLOGY CRITERIA. (1) USE. The criteria set out in ~~and adopted under~~ this section shall be used by the department to review applications for approval to acquire technology determined under s. HSS 123.05(6) no longer to constitute innovative medical technology~~,~~ unless technology-specific criteria have been adopted under sub. (4). The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

HSS 123.22(4) TECHNOLOGY-SPECIFIC CRITERIA. The department finds that the public health and welfare necessitates adopting rules governing acquisition of technology under this section pursuant to the emergency rule-making procedures set forth in s. 227.027, Stats. The department may publish emergency rules pursuant to this subsection on or after the effective date of the rule adopted under s. HSS 123.05(6)(b) determining the technology no longer to be innovative medical technology. Rules adopted under this subsection shall set forth technology-specific criteria to be used in the review of applications subject to this section and shall consider cost containment as the first priority. ~~This subsection does not apply to magnetic resonance imaging (MRI).~~

SECTION 5. HSS 123.24 and 123.25 are created to read:

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 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 percent of these discharges for any hospital; and

2. Determining the estimated annual total number of MRI procedures by multiplying the number obtained under subd. 1. by 1.6666, to arrive at estimated total procedures, including outpatient procedures.

(c) The department shall not approve an application under this section unless the applicant provides referral agreements with appropriate physicians and clinics indicating a commitment to use the MRI service or refer patients to the MRI service. These agreements shall include estimates of the number of MRI scans for patients of each member of the applicant's medical staff and for patients referred by in-state and out-of-state physicians.

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

(a) The applicant proves that the proposed MRI device has been classified by the U.S. food and drug administration as a class I, class II or class III device under 21 USC 360c to k;

(b) The applicant provides written documentation that the area housing the MRI device, including necessary arrangements for mobile MRI equipment, will be constructed in accordance with standards established by the U.S. food and drug administration, the manufacturer and the national electrical manufacturers association and in accordance with applicable federal and state standards;

(c) The applicant includes with the application a written plan for an ongoing quality assurance program for MRI which includes at least the following:

1. A safety manual governing the equipment and its location, providing coverage of security measures and hazards;

2. Procedures for managing emergencies within the MRI facility or with mobile equipment, in conformity with accepted medical practices; and

3. Protocols that ensure that all MRI scans performed are medically necessary and will not unnecessarily duplicate other services;

(d) The applicant documents that adequate numbers of at least the following personnel will be available, either through direct employment or through an agreement with the manufacturer or a service contract,

consistent with the applicant's projected utilization determined under sub. (3)(b), patient needs and the facility's operational needs:

1. A director of the MRI service who is a board-certified or board-eligible radiologist, whose primary responsibility over the last 3 years has been in the interpretation of cross-sectional imaging for all body areas and who has had at least 60 hours of instruction in the methods and principles of MRI at a facility with an operational MRI device;

2. One or more licensed physicians who have attained a thorough knowledge of the methods and principles of MRI through continuing medical education (CME) credits, experience or post-graduate education which qualifies them to interpret MRI scans in the specialty field appropriate to each physician;

3. A medical physicist who is certified by the American board of radiology and has a thorough knowledge of MRI techniques; and

4. Technologists who have been specially trained in MRI methods;

(e) The applicant demonstrates that MRI will function as an integrated component of a comprehensive diagnostic imaging inpatient or outpatient service, by documenting in writing that it has access, either on-site or through formal referral arrangements, to equipment and personnel for conventional radiology, computed tomography, ultrasound, angiography and nuclear medicine;

(f) The applicant demonstrates that the proposed MRI service will serve as a regional resource for physicians by providing the department with the following:

1. A written plan for a system of referrals, which shall include a feedback mechanism for providing patient information to the referring physician and facility;

2. A written plan for maintaining current listings of appropriate clinical applications of MRI for the guidance of on-site and referring physicians and facilities; and

3. A written plan for a continuing education and training program, which shall include education of all interested physicians in the specific indications and contraindications of MRI use; and

(g) The applicant provides a written plan for scheduling patients that ranks patients in order of priority according to standards of need and appropriateness rather than source of referral.

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

(a) Documenting that the projected average total cost per MRI procedure, including but not limited to fixed and variable operating costs, is similar to costs for similar MRI services provided in similar

settings. In projecting the average total cost per MRI procedure, the applicant shall base this calculation on the projected utilization determined under sub. (3)(b);

(b) Documenting that the projected average charge per MRI procedure, excluding the charges for professional fees, ancillary services and hospitalization, is similar to charges for similar MRI services provided in similar settings;

(c) Documenting the projected overall charge per MRI procedure, which includes at least the average charge per MRI procedure under par. (b) plus charges for professional fees; and

(d) Documenting the net financial impact on its hospital rates, if the applicant is hospital-based.

(6) MOBILE MRI EQUIPMENT. For an application relating to mobile MRI equipment, the applicant shall be the person acquiring the MRI equipment.

(7) CONCURRENT REVIEW. The provisions in s. HSS 123.08(10) shall be used for concurrent review when there are 2 or more applications. The department shall approve the application or applications receiving the highest score based on a comparative analysis of the applications using all applicable review criteria in s. HSS 123.13, the review criteria in subs. (3) to (6) and the following special review criteria:

(a) Preference shall be given to the application proposing a multifacility or shared service arrangement and, if more than one application proposes a multifacility or shared service arrangement, the one that provides written documentation demonstrating the greatest number and diversity of patient referrals from referring specialists;

(b) Preference shall be given to the application providing the best geographical accessibility for the population being served in the health service area as determined by an analysis by the department of the geographical market areas that have been identified by each applicant as areas where the applicant intends to focus its resources and marketing strategies for the proposed MRI device. Each applicant shall provide the department with the number of anticipated patient referrals from each identified market area and the patient origin by county for all referrals; and

(c) Preference shall be given to the application providing the greatest number of MRI scan hours per week in relation to the number of qualified staff set forth in sub. (4)(d).

(8) DATA REPORTING REQUIREMENTS. All entities in the state having MRI shall provide the department and the appropriate HSA with data relating to the number of patients served, patient utilization, operating costs, patient origin and any other information deemed necessary by the department to determine compliance with this section. The information shall be provided, upon request, in a format prescribed by the department for purposes of evaluation and project review. The department may not request the information more often than twice a year.

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

APPENDIX F

METHODOLOGY FOR DETERMINING THE NUMBER OF

CLINICALLY-APPLICABLE MRI DISCHARGES

[s. HSS 123.24(3)(a) and (b)]

Major ICD-9-CM Groupings		Inpatient MRI Utilization Weights
001-139	Infectious and parasitic diseases	6.25%
140-239	Neoplasms	20.93%
290-319	Mental disorders	.11%
320-389	Diseases of the nervous system and sense organs	11.46%
390-459	Diseases of the circulatory system and connective tissue	15.29%
710-739	Diseases of the musculoskeletal system and connective tissue	7.78%
740-759	Congenital anomalies	1.99%
800-999	Injury and poisoning	.56%

The methodology to determine the number of inpatient clinically-applicable MRI discharges is as follows:

1. Count the number of principal diagnosis inpatient discharges that correspond to each major grouping of ICD-9-CM codes listed above; and

2. Multiply the number for each major grouping by the corresponding inpatient MRI utilization weight and add the products together to produce the number of inpatient clinically-applicable MRI discharges.

Note: ICD-9-CM codes refer to the standard disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics. The major ICD-9-CM groupings and inpatient MRI utilization weights are based on the work of a panel of experts and high correlation averages as reported in the American Hospital Association's publication, NMR - Issues for 1985 and Beyond.

HSS 123.25 EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY CRITERIA. (1) USE. The criteria set out in this section shall be used by the department to review applications relating to extracorporeal shock wave lithotripsy. The applicable criteria of s. HSS 123.13 shall also be used in the review of applications subject to this section.

(2) DEFINITIONS. In this section:

(a) "ESWL procedure" means one patient treatment which includes setup time, using a computerized fluoroscopic x-ray system to position the stone in the passage of the shock waves and to monitor stone destruction, coordinating the shock waves with the electrocardiogram, delivering the shock waves and cleanup time.

(b) "Extracorporeal shock wave lithotripsy" or "ESWL" means a noninvasive technique for disintegrating urinary stones by focusing shock waves on a urinary stone from outside the body.

(c) "Lithotriptor" means the device used to generate the shock waves which disintegrate the urinary stones.

(d) "Percutaneous stone surgery" means removal of urinary stones by means of an incision through the skin rather than by ESWL.

(e) "Urinary stones" mean renal or kidney and ureteral calculi.

(3) NEED FOR EXTRACORPOREAL 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 two ESWL procedures. The department shall analyze the 3-year utilization projection based on written documentation provided by the applicant which includes:

1. The proposed area from which the applicant will draw its patients, including other states;

2. A description of the assumptions and methodology used to project utilization; and

3. The projected utilization from the proposed area under subd. 1. substantiated by referral agreements with appropriate physicians indicating their intent to use the lithotriptor or refer their patients to the lithotriptor. These agreements shall include estimates of the number of ESWL procedures for patients of each member of the applicant's medical staff and for patients referred by in-state and out-of-state physicians.

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

(a) The applicant proves that the proposed lithotriptor has been classified by the U.S. food and drug administration as a class I, class II or class III device under 21 USC 360c to k;

(b) The applicant provides written documentation that the area housing the lithotriptor, including necessary arrangements for mobile ESWL equipment, will be constructed in accordance with standards established by the U.S. food and drug administration and the manufacturer and in accordance with applicable federal and state standards;

(c) The applicant includes with the application a written plan for an ongoing quality assurance program for ESWL which includes at least the following:

1. A safety manual governing the equipment and its location, providing coverage of security measures and hazards;

2. Procedures for managing emergencies within the ESWL facility or with mobile equipment, in conformity with accepted medical practices; and

3. Protocols that ensure that all ESWL procedures performed are medically necessary and will not unnecessarily duplicate other services;

(d) The applicant documents that at least the following personnel will be available when patients are undergoing treatment:

1. A urologist who has attained a thorough knowledge of extracorporeal shock wave lithotripsy either by documented specific training or postgraduate education and experience;

2. An anesthesiologist; and

3. A technician with documented education and experience in radiology and lithotriptor technology;

(e) The applicant demonstrates in writing that it is able to provide the following care as needed for the patient to sustain operation of the ESWL service:

1. Medical services, which include at least:

a. Anesthesiology;

b. Cardiology;

c. Radiology, including diagnostic x-ray, fluoroscopy, intravenous pyelogram tomography, ultrasound, and placement of percutaneous nephrostomy for percutaneous stone surgery; and

d. Urology, capable of performing percutaneous nephrostomy, ureteroscopy, medical management of calculi, transurethral ureteral manipulation of the calculi, and surgery to remove calculi from the urinary tract;

2. Nursing services;

3. Laboratory services, as follows:

a. Chemistry;

b. Hematology;

c. Microbiology; and

d. Urinalysis; and

4. Ancillary services, which include at least:

a. Pharmacy; and

b. Recovery room;

(f) The applicant demonstrates that many physicians will have access to and use the lithotriptor by providing the department with the following:

1. A written plan for a system of referrals, which shall include a feedback mechanism for providing patient information to the referring physician and facility; and

2. A written plan for a continuing education and training program, which shall include education of all interested physicians in the specific indications and contraindications of ESWL use; and

(g) The applicant provides a written plan for scheduling patients that ranks patients in order of priority according to standards of need and appropriateness rather than source of referral.

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

(a) Documenting that the projected average total cost per ESWL procedure, including but not limited to fixed and variable operating costs, is similar to costs for similar ESWL services provided in similar settings. In projecting the average total cost per ESWL procedure, the applicant shall base this calculation on the projected utilization determined under sub. (3)(b);

(b) Documenting that the projected average charge per ESWL procedure, excluding the charges for professional fees, ancillary services and hospitalization, is similar to charges for similar ESWL services provided in similar settings;

(c) Documenting the projected overall charge per ESWL procedure, which includes at least the average charge per ESWL procedure under par. (b) plus charges for professional fees, ancillary services and hospitalization; and

(d) Documenting the net financial impact on its hospital rates, if the applicant is hospital-based, including the net change in surgical revenues which results from substitution of the new technology.

(6) MOBILE ESWL EQUIPMENT. For an application relating to mobile ESWL equipment, the applicant shall be the person acquiring the ESWL equipment.

(7) CONCURRENT REVIEW. The provisions in s. HSS 123.08(10) shall be used for concurrent review when there are 2 or more applications. The department shall approve the application or applications receiving the highest score based on a comparative analysis of the applications using all applicable review criteria in s. HSS 123.13, the review criteria in subs. (3) to (6) and the following special review criteria:

(a) Preference shall be given to the application proposing a multifacility or shared service arrangement and, if more than one application proposes a multifacility or shared service arrangement, the one that provides written documentation demonstrating the greatest number and diversity of patient referrals from referring specialists;

(b) Preference 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) Preference 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.

The repeals 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. 227.026(1), Stats.

Wisconsin Department of Health
and Social Services

Date: January 30, 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

Mailing Address:
Post Office Box 7850
Madison, WI 53707

January 30, 1986

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

Dear Mr. Prestegard:

As provided in s. 227.023, Stats., there is hereby submitted a certified copy of HSS 123.24 and 123.25, administrative rules relating to criteria for the review of applications to purchase a magnetic resonance imaging device or an extracorporeal shock wave lithotriptor for use in medical diagnosis or treatment.

These rules are also being submitted to the Secretary of State as required by s. 227.023, Stats.

Sincerely,

Linda Reivitz
SECRETARY