N.J.A.C. TITLE 8
CHAPTER 33Q

Certificate of Need and Licensure:
TRANSPLATATION SERVICES

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Certificate of Need and Acute Care Licensure Program

CHAPTER 33Q

TRANSPLANTATION SERVICES

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SUBCHAPTER 1. ORGAN TRANSPLANTATION SERVICES

8:33Q-1.1 Purpose and scope

The purpose of this subchapter is to set forth certificate of need requirements for new and existing kidney, heart, liver or pancreas transplantation services in the State of New Jersey, in accordance with Federal and State law and policy. The requirements were developed by the Department for the purpose of assuring the orderly development of needed organ transplant services of the highest quality, efficiently provided and utilized.

8:33Q-1.2 General criteria

(a) Applicants for organ transplantation services shall have a formal graduate medical education program with accredited residences and/or fellowships already in place for internal medicine and general surgery. Heart transplant centers shall have cardiology fellowships and preference will be given to those who also have a cardio-thoracic fellowship program. The applicant shall document the ability to implement a program of continuing education and training for the following groups: nurses, technicians, service personnel, and other hospital staff.

(b) A new transplantation program shall achieve and maintain institutional membership in the National Organ Procurement and Transplantation Network, currently operating as the United Network for Organ Sharing (UNOS), within one year of certificate of need approval.

(c) New programs shall be reviewed by the Department of Health and Senior Services within two years of initiation. If minimum performance standards of this subchapter are not met within three years from program initiation, the license may be revoked or not renewed.

(d) Priority consideration will be given to applicants that propose to provide organ transplantation service within the facility's current capacity.

(e) As of November 18, 2002, existing and new licensed kidney transplantation programs shall be permitted to initiate pancreas transplantation services through a licensure and inspection process without additional certificate of need review.

8:33Q-1.3 Performance standards

(a) The applicant for a kidney, heart, liver or pancreas transplant service shall have an institutional plan with the capability and commitment to perform the following minimum transplant procedures annually by the end of the second full year of operation:

1. Kidney: a minimum of 25 procedures;

2. Heart: a minimum of 12 procedures;

3. Liver: a minimum of 15 procedures; and

4. Pancreas: a minimum of 15 procedures.

(b) Each institutional plan for a transplantation service must contain at a minimum:

1. The basis for projecting the performance rate to be achieved by the end of the second year of operation that is considered reasonable by the Department of Health and Senior Services, which shall include, but not be limited to, the availability of donor organs and patient needs;

2. The number of transplants performed during the previous 12 months at similar centers in the local region of the Organ Procurement and Transplantation Network; and

3. Impact statements on the quality, cost, access and organization of existing transplantation services of the type being applied for in the local region of the Organ Procurement and Transplantation Network, describing anticipated effects of the proposed service on such existing programs.

8:33Q-1.4 Personnel

(a) The transplant program shall have on site at least one transplant surgeon and one transplant physician who are clinical members of the National Organ Procurement Transplantation Network, currently operating as the United Network for Organ Sharing (UNOS), for the applicable organ, who are qualified as follows:

1. The transplant surgeon shall have a minimum of one year formal training or equivalent experience during residency, and one year of experience at a transplant program meeting UNOS membership criteria in the area of transplantation in which he or she plans to practice. In lieu of one year formal training and one year of experience, three years of experience with a transplant program meeting criteria for institutional membership in UNOS is acceptable. For kidney transplantation, the surgeon shall have certification by either the American Board of Surgery, the American Board of Urology or its equivalent. For liver and pancreas transplantation, the surgeon shall have American Board of Surgery certification or its equivalent. For heart transplantation, the surgeon shall be certified by the American Board of Thoracic Surgery or its equivalent. The transplant surgeon must have been the primary surgeon on a minimum of 10 transplants performed within the past two years.

2. The transplant physician shall be a physician with an M.D. or D.O. degree, or equivalent degree from another country, who is licensed to practice medicine in New Jersey and has been accepted on the medical staff of the applicant hospital. He or she shall be Board Certified in internal medicine or pediatrics. He or she shall have a least one year of specialized formal training in transplantation medicine or a minimum of two years documented experience in transplantation medicine with a transplant program that meets the qualifications for membership in UNOS. For renal transplantation, the transplant physician shall be Board Certified or Board Qualified in the subspecialty of nephrology. In general, a transplant physician shall be Board Certified or Board Qualified in the subspecialty of the transplanted organ. However, a transplant physician with extensive experience in transplantation of one organ may qualify as a transplant physician for another organ if organ-specific subspecialists also participate in patient selection and post-transplant patient care.

(b) The applicant shall have onsite a full-time transplant coordinator who has one year of related experience in a transplant program.

8:33Q-1.5 Certification of nondiscriminatory practices

(a) Every facility applying to provide or providing solid organ transplant services pursuant to this subchapter shall provide the Department with, and shall maintain current, a written certification of compliance with all Federal and State laws regarding nondiscrimination in the admission and/or treatment of patients as those laws may be amended from time to time.

(b) The applicant shall establish written procedures for selecting transplant candidates and distributing organs in a fair and equitable manner. Selection criteria shall incorporate and comply with National Organ Procurement and Transplantation Network organ allocation

priorities that are based on objective medical criteria, including medical urgency and time on the waiting list. These criteria shall be included in the certificate of need application.

8:33Q-1.6 Physical requirements

(a) The transplant beds shall be located in an environment that will afford the patient privacy, quiet, and protection from infection while providing visual access. An isolation room, designed to minimize infection hazards of or from the patient, shall be made available for each transplant patient. Each isolation room shall contain only one bed and shall comply with acute-care patient room standards (Guidelines for Construction and Equipment of Hospitals and Medical Facilities, 1992-1993 edition American Institute of Architects, the American Institute of Architects Press, 1735 New York Ave., N.W., Washington, DC 20006, as amended and supplemented, incorporated herein by reference) as well as the following:

1. Room entry shall be through a work area that provides for aseptic control, including facilities that are separate from patient areas for hand washing, gowning, and storage of clean and soiled materials;

i. Separate enclosed anteroom(s) for isolation rooms are not required as a minimum but, if used, viewing panel(s) shall be provided for observation of each patient by staff from the anteroom;

ii. One separate anteroom may serve several isolation rooms; and

2. Toilet, bathtub (or shower), and hand washing facilities shall be provided for each isolation room. These shall be arranged to permit access from the bed area without the need to enter or pass through the work area of the vestibule or anteroom.

8:33Q-1.7 Institutional commitment

(a) Applicants shall document that the following services will be provided by the hospital in such numbers and types to adequately meet the objectives of the proposed transplantation service:

1. Applicants shall demonstrate in the application the allocation of operating and recovery room resources, intensive care resources, surgical beds and personnel to the transplant program;

2. Each applicant shall show evidence that the following ancillary health support services, that include board certified physicians, nurses and technicians, are available on-call 24-hours daily:

i. Pediatrics, where younger recipients may be involved.

ii. Infectious disease;

iii. Nephrology with approved end stage renal disease dialysis capability;

iv. Pulmonary medicine with respiratory therapy support;

v. Pathology;

vi. Immunology;

vii. Anesthesiology;

viii. Physical therapy;

ix. Pharmacology;

x. Radiology; and

xi. Nutrition;

3. Each center shall have access to the services of a laboratory certified under the National Organ Transplant Act, or a written agreement that such services will be available within 90 days of certificate of need approval;

4. The applicant shall have immediate access on site, or by contract, within 90 days of certificate of need approval, to laboratory facilities capable of virology, cytology, microbiology and monitoring of immunosuppressive drugs;

5. The applicant shall document blood bank support with the capacity to supply blood components for the number of transplants that are projected, the ability to irradiate blood components, and to ensure the availability of a blood separator and central blood storage;

6. The applicant shall document the availability on site or by contractual arrangement of the psychiatric and social support services essential for the total care of transplant recipients and for helping families cope with the transplant experience; and

7. As part of the hospital's quality assurance program, the transplantation service shall present and implement a system for evaluating the quality and appropriateness of patient care and patient outcomes, including survival rates and any complications.

8:33Q-1.8 Compliance

(a) Certificate of need applicants for new transplantation services shall document the ability to meet minimum standards and criteria contained in this subchapter within three years from the initiation of the service and for each year thereafter. Failure to achieve the minimum level by the end of the second year of operation will result in notification of Department of Health and Senior Services intention to rescind certificate of need approval and move for licensing sanctions that may include closure of the service. The inability to achieve minimum utilization levels during

the third year of operation or thereafter may result in rescission of the certificate of need or licensing sanctions.

(b) Existing transplantation services shall meet the minimum criteria and standards contained in this subchapter. Existing providers failing to achieve the minimum utilization standards specified in this subchapter by November 19, 1991 and each year thereafter will be subject to licensing or reimbursement sanctions that may include closure of the service.

8:33Q-1.9 Performance data reports

(a) Because transplant activity and outcome data for each center will be a means of determining continuing certification, each service shall maintain performance reports for submission to the Department of Health and Senior Services annually.

(b) Minimum data maintained shall describe transplants performed, including, but not limited to:

1. Age, race, sex, and ability to pay of those on the waiting list;

2. Numbers and types of procedures;

3. Patient and graft survival rates over varying periods of time by age, sex and race;

4. Patient charges; and

5. Source(s) of payment.