

**CHAPTER 33Q
TRANSPLANTATION SERVICES**

Authority

N.J.S.A. 26:2H-5 and 26:2H-8

Source and Effective Date

R.2002 d.384, effective October 24, 2002.
See: 34 N.J.R. 1766(a), 34 N.J.R. 3966(b).

Chapter Expiration Date

Chapter 33Q, Transplantation Services, expires on October 24, 2007.

Chapter Historical Note

Chapter 33Q, Transplantation Services, was adopted as new rules by R.1990 d.567, effective November 19, 1990. See: 22 N.J.R. 2496(a), 22 N.J.R. 3579(a).

Pursuant to Executive Order No. 66(1978), Chapter 33Q, Transplantation Services, expired on November 19, 1995.

Chapter 33Q, Transplantation Services, was adopted as new rules by R.1996 d.106, effective February 20, 1996. See: 27 N.J.R. 4210(a), 28 N.J.R. 1266(a).

Pursuant to Executive Order No. 66(1978), Chapter 33Q, Transplantation Services, expired on February 20, 1998.

Chapter 33Q, Transplantation Services, was adopted as new rules by R.1999 d.140, effective May 3, 1999. See: 30 N.J.R. 1534(a), 31 N.J.R. 1187(a).

Chapter 33Q, Transplantation Services, was readopted as R.2002 d.384, effective October 24, 2002. See: Source and Effective Date. See, also, section annotation.

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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 residencies 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.

Amended by R.2002 d.384, effective November 18, 2002.
See: 34 N.J.R. 1766(a), 34 N.J.R. 3966(b).
Added (e).

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 at 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.