



N.J.A.C. 8:33Q, Transplantation Services, is organized at Subchapter 1, Organ Transplantation Services, and establishes the standards, personnel qualifications, physical requirements, regulatory compliance, and reporting requirements for new and existing kidney, heart, liver, and pancreas transplantation services in New Jersey.

The Commissioner has reviewed N.J.A.C. 8:33Q and has determined that the existing chapter remains necessary, proper, reasonable, efficient, understandable, and responsive to the purposes for which the Department originally promulgated it, as amended and supplemented over time, and, with the technical changes, should be readopted.

**Full text** of the technical changes follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

#### SUBCHAPTER 1. ORGAN TRANSPLANTATION SERVICES

##### 8:33Q-1.2 General criteria

(a)-(b) (No change.)

(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)-(e) (No change.)

##### 8:33Q-1.3 Performance standards

(a) (No change.)

(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.-3. (No change.)

#### 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)] **(Guidelines for Design and Construction of Hospitals, 2018 edition, The Facilities Guidelines Institute, ISBN-13 978-0-87258-935-3, available through the Facility Guidelines Institute, telephone (800) 242-2626, website [www.fgiguideines.org](http://www.fgiguideines.org), incorporated herein by reference, as amended and supplemented)**, as well as the following:

1.-2. (No change.)

#### 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 a notification [of] **from the** Department of Health [and Senior Services] **advising of its** intention to rescind **the** 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) (No change.)

#### 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) (No change.)