

HEALTH AND SENIOR SERVICES  
SENIOR SERVICES AND HEALTH SYSTEMS BRANCH  
HEALTH FACILITIES EVALUATION AND LICENSING DIVISION  
OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE  
FACILITY LICENSURE

Transplantation Services

Readoption: N.J.A.C. 8:33Q

Proposed: December 3, 2007 at 39 N.J.R. 5039(a).

Adopted: \_\_\_\_\_ by \_\_\_\_\_

Heather Howard, Commissioner, Department of Health and  
Senior Services (with the approval of the Health Care  
Administration Board).

Filed: \_\_\_\_\_ without change.

Authority: N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5

Proposal Number: PRN 2007-344 .

Effective Date:

Expiration Date:

Summary of Public Comments and Agency Responses:

The Department of Health and Senior Services (Department)  
received comments from the following:

1. David A. Laskow, MD, Director, Kidney/Pancreas Transplant Service, Robert Wood Johnson University Hospital;
2. Michael E. Shapiro, MD, Chief, Organ Transplantation Surgery Section, Department of Surgery, Hackensack University Medical Center.

8:33Q-1.3 Performance standards

COMMENT: Identical comments were submitted by the two commenters that indicate that there is no medical evidence to support the need for volume requirements for pancreas transplants. The commenters state that “none of the national oversight agencies (Medicare or UNOS) have adopted volume requirements for this service.” The commenters also state that “[t]he surgical technique for pancreas transplant surgery is essentially the same as that used in kidney transplants. The location, blood supply, underlying structures, and proximity of the two organs result in the use of the same surgical skills and techniques for transplanting either of these organs.”

The commenters therefore recommend the elimination of this requirement when these procedures are performed at institutions that also transplant kidneys. Both commenters expressed the position that the enforcement of the minimum

volume requirement for kidney transplantation (25 procedures per year) would assure the quality of care for pancreas as well as kidney transplantation services.

RESPONSE: The minimum volume requirement for pancreas transplantation services set forth at N.J.A.C. 8:33Q-1.3 is intended to establish a minimum threshold volume for planning purposes for any potential new pancreas transplantation service seeking certificate of need approval. A certificate of need applicant for a new pancreas transplantation service is required to develop an institutional plan that documents the institutional capability and commitment to perform a minimum of 15 pancreas transplantation procedures by the second year of operation. The Department, however, had previously amended this chapter (See 34 N.J.R. 1766(a) and 3966(b)) to permit the initiation of pancreas transplantation services at existing and new kidney transplantation providers through a licensure and inspection process without the need for further certificate of need review (N.J.A.C. 8:33Q-1.2(e)). This prior amendment was adopted in recognition of the similarities of the patient population, surgical techniques and underlying diseases for kidney and pancreas transplant patients, as noted by the commenters.

All five of the state's kidney transplantation providers also provide pancreas transplantation services. Three of these pancreas transplant

providers initiated their respective services through the licensing and inspection process permitted at N.J.A.C. 8:33Q-1.2(e), including the two newest kidney transplantation providers represented by the commenters. The minimum pancreas volume standard remains in the chapter in the event that a need for additional pancreas transplantation programs surfaces in the future, thereby requiring certificate of need review and approval. Additional pancreas transplantation services may be considered at potential hospital providers that do not perform kidney transplantation. Furthermore, the failure of a currently licensed pancreas transplantation provider to achieve the minimum annual volume standard set forth at N.J.A.C. 8:33Q-1.3 would not be considered a violation of state licensure requirements unless, in accordance with N.J.A.C. 8:33-4.16(b), the requirement was included as a condition of a certificate of need approval for the service. For the reasons stated above, the Department is not including changes upon adoption in response to these comments. (1, 2)

#### 8:33Q-1.6 Physical requirements

COMMENT: Both commenters recommended the elimination of the physical plant requirement of a “separate enclosed isolation room with anteroom and viewing panel” since there is no medical evidence to support this requirement. The commenters consider this requirement to be obsolete, stating that advances in knowledge over the past 20 years

indicate that the requirement is not only unnecessary, but may be detrimental to patient care. The commenters state further that the use on an anteroom isolates the patient to such a degree that contact with medical/nursing staff and family becomes limited, thereby creating social isolation that could lead to depression or contribute to a failure to detect subtle changes in the patient's condition. The commenters state that the focus should be on contact precautions (that is, frequent hand washing) and protective barriers (that is, gowns, gloves) rather than isolation rooms and anterooms.

The commenters believe that their recommendations are consistent with the recommendation of the Commission on Rationalizing Health Care Resources, which emphasized the importance of reviewing and revising regulations to keep them consistent with modern medical practice.

RESPONSE: The Department recognizes that the need for airborne infection control isolation rooms and/or protective environment rooms, notwithstanding the requirements set forth in the certificate of need rule at N.J.A.C. 8:33Q-1.6, can be found in the infection control subchapter of the hospital licensing standards as set forth at N.J.A.C. 8:43G-14. Both the hospital licensing rules and this chapter incorporate by reference the American Institute of Architects "Guidelines for Design and Construction of Health Care Facilities" (AIA Guidelines) with respect to physical plant requirements. The most recent edition of the AIA Guidelines, published in

2006, indicates that the applicability of the need for airborne infection control isolation rooms and/or protective environment rooms are predicated on an infection control risk assessment that is based on the patient populations served by the provider. In addition, the rule being cited by the commenter, N.J.A.C. 8:33Q-1.6(a)1, does not require the use of a “separate enclosed isolation room with anteroom and viewing panel.” The rule requires the presence of a viewing panel only in the event that a separate enclosed anteroom is used. The Department considers the existing standards in the chapter to provide sufficient flexibility to health care providers to ensure that appropriate measures are taken to provide a safe environment for all transplant patients. The Department is therefore not making a change on adoption in response to the comment.

#### Federal Standards Statement

The rules proposed for readoption do not impose standards on health care providers in New Jersey that exceed those contained in Federal law or regulation (see 42 U.S.C. §§ 1395 et seq.; 42 CFR Parts 482, 488 and 498).

**Full text** of the readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:33Q.

