

Notification for New Lung, Heart and Lung, Pancreas and Islet Cells, and Intestines Transplantation Programs

Hospitals proposing to establish new lung, heart and lung, pancreas and islet cells, and intestines transplantation programs must comply with the requirements of Rule 59C-1.044, F.A.C., pursuant to Section 408.0455, F.S. (Chapter 2019-136, Laws of Florida). Please provide a program description that outlines how the hospital will meet the following current requirements of Rule 59C-1.044, F.A.C.

- A. A hospital establishing a lung, heart and lung, pancreas and islet cells, and/or intestines transplantation program must have the following services, pursuant to 59C-1.044(3), F.A.C.
 - a. Staff and other resources necessary to care for the patient's chronic illness prior to transplantation, during transplantation, and in the post-operative period, and services and facilities for inpatient and outpatient care must be available on a 24-hour basis.
 - b. If cadaveric transplantation will be part of the transplantation program, a written agreement with an organ acquisition center for organ procurement is required. A system by which 24-hour call can be maintained for assessment, management and retrieval of all referred donors, cadaver donors or organs shared by other transplant or organ procurement agencies is mandatory.
 - c. An age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required.
 - d. A clinical review committee for evaluation and decision-making regarding the suitability of a transplant candidate.
 - e. Written protocols for patient care for each type of organ transplantation program including, at a minimum, patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital, and immediate post-discharge phases of the program.
 - f. Detailed therapeutic and evaluative procedures for the acute and long term management of each transplant program patient, including the management of commonly encountered complications.
 - g. Equipment for cooling, flushing, and transporting organs. If cadaveric transplants are performed, equipment for organ preservation through mechanical perfusion is necessary. This requirement may be met through an agreement with an organ procurement Agency.
 - h. An onsite tissue-typing laboratory or a contractual arrangement with an outside laboratory within the State of Florida, which meets the requirements of the American Society of Histocompatibility.
 - i. Pathology services with the capability of studying and promptly reporting the patient's response to the organ transplantation surgery, and analyzing appropriate biopsy material.
 - j. Blood banking facilities.
 - k. A program for the education and training of staff regarding the special care of transplantation patients.
 - l. Education programs for patients, their families and the patient's primary care physician regarding after-care for transplantation patients.

- B. A hospital establishing a new lung, heart and lung, pancreas and islet cells, and/or intestines transplantation program must meet the following staffing requirements, pursuant to 59C-1.044(4), F.A.C.
 - a. A staff of physicians with expertise in caring for patients with end-stage disease requiring transplantation. The staff must have medical specialties or sub-specialties appropriate for the type of transplantation program established. The program must employ a transplant physician, and a transplant surgeon, if applicable, as defined by the United Network for Organ Sharing (UNOS) June 1994. A physician with one year experience in the management of infectious diseases in the transplant patient must be a member of the transplant team.
 - b. A program director who must have a minimum of 1 year of formal training and 1 year of experience at a transplantation program for the same type of organ transplantation program established.
 - c. A staff with experience in the special needs of children if pediatric transplantations are performed.

- d. A staff of nurses, and nurse practitioners with experience in the care of chronically ill patients and their families.
 - e. Contractual agreements with consultants who have expertise in blood banking and are capable of meeting the unique needs of transplant patients on a long term basis.
 - f. Nutritionists with expertise in the nutritional needs of transplant patients.
 - g. Respiratory therapists with expertise in the needs of transplant patients.
 - h. Social workers, psychologists, psychiatrists, and other individuals skilled in performing comprehensive psychological assessments, counselling patients, and families of patients, providing assistance with financial arrangements, and making arrangements for use of community resources.
- C. Hospitals providing lung, heart and lung, pancreas and islet cells, and/or intestines transplantation programs must submit data (the total number of transplants by organ type which occurred in each month of the quarter) to the Agency or its designee, within 45 days after the end of each calendar quarter, pursuant to 59C-1.044(5), F.A.C.
- D. Hospitals providing lung, heart and lung, pancreas and islet cells, and/or intestines transplantation services must be a teaching or research hospital with training programs relevant to the type of organ transplantation program proposed to be established pursuant to 59C-1.044(10)(a), F.A.C.
- E. Hospitals providing lung, heart and lung, pancreas and islet cells, and/or intestines transplantation programs must have established interactive programs of basic and applied research in organ failure, transplantation, immunoregulatory responses, and related biology pursuant to 59C-1.044(10)(b), F.A.C.