

Notification for New Kidney Transplantation Programs

Hospitals proposing to establish new kidney 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 kidney 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 the kidney 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 kidney 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 a kidney transplantation program. 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 kidney transplantation program.
 - 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 with kidney transplantation programs must submit data (the total number of kidney transplants 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 kidney transplantation services must have the following services and staffing pursuant to 59C-1.044(8)(a), F.A.C.
- a. Inpatient services must be available which must include renal dialysis, and pre- and post operative care. There must be 24-hour availability of onsite dialysis under the supervision of a board-certified or board eligible nephrologist. If pediatric patients are served, a separate pediatric dialysis unit must be established.
 - b. Outpatient services must be available which must include renal dialysis services and ambulatory renal clinic services.
 - c. Ancillary services must include pre-dialysis, dialysis, and post transplantation nutritional services; bacteriologic, biochemical, and pathological services; radiologic services; and nursing services with the capability of monitoring and support during dialysis and assisting in home care including vascular access, and home dialysis management, when applicable.
- E. Hospitals providing adult kidney transplantation programs must meet the following staffing and laboratory requirements pursuant to 59C-1.044(8)(b), F.A.C.
- a. The kidney transplantation program must be under the direction of a physician with experience in physiology, immunology and immuno-suppressive therapy relevant to kidney transplantation.
 - b. The transplant surgeon must be board-certified in surgery or a surgical subspecialty, and must have a minimum of 18 months training in a transplant center.
 - c. The transplant team performing kidney transplantation must include physicians who are board-certified or board-eligible in the areas of Anesthesiology, Nephrology, Psychiatry, Vascular Surgery, and Urology.
 - d. Additional support personnel must be available including a nephrology nurse with experience in nursing care of patients with permanent kidney failure, and a renal dietician.
 - e. The hospital must have a laboratory with the capability of performing and promptly reporting bacteriologic, biochemical and pathologic analysis.
 - f. The kidney transplant program must have an anesthesiologist experienced in kidney transplantation.
- F. Hospitals providing pediatric kidney transplantation services must have a medical director who is sub-board-certified or sub-board-eligible in pediatric nephrology, a dialysis unit head nurse with special training and expertise in pediatric dialysis, nurse staffing at a nurse to patient ratio of 1 to 1 in the pediatric dialysis unit, a registered dietician with expertise in nutritional needs of children with chronic renal disease, a surgeon with experience in pediatric renal transplantation, a radiology service with specialized equipment for obtaining x-rays on pediatric patients, and education services to include home and hospital programs to ensure minimal interruption in school education, pursuant to 59C-1.044(8)(c), F.A.C.