

Notification for New Allogeneic and Autologous Bone Marrow Transplantation Programs

Hospitals proposing to establish new allogeneic and/or autologous bone marrow 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 new bone marrow 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. An age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required.
 - c. A clinical review committee for evaluation and decision-making regarding the suitability of a transplant candidate.
 - d. Written protocols for patient care for the bone marrow 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.
 - e. Detailed therapeutic and evaluative procedures for the acute and long term management of each transplant program patient, including the management of commonly encountered complications.
 - f. 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.
 - g. Pathology services with the capability of studying and promptly reporting the patient's response to the organ transplantation surgery, and analyzing appropriate biopsy material.
 - h. Blood banking facilities.
 - i. A program for the education and training of staff regarding the special care of transplantation patients.
 - j. 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 bone marrow 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 bone marrow 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 staff with experience in the special needs of children if pediatric transplantations are performed.
 - c. A staff of nurses, and nurse practitioners with experience in the care of chronically ill patients and their families.
 - d. 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.
 - e. Nutritionists with expertise in the nutritional needs of transplant patients.
 - f. Respiratory therapists with expertise in the needs of transplant patients.

- g. 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 bone marrow transplantation programs must submit data (the total number of bone marrow 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 pediatric allogeneic and/or autologous bone marrow transplantation services must be a teaching hospital or research hospital with training programs relevant to pediatric bone marrow transplantation, and must have the following staff, facilities and programs pursuant to 59C-1.044(9)(a), F.A.C.
- a. Hospitals must be able to project that at least 10 pediatric transplants will be performed each year. If both allogeneic and autologous pediatric transplants are performed, at least 10 of each must be projected. New units must be able to project the minimum volume for the third year of operation
 - b. A program director who is a board certified hematologist or oncologist with experience in the treatment and management of pediatric acute oncological cases involving high dose chemotherapy or high dose radiation therapy and has formal training in pediatric bone marrow transplantation.
 - c. Clinical nurses with experience in the care of critically ill immuno-suppressed patients and nursing staff dedicated full time to the program.
 - d. An interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders. The team must direct permanent follow-up care of the bone marrow transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications.
 - e. Age appropriate inpatient transplantation units for post-transplant hospitalization. Post-transplantation care must be provided in a laminar air flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. The designated transplant unit must have a minimum of 2 beds. This unit can be part of a facility that also manages patients with leukemia or similar disorders.
 - f. A radiation therapy division onsite which is capable of sub-lethal x-irradiation, bone marrow ablation, and total lymphoid irradiation. The division must be under the direction of a board certified radiation oncologist.
 - g. An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital. The program must include outcome monitoring and long-term patient follow-up.
 - h. An established research-oriented oncology program.
- E. Hospitals providing pediatric allogeneic bone marrow transplantation services must also have the following additional laboratory services and facilities pursuant to 59C-1.044(9)(a)2., F.A.C.
- a. A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, or T-cell depletion, separation of lymphocyte and hematological cell subpopulations and their removal for prevention of graft versus host disease. This requirement may be met through contractual arrangements.
 - b. An onsite laboratory equipped for the evaluation and cryopreservation of bone marrow.
 - c. An age appropriate patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence.
 - d. An age appropriate outpatient unit for close supervision of discharged patients.
- F. Hospitals providing adult allogeneic bone marrow transplantation services must be a teaching hospital or research hospital and must have the following staff, facilities and programs pursuant to 59C-1.044(9)(b), F.A.C.

- a. Hospitals must be able to project that at least 10 adult allogeneic transplants will be performed each year. New units must be able to project the minimum volume for the third year of operation.
 - b. A program director who is a board certified hematologist or oncologist with experience in the treatment and management of adult acute oncological cases involving high dose chemotherapy or high dose radiation therapy and has formal training in bone marrow transplantation.
 - c. Clinical nurses with experience in the care of critically ill immuno-suppressed patients and nursing staff dedicated full time to the program.
 - d. An interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders. The team must direct permanent follow-up care of the bone marrow transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications.
 - e. Inpatient transplantation units for post-transplant hospitalization. Post-transplantation care must be provided in a laminar air flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. The designated transplant unit must have a minimum of 2 beds. This unit can be part of a facility that also manages patients with leukemia or similar disorders.
 - f. A radiation therapy division onsite which is capable of sub-lethal x-irradiation, bone marrow ablation, and total lymphoid irradiation. The division must be under the direction of a board certified radiation oncologist.
 - g. A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, or T-cell depletion, separation of lymphocyte and hematological cell subpopulations and their removal for prevention of graft versus host disease. This requirement may be met through contractual arrangements.
 - h. An onsite laboratory equipped for the evaluation and cryopreservation of bone marrow.
 - i. An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital. The program must include outcome monitoring and long-term patient follow-up.
 - j. An established research-oriented oncology program.
 - k. A patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence.
 - l. An outpatient unit for close supervision of discharged patients.
- G. Hospitals providing adult autologous bone marrow transplantation services must be a teaching hospital, research hospital, or a community hospital that has a research program, or who is affiliated with a research program, and must have the following staff, facilities and programs pursuant to 59C-1.044(9)(c), F.A.C.
- a. Hospitals must be able to project that at least 10 adult autologous transplants will be performed each year. New units must be able to project the minimum volume for the third year of operation.
 - b. A program director who is a board certified hematologist or oncologist with experience in the treatment and management of adult acute oncological cases involving high dose chemotherapy or high dose radiation therapy and has formal training in bone marrow transplantation or at least 1 year of documented experience in performing autologous bone marrow transplantation.
 - c. Clinical nurses with experience in the care of critically ill immuno-suppressed patients and nursing staff dedicated full time to the program.
 - d. An interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders. The team must direct permanent follow-up care of the bone marrow transplantation patients.

- e. Inpatient transplantation units for post-transplant hospitalization. Post-transplantation care must be provided in a laminar air flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. The designated transplant unit must have a minimum of 2 beds. This unit can be part of a facility that also manages patients with leukemia or similar disorders.
- f. A radiation therapy division onsite which is capable of sub-lethal x-irradiation and total lymphoid irradiation. The division must be under the direction of a board certified radiation oncologist.
- g. An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital, or the hospital may enter into an agreement with an outpatient provider having a research program. Under the agreement, the outpatient research program may perform specified outpatient phases of adult autologous bone marrow transplantation, including blood screening tests, mobilization of stem cells, stem cell rescue, chemotherapy, and reinfusion of stem cells.
- h. An established research-oriented oncology program.