

**59A-3.XXX Organ Transplant Services programs.**

(1) General Requirements. A hospital licensed to provide transplant services prior to July 1, 2020, shall be licensed to provide transplant services as of the effective date of this rule and must meet all provisions of this rule within one year from the effective date. Licensure designations for organ transplant programs include heart, intestines, kidney, liver, lung, pancreas and allogeneic islet cells, and hematopoietic stem cell transplant / bone marrow transplant. Separate requirements and designations exist ~~are required~~ for adult and pediatric programs. ~~Hematopoietic stem cell transplant / bone marrow transplant programs must have separate designations for autologous only and autologous plus allogeneic programs.~~

(a) A licensee of a hospital may apply for licensure to provide an organ transplant program by submitting a hospital license application as specified in subsection 59A-3.066(2), F.A.C., indicating the addition of one or more organ transplant programs. A licensee of a hospital must seek, obtain and maintain certification as described in Title 42 CFR Part 121, Subpart K and Title 42 CFR Part 482 Subpart E for the comparable Medicare transplant programs.

(b) Quality Standards and Reporting.

1. ~~(p)~~ A hospital providing adult and/or pediatric heart, intestines, kidney, liver, lung, or pancreas and allogeneic islet cells transplants must have available upon request of the Agency, the number of transplants performed and the one-year post transplant graft and patient survival measures.

2. ~~(e)~~ A hospital providing adult and / or pediatric heart, kidney, liver, lung or intestine transplants must meet the minimum clinical experience as described in Title 42 Code of Federal Regulations section 482.80 within one year from initial licensure of each transplant program.

3. ~~(t)~~ Hospitals with licensed solid organ transplant programs must include solid organ

transplant utilization data with the quarterly data submission required under section 408.05, Fla. Stat.

~~(4) A hospital providing adult and/or pediatric HSCT / BMT or gene or cell therapy treatment heart, intestines, kidney, liver, lung, or pancreas and allogeneic islet cells transplants must have available upon request of the Agency, the number of transplants performed and the one-year post transplant graft and patient survival measures.~~

(c) All Hospitals Providing Transplant Services.

~~(e3) In addition to all Centers for Medicare and Medicaid Services (CMS) Organ Procurement and Transplantation Network (OPTN) requirements for solid organ transplants and Foundation for the Accreditation of Cellular Therapy (FACT) requirements for HSCT and BMT, aAll hospitals providing any organ transplant service must have aAn age-appropriate (adult or pediatric) at a minimum:~~

1. ~~An age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required;~~
2. A clinical review committee for evaluation and decision-making regarding the suitability of a transplant candidate;
3. ~~Services and facilities for inpatient and outpatient care, available on a 24-hour basis, for the patient's chronic illness prior to transplantation, during transplantation, and in the post-transplant operative period;~~
4. Policies and procedures for patient care specifying patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital, and immediate post-discharge phases of the program;
5. Detailed therapeutic and evaluative procedures for the acute and long-term management of

each patient and the management of common complications;

6. A program for the education and training of staff regarding the special care of transplantation patients;

7. A program to facilitate Primary and Secondary Education services (K-12) including home and hospital programs shall be provided or contracted to minimize interruption in the patient's school education when clinically appropriate;

8. A program for the education of patients, and their caregivers ~~families and the patient's primary care physician~~ regarding pre-transplant, post-transplant ~~operative~~ and post-discharge care for transplantation patients; and

9. Clinical and pathology laboratory services meeting the requirements in Rule 59A-3.242(1), F.A.C. Services may be provided directly as a hospital service or by contract to meet the needs of the patients. CLIA-certified specialties must include Histocompatibility for transplant services, Microbiology, Chemistry, Hematology, Immunohematology (blood bank), ~~Apheresis services~~, and Histopathology and also Apheresis services with the capability of studying and promptly reporting the patient's response to the organ transplantation surgery, and analyzing appropriate biopsy material.;

[10.5. All transplant programs must have An age appropriate intensive care attending physician immediately available on-site 24 hours a day 365 days a year.]

11. Inpatient renal replacement therapy directly by the hospital or by contract available onsite at all times, including a separate pediatric renal replacement therapy service if pediatric patients are served;

12. Outpatient services, including renal replacement therapy services and ambulatory renal clinic services may be provided directly at the hospital or by contract to meet the needs of the

patients.;

**(2) Solid Organ Transplant Services.**

(a) ~~(b1.)~~ All hospitals providing solid organ transplant services must meet and maintain the general and program-specific service requirements. Hospitals providing solid organ transplant services for heart, intestines, kidney, liver, lung, or pancreas and allogeneic islet cells must:

1. Be a member of the Organ Procurement and Transplantation Network (OPTN);
2. Have a written agreement with an Organ and Tissue Procurement Organization (OPO)

licensed under chapter 765, F.S.; and

~~e.3. Have equipment for cooling, flushing, and transporting organs. If cadaveric transplants are performed, equipment for organ preservation through mechanical perfusion is required. This requirement may be met through an agreement with an OPO.~~

**(2) HSCT**

~~(c3) In addition to all CMS and OPTN requirements, a~~ All hospitals providing any organ transplant service must have at a minimum:

- ~~1. An age appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required;~~
- ~~2. A clinical review committee for evaluation and decision-making regarding the suitability of a transplant candidate;~~
- ~~3. Services and facilities for inpatient and outpatient care, available on a 24-hour basis, for the patient's chronic illness prior to transplantation, during transplantation, and in the post-operative period;~~
- ~~4. Policies and procedures for patient care specifying patient selection criteria for patient management and evaluation during the pre-hospital, in hospital, and immediate post-discharge~~

phases of the program;

5. Detailed therapeutic and evaluative procedures for the acute and long-term management of each patient and the management of common complications;

6. A program for the education and training of staff regarding the special care of transplantation patients;

7. Education services including home and hospital programs to minimize interruption in the patient's school education;

8. A program for the education of patients, their families and the patient's primary care physician regarding post-operative and post-discharge care for transplantation patients; and

9. Clinical and pathology laboratory services meeting the requirements in Rule 59A-3.242(1), F.A.C. Services may be provided directly as a hospital service or by contract to meet the needs of the patients. CLIA-certified specialties must include Histocompatibility for transplant services, Microbiology, Chemistry, Hematology, Immunohematology (blood bank), and Histopathology with the capability of studying and promptly reporting the patient's response to the organ transplantation surgery, and analyzing appropriate biopsy material.;

**(be) Solid Organ Transplant Programs shall be in a teaching hospital or have a clinical / basic research program or have an affiliation with a teaching / research hospital as defined in s. 408.07(46), Fla. Stat. Liver, lung, pancreas and allogeneic islet cells, intestines, multi-organ, and hematopoietic stem cell transplant / bone marrow transplant programs, excluding hematopoietic stem cell transplant / bone marrow transplant programs for adults providing autologous transplants only, are limited to a teaching or research hospital with training programs relevant to the transplant program.**

**1. Lung, pancreas and allogeneic islet cells, intestines, and multi-organ transplant programs**

must have interactive programs of basic and applied research in organ failure, transplantation, immunoregulatory responses, and related biology.

(d) All hospitals providing solid organ transplant services must meet the following staffing requirements:

1. A staff of physicians licensed pursuant to chapters 458 or 459, F.S. with expertise in caring for age-appropriate patients with end-stage disease requiring solid organ transplantation. The physicians shall be members of the organized medical staff and have medical specialties or sub-specialties appropriate for the type of transplant program. Each transplant program shall have a designated physician member of the organized medical staff, meeting the education, training, certification, and experience qualifications required by the hospital's governing board or delegated committee, to serve as and meet other OPTN requirements.

a. The program director, responsible for the day-to-day administration of the transplant program;

b. The primary transplant physician, responsible for providing and coordinating the pre- and post-transplantation care of patients; and

c. The primary transplant surgeon, responsible for providing and coordinating the transplantation surgical services.

2. A staff of registered professional nurses, including advanced practice registered nurses, if applicable, with experience in the care of chronically ill patients and their families;

3. A registered professional nurse or other licensed clinician approved by the program director to serve as clinical transplant coordinator;

4. Physician consultants who have expertise in immunohematology and are capable of meeting the unique needs of transplant patients on a long-term basis;

5. A pharmacist with expertise in the pharmacological needs of transplant patients;

6. A registered dietician with expertise in the nutritional needs of transplant patients;

7. A staff of respiratory therapists with expertise in the needs of transplant patients; and,

8. A staff of social workers, psychologists, and /or 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.

9. Physician consultants who have expertise in infectious disease and are capable of meeting the unique needs of transplant patients on a long-term basis;

10. Radiology and interventional radiology services shall be available on-call 24 hours a day 7 days a week to provide complex interventional and vascular procedures.

(e) Liver, lung, pancreas and allogeneic islet cells, intestines, multi organ, and hematopoietic stem cell transplant / bone marrow transplant programs, excluding hematopoietic stem cell transplant / bone marrow transplant programs for adults providing autologous transplants only, are limited to a teaching or research hospital with training programs relevant to the transplant program.

1. Lung, pancreas and allogeneic islet cells, intestines, and multi organ transplant programs must have interactive programs of basic and applied research in organ failure, transplantation, immunoregulatory responses, and related biology.

2. Hematopoietic stem cell transplant / bone marrow transplant programs, excluding hematopoietic stem cell transplant / bone marrow transplant programs for adults providing autologous transplants only, must have an ongoing research program that is integrated either

within the hospital or by written agreement with a hematopoietic stem cell transplant / bone marrow transplant transplantation program operated by a teaching hospital. The program must include outcome monitoring and long-term patient follow-up.

3. Hematopoietic stem cell transplant / bone marrow transplant programs for adults providing only autologous transplants may be established at:

a. Teaching hospitals;

b. Research hospitals; or

c. Community hospitals with a research program or affiliated with a research program. The research program may be integrated within the hospital, by written agreement with a hematopoietic stem cell transplant / bone marrow transplant center operated by a teaching hospital, or by an agreement with an outpatient provider with a research program.

Under the agreement, the outpatient research program may perform one or more of the following outpatient phases of hematopoietic stem cell transplant / bone marrow transplant transplantation: blood screening tests, mobilization of stem cells, stem cell rescue, chemotherapy, and reinfusion of stem cells.

(df) Heart, lung, and heart-lung transplant programs must maintain:

1. A cardiologist member of the organized medical staff meeting the age-appropriate education, training, and certification requirements as established by the program director;

2. 5. For lung and heart-lung transplant programs, a pulmonologist member of the organized medical staff meeting the age-appropriate education, training, and certification requirements as established by the program director, and experienced in lung both open-heart surgery and heart transplantation

3. 2. An anesthesiologist member of the organized medical staff meeting the age-appropriate



education, training, and certification requirements as established by the program director, and experienced in both open-heart surgery and heart transplantation; and

43. A single occupancy isolation room in an age-appropriate intensive care unit.

5. An extracorporeal membrane oxygenation (ECMO) program.

~~[5. All transplant programs must have an intensive care attending physician immediately available on site 24 hours a day 365 days a year.]—Lung~~

~~5. For lung and heart lung transplant programs, a pulmonologist member of the organized medical staff meeting the age appropriate education, training, and certification requirements as established by the program director, and experienced in lung both open heart surgery and heart transplantation;~~

(g) Liver transplant programs must maintain:

1. Physician and Staff trained in liver transplantation and in the care of patients with hepatic diseases; and

2. The following available in the hospital or by contract:

a. ~~A department of gastroenterology, including clinics and procedure rooms; and~~

b. Gastroenterology and interventional radiology services shall be available to provide complex biliary and vascular procedures, including transhepatic cholangiography, portal venography and arteriography.

c. An anesthesiologist member of the organized medical staff meeting the age-appropriate education, training, and certification requirements as established by the program director, and experienced in abdominal transplantation.

(h) Intestine transplant programs will only be licensed in conjunction with a liver transplant

program and an intestinal rehabilitation program.

(i) Kidney transplant programs must maintain:

1. A nephrologist member of the organized medical staff meeting the age-appropriate education, training, and certification requirements as established by the program director;

2. An anesthesiologist member of the organized medical staff meeting the age-appropriate education, training, and certification requirements as established by the program director, and experienced in kidney transplantation;

3. Nursing staff experienced in nursing care of patients with permanent kidney failure;

4. Inpatient renal replacement therapy available onsite at all times, including a separate pediatric renal replacement therapy unit if pediatric patients are served;

5. Outpatient services, including renal replacement therapy services and ambulatory renal clinic services may be provided directly at the hospital or by contract to meet the needs of the patients; and

6. Ancillary services, including nutritional, radiologic, and nursing services capable of monitoring and support during pediatric renal replacement therapy and assisting with educating the patient while in the hospital with in home care vascular access and home pediatric renal replacement therapy management, when applicable.

7. Radiology and interventional radiology services shall be available on call 24 hours a day 7 days a week to provide complex interventional and vascular procedures.

(j) Pediatric kidney transplant programs must meet the following additional requirements:

1. The program director must be board certified or eligible in pediatric nephrology;

2. The nurse manager of the pediatric renal replacement therapy unit must have special training and expertise in pediatric renal replacement therapy;

3. The nurse to patient ratio in the pediatric renal replacement therapy unit must be 1:1;

4. The registered dietician must have expertise in nutritional needs of children with chronic renal disease; and

5. The radiology service must have specialized equipment for obtaining x-rays on pediatric patients.

(k) Pancreas and allogeneic islet cell transplant programs will only be approved in conjunction with a kidney transplant program.

(l) . An anesthesiologist member of the organized medical staff meeting the age-appropriate education, training, and certification requirements as established by the program director, and experienced in abdominal transplantation.

## **(2) Hematopoietic Stem Cell Transplant Services.**

### **(a) Adult Hematopoietic Stem Cell Transplant Services.**

**(1.)2. Hematopoietic stem cell transplant / bone marrow transplant programs, excluding hematopoietic stem cell transplant / bone marrow transplant programs for adults providing autologous transplants only, must have an ongoing research program that is integrated either within the hospital or by written agreement with a hematopoietic stem cell transplant / bone marrow transplant transplantation program operated by a teaching hospital. The program must include outcome monitoring and long term patient follow up.**

**3. Hematopoietic stem cell transplant / bone marrow transplant programs for adults providing only autologous transplants may be established at:**

**a. Teaching hospitals;**

**b. Research hospitals; or**

**c. Community hospitals with a research program or affiliated with a research program. The**

research program may be integrated within the hospital, by written agreement with a hematopoietic stem cell transplant / bone marrow transplant center operated by a teaching hospital, or by an agreement with an outpatient provider with a research program. Under the agreement, the outpatient research program may perform one or more of the following outpatient phases of hematopoietic stem cell transplant / bone marrow transplant transplantation: blood screening tests, mobilization of stem cells, stem cell rescue, chemotherapy, and reinfusion of stem cells.

2. Hematopoietic stem cell transplant / bone marrow transplant programs, excluding hematopoietic stem cell transplant / bone marrow transplant programs for adults providing autologous transplants only, must have an ongoing research program that is integrated either within the hospital or by written agreement with a hematopoietic stem cell transplant / bone marrow transplant transplantation program operated by a teaching hospital. The program must include outcome monitoring and long term patient follow up.

3. Hematopoietic stem cell transplant / bone marrow transplant programs for adults providing only autologous transplants may be established at:

a. Teaching hospitals;

b. Research hospitals; or

c. Community hospitals with a research program or affiliated with a research program. The research program may be integrated within the hospital, by written agreement with a hematopoietic stem cell transplant / bone marrow transplant center operated by a teaching hospital, or by an agreement with an outpatient provider with a research program. Under the agreement, the outpatient research program may perform one or more of the following outpatient phases of hematopoietic stem cell transplant / bone marrow transplant transplantation:

blood screening tests, mobilization of stem cells, stem cell rescue, chemotherapy, and reinfusion of stem cells.

(a) Allogeneic and Autologous Hematopoietic stem cell transplant / bone marrow transplant programs for adults and pediatric patients shall be in a teaching hospital or have a research program or have an affiliation with a teaching / research hospital and must meet the following common requirements:

1. The program director must have formal age appropriate training in hematopoietic stem cell transplant / bone marrow transplant and meet all standards set forth by FACT transplantation and be a board-certified hematologist or oncologist with experience in the treatment and management of adult acute oncological cases using ablative and non-ablative conditioning regimens involving chemotherapy and/or radiation therapy. The hospital's governing board may appoint a board eligible hematologist or oncologist with at least one year of experience performing autologous hematopoietic stem cell transplant / bone marrow transplant transplants to serve as program director if transplants are limited to autologous transplantations;

2. Nursing staff must be dedicated full time to the program and have age appropriate experience with the care of critically ill immuno-suppressed patients;

3. An interdisciplinary transplantation team with age appropriate expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopietic malignancies, and non-neoplastic disorders shall direct permanent follow-up care of the hematopoietic stem cell transplant / bone marrow transplant transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications;

4. Adult Age appropriate inpatient post-transplantation care must be provided in a location consistent with FACT standards relevant to the service provided, including but not limited to:

. laminar air flow room or in a single occupancy room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. This unit can be part of a program that also manages patients with leukemia or similar disorders; and

(a.)5. A Age appropriate radiation therapy services division, under the direction of a board-certified radiation oncologist, must be available and may be met with contracted services. onsite and capable of sub-lethal x irradiation, hematopoietic stem cell transplant / bone marrow transplant ablation, and total lymphoid irradiation.

(o) Hematopoietic stem cell transplant / bone marrow transplant programs providing allogeneic transplants to adult and / or pediatric patients must meet FACT and National Marrow Donor Program (NMDP) requirements and have:

1. A laboratory equipped to handle Cellular processing, cryopreservation, storage and apheresis services studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, T cell depletion, and 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;

2. An onsite laboratory equipped for the evaluation and cryopreservation of hematopoietic stem cell transplant / bone marrow transplant; and

3. An adult age appropriate outpatient unit for close monitoring supervision of discharged patients.

(l) Hematopoietic stem cell transplant / bone marrow transplant programs for pediatric

~~patients must meet the following common requirements:~~

~~1. The program director must have formal training in pediatric hematopoietic stem cell transplant / bone marrow transplant transplantation, and shall be board certified as a hematologist or oncologist with experience in the treatment and management of pediatric acute oncological cases using ablative and non-ablative conditioning regimens involving chemotherapy and/or radiation therapy;~~

~~2. Nursing staff must be dedicated full time to the program and have experience with the care of critically ill immuno-suppressed patients;~~

~~3. The transplantation team must have expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders;~~

~~4. An interdisciplinary team must direct permanent follow up care of the hematopoietic stem cell transplant / bone marrow transplant transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications;~~

~~5. A radiation therapy division, under the direction of a board certified radiation oncologist, must be available onsite and capable of sub-lethal x-irradiation, hematopoietic stem cell transplant / bone marrow transplant ablation, and total lymphoid irradiation; and~~

~~6. Pediatric inpatient post transplantation care must be provided in a laminar air flow room; or in a single occupancy room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. This unit can be part of a program that also manages patients with leukemia or similar disorders.~~

~~(m) Hematopoietic stem cell transplant / bone marrow transplant programs providing allogeneic transplants to pediatric patients must have:~~

- ~~1. A pediatric outpatient unit for close supervision of discharged patients;~~
- ~~2. An onsite laboratory equipped for the evaluation and cryopreservation of hematopoietic stem cell transplant / bone marrow transplant; and~~
- ~~3. A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, T-cell depletion, and 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.~~

~~(n) Hematopoietic stem cell transplant / bone marrow transplant programs for adults must meet the following common requirements:~~

- ~~1. The program director must have formal training in hematopoietic stem cell transplant / bone marrow transplant transplantation and be a board-certified hematologist or oncologist with experience in the treatment and management of adult acute oncological cases using ablative and non-ablative conditioning regimens involving chemotherapy and/or radiation therapy. The hospital's governing board may appoint a board-eligible hematologist or oncologist with at least one year of experience performing autologous hematopoietic stem cell transplant / bone marrow transplant transplants to serve as program director if transplants are limited to autologous transplantations;~~
- ~~2. Nursing staff must be dedicated full time to the program and have experience with the care of critically ill immuno-suppressed patients;~~
- ~~3. An interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders shall direct permanent follow-up care of the hematopoietic stem cell transplant / bone marrow transplant transplantation patients, including the~~



~~maintenance of immunosuppressive therapy and treatment of complications;~~

~~4. Adult inpatient post transplantation care must be provided in a laminar air flow room or in a single occupancy room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. This unit can be part of a program that also manages patients with leukemia or similar disorders; and~~

~~5. A radiation therapy division, under the direction of a board certified radiation oncologist, must be available onsite and capable of sub-lethal x irradiation, hematopoietic stem cell transplant / bone marrow transplant ablation, and total lymphoid irradiation.~~

~~(o) Hematopoietic stem cell transplant / bone marrow transplant programs providing allogeneic transplants to adults must have:~~

~~1. A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, T-cell depletion, and 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;~~

~~2. An onsite laboratory equipped for the evaluation and cryopreservation of hematopoietic stem cell transplant / bone marrow transplant; and~~

~~3. An adult outpatient unit for close supervision of discharged patients.~~

~~(p) A hospital providing adult and/or pediatric heart, intestines, kidney, liver, lung, or pancreas and allogeneic allogeneic islet cells transplants must have available upon request of the Agency, the number of transplants performed and the one year post transplant graft and patient survival measures.~~

~~(q) A hospital providing adult heart, kidney, liver, or lung transplants must meet the minimum clinical experience as described in Title 42 Code of Federal Regulations section~~

~~483.80 within one year from initial licensure of each transplant program.~~

~~(r) Hospitals with licensed organ transplant programs must include organ transplant utilization data with the quarterly data submission required under section 408.05.~~

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