

CHAPTER 158. VITAL ORGAN TRANSPLANTATION SERVICES

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GENERAL PROVISIONS**§ 158.1. Principle.**

Transplantation services shall be performed only in hospitals and shall be performed in accordance with accepted and prevailing standards of medical practice.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.32 (relating to heart transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Board certified—A physician licensed to practice medicine in this Commonwealth who has successfully passed an examination and has maintained certification in the relevant medical specialty area or subspecialty area, or both, recognized by one of the following groups:

- (i) The American Board of Medical Specialties.
- (ii) The American Osteopathic Association.
- (iii) The foreign equivalent of either group listed in subparagraph (i) or (ii).

Onsite—In the physical structure at which vital organ transplantation services are being offered or in an adjoining structure.

Organ Procurement and Transplantation Network—A private nonprofit entity created under 42 U.S.C.A. § 274 to coordinate organ procurement and allocation for transplants in the United States and whose duties include the establishment of membership and medical criteria for institutions that perform vital organ transplants.

Pediatric transplantation program—Describes that program where vital organ transplantation services are provided to all patients under 18 years of age, except for those whose physical development precludes them from being handled as a pediatric patient when receiving transplantations.

Preboard certification status—A physician licensed to practice medicine in this Commonwealth who has completed the requirements necessary to take a certification examination offered by a medical specialty board recognized by the American Board of Medical Specialties, the American Osteopathic Association, or the foreign equivalent of either group and who has been eligible to take the examination for no longer than 3 years.

Transplantation center—The entire unit of a hospital which is devoted to the provision of vital organ transplantation services. Within a transplantation center, separate programs shall be established for each type of vital organ transplanted.

Transplantation program—The offering of a surgical service which involves the transfer of a vital organ from one individual to another. Each type of organ transplantation constitutes a separate transplantation program.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.32 (relating to heart transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.3. Scope.

(a) When a hospital provides transplantation services, it shall make a sufficient commitment of resources and planning to all transplantation services which it provides. This commitment shall be demonstrated as follows:

(1) Commitment of the hospital to the transplantation service shall be present at all levels and broadly evident throughout the facility. This requires a major commitment of resources. These shall include many other departments, as well as the principal sponsoring departments.

(2) The hospital shall have both the expertise and the commitment for participation in medical, surgical and other relevant areas. The hospital shall identify individuals in these areas to achieve an identifiable and stable transplant team.

(3) The component teams shall be integrated into a comprehensive team with clearly defined leadership and corresponding responsibility.

(4) The hospital shall have active medical and surgical programs in the specific areas in which transplantation services are offered.

(5) The commitment to medical staff shall include the elements in § 158.13 (relating to medical staff).

(6) The nursing service shall identify a team trained not only in the support of the patient, but also in the special problems of managing immunosuppressed patients.

(7) Adequate social services resources shall be available.

(8) Mechanisms shall be in place for managing the transplantation program which assures that:

(i) Patient selection criteria are consistent with those set forth in the hospital's written patient selection criteria.

(ii) The hospital is responsible for the ethical and medical considerations involved in the patient selection process and application of patient selection criteria.

- (9) Adequate plans exist for organ procurement which meet legal and ethical criteria.
- (b) Each transplantation program shall be a participating member of the Organ Procurement and Transplantation Network and shall comply with its standards, guidelines and bylaws.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

PROGRAM, SERVICE AND PERSONNEL REQUIREMENTS

§ 158.11. Medical director.

- (a) The medical director of the transplantation center shall be an active member of the medical staff who is a qualified transplantation surgeon or transplantation physician and who is either certified by the American Board of Surgery or the American Board of Internal Medicine or an equivalent Board.
- (b) An interim director may be appointed during the period of time between the departure of the prior director and the selection of a new director. The interim director shall be a physician who is able to demonstrate qualifications acceptable to the medical staff of the hospital and to the Department. The hospital shall apply to the Department for an exception under the procedures in §§ 51.31—51.34 (relating to exceptions). If the exception is granted, the Department will specify the maximum period of time for which the interim director shall be appointed.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.34 (relating to lung and heart/lung transplantation programs); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.12. Transplantation coordinator.

Each transplantation center shall have onsite on a full time basis at least one transplantation coordinator. Transplantation coordinators shall be certified by the American Board of Transplant Coordinators within 2 years of obtaining this position.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.34 (relating to lung and heart/lung transplantation programs); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.13. Medical staff.

(a) Each transplantation program shall have at least one transplantation surgeon and one transplantation physician who are either Board certified or who have attained preboard certification status, members of the hospital's active medical staff and who meet the requirements established by the Organ Procurement and Transplantation Network to serve in that capacity.

(b) Each transplantation center shall have supporting medical staff to provide necessary services to transplant patients. Required medical staff shall be available at all times and shall include the following:

(1) Nephrology services comprised of at least one nephrologist who is either Board certified or who has attained preboard certification status in nephrology with the American Board of Internal Medicine or an equivalent Board. The nephrologist may also serve as the transplant physician.

(2) Pathology services with a pathologist who is either certified or who has attained preboard certification status with the American Board of Clinical Pathology or an equivalent Board. The pathology service shall be available for studying and reporting promptly the pathological responses to transplantation.

(3) Anesthesiology services with an anesthesiologist who is either certified or who has attained preboard certification status with the American Board of Anesthesiology or an equivalent Board. Anesthesiology shall identify a team for transplantation that is trained in transplant surgery and is available at all times.

(4) Radiology services with a radiologist who is certified by the American Board of Radiology or an equivalent Board. A radiologist shall have 1 year of training or 2 years experience in imaging techniques used in transplantation of the applicable organ and shall be available at all times.

(5) An internist who is certified in infectious diseases by the American Board of Internal Medicine or an equivalent Board and who shall be readily available to transplant patients. The internist shall have both the professional skills and the laboratory resources needed to discover, identify and manage the complications from organisms encountered in transplant patients.

(6) Psychiatric services with a psychiatrist who is either currently certified or who has attained preboard certification status in psychiatry with the American Board of Psychiatry and Neurology or an equivalent Board. The psychiatrist shall be available to meet the psychiatric needs of transplant patients.

Cross References

This section cited in 28 Pa. Code § 158.3 (relating to scope); 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.34 (relating to lung and heart/lung transplantation programs); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.14. Nursing staff; other health care personnel.

(a) Nursing personnel shall include nurses with specialized education which includes theory, advanced technical skills and supervised experience in a surgical intensive care unit or in a postoperative transplantation unit before assuming primary responsibility for the nursing care of transplantation patients.

(b) There shall be nursing service goals and objectives, standards of nursing practice, procedure manuals and written job descriptions for each level of personnel which shall include the following:

(1) A means for assessing the nursing care needs of the patients and determining adequate staffing to meet those needs.

(2) Staffing patterns that are adequate to meet the nursing goals, standards of practice and the needs of the patients.

(3) An adequate number of licensed and unlicensed assistive personnel to assure that staffing levels meet the total nursing needs of the patient.

(4) Nursing personnel assigned to duties consistent with their training, experience and scope of practice, when applicable.

(c) Surgical suite nursing services shall be under the direction and supervision of a registered professional nurse with specific education and experience in dealing with transplantation patients.

(d) In addition to the requirements for the nursing staff in subsections (a)—(c), there shall be service goals and objectives, standards of patient care, procedure manuals and written job descriptions for each level of other health care personnel which includes the following:

(1) A means for assessing the needs of patients and determining adequate staffing to meet those needs.

(2) Staffing patterns that are adequate to meet patient care goals, standards of practice and needs of patients.

(3) An adequate number of licensed and unlicensed health care personnel to assure that staffing levels meet the total needs of patients.

(4) Health care personnel in the transplantation program shall be assigned to duties consistent with their training, experience and scope of practice when applicable.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.34 (relating to lung and heart/lung transplantation programs); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.15. Laboratories.

(a) The transplantation center shall maintain, or by agreement have access to, a tissue typing laboratory with appropriate space and resources to perform required histocompatibility testing and cross matches.

(b) The transplantation center shall maintain, or by agreement have access to, laboratory facilities capable of performing virology, cytology, clinical chemistry, microbiology and monitoring of immunosuppressive drugs.

(c) The transplantation center shall have blood bank support with the capacity to supply blood components for the number of transplants that are projected, the ability to irradiate blood components and the availability of a blood separator and central blood repository.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.34 (relating to lung and heart/lung transplantation programs); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.16. Support services.

(a) The transplantation center shall maintain, or by agreement have access to, a rehabilitation center which can provide physical rehabilitation, psychological services and vocational and occupational therapy.

(b) The transplantation center shall maintain, or by agreement have access to, the social support services necessary for the care of transplant recipients and for the assistance to families coping with the transplant experience.

(c) The transplantation center shall maintain a service for counseling recipients which is directed to their particular needs and problems. Additionally, as appropriate, the transplantation service shall provide counseling to donors and to their relatives.

(d) The transplantation center shall maintain the following facilities:

- (1) Adequately equipped operating rooms.
- (2) Adequate equipment and supplies.
- (3) Intensive care facilities capable of maintaining transplant patients.
- (4) Facilities for acute hemodialysis.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.34 (relating to lung and heart/lung transplantation programs); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.17. Selection criteria.

(a) The transplantation program shall have written procedures for selecting transplantation candidates and distributing organs in a fair and equitable manner. Selection criteria shall comply with the National Organ Procurement and Transplantation Network organ allocation priorities and shall be based on objective medical criteria and time on a waiting list.

(b) The transplantation program shall have written policies in place to assure that:

(1) Patient selection decisions are consistent with criteria set forth in the written patient selection criteria.

(2) The transplantation program is responsible for ethical and medical considerations in the patient selection process.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.34 (relating to lung and heart/lung transplantation programs); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.18. Referrals, hours of operation.

(a) The transplantation center shall accept referrals from all physicians.

(b) Transplantation services shall be accessible 24- hours-a-day, 7-days-a-week.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.34 (relating to lung and heart/lung transplantation programs); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.19. Volume of procedures.

(a) Each transplantation program shall perform an adequate number of procedures to maximize quality.

(b) Each transplantation program shall meet the expected survival rate as set forth by the Organ Procurement and Transplantation Network in its bylaws. Those programs whose actual survival rates fall below their expected survival rates will be reviewed by the Department to determine if this deviation can be accounted for by patient mix or some other unique clinical aspect of the transplantation program.

(c) If the transplantation program is unable to provide an explanation for its failure to meet the expected survival rate, the Department will undertake a review of that program to determine if it is in compliance with the criteria in this chapter. The hospital shall cooperate with the Department in this review.

Cross References

This section cited in 28 Pa. Code § 158.31 (relating to kidney transplantation program); 28 Pa. Code § 158.33 (relating to liver transplantation program); 28 Pa. Code § 158.34 (relating to lung and heart/lung transplantation programs); 28 Pa. Code § 158.35 (relating to pancreas transplantation programs); and 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.20. Post-transplantation care.

- (a) The transplantation center shall maintain a program for continuing patient follow-up care throughout the recipient's life.
- (b) This program shall include the following:
 - (1) A system for referring physicians that integrates patient referral and continued patient supervision.
 - (2) The interchange of medical and other information necessary in the care and treatment of patients transferred between physicians responsible for patient care and the transplantation surgery.
 - (3) The provisions of a discharge plan to the referring physician.
 - (4) An obligation to follow the patient at appropriate intervals to assess the outcome of the transplant and to provide consultative care as necessary.

SUPPLEMENTARY CRITERIA

§ 158.31. Kidney transplantation program.

- (a) The general standards in §§ 158.1—158.19 apply to kidney transplantation programs. Additionally, the criteria contained in this section apply only to kidney transplantation programs.
- (b) A kidney transplantation program shall have overall plans and resources to assure a reasonable concentration of experience.
- (c) A kidney transplantation program shall participate in and be certified by the Federal ESRD (End Stage Renal Disease) (Medicare) program and as an ESRD center.
- (d) A hospital which has a kidney transplantation program shall have a Division of Urology comprised of at least one urologist who is either certified by or who has attained preboard certification status with the American Board of Urology or an equivalent Board. The urologist shall be available to act as a consultant when appropriate for the preoperative, operative and postoperative surgical evaluation and management of transplant patients and living donors.

(e) In addition to dialysis facilities for acute hemodialysis, a kidney transplantation program shall be capable of providing peritoneal dialysis.

Cross References

This section cited in 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.32. Heart transplantation program.

(a) The general standards in §§ 158.1—158.19 apply to heart transplantation programs. Additionally, the criteria contained in this section apply only to heart transplantation programs.

(b) A heart transplantation program shall have overall plans and resources to assure a reasonable concentration of experience.

(c) A heart transplantation program shall have on staff and available at all times a cardiologist and a pulmonologist both of whom are either certified by or have attained preboard certification status with the respective appropriate American Board or an equivalent Board. Either of these specialists may also serve as the transplant physician.

(d) The hospital shall have a cardiac catheterization service which meets all of the regulatory requirements for this service. The cardiac catheterization laboratory shall be available to perform these procedures on an emergency basis.

(e) The hospital shall have an open heart surgery program and shall meet all of the regulatory requirements for this service.

(f) The hospital shall meet the following conditions:

- (1) Possess expertise in other relevant areas including cardiology, cardiovascular surgery and pulmonary diseases.
- (2) Identify individuals in these areas to achieve a stable transplant team.

Cross References

This section cited in 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.33. Liver transplantation program.

(a) The general standards in §§ 158.1—158.19 apply to liver transplantation programs. Additionally, the criteria contained in this section apply only to liver transplantation programs.

(b) A liver transplantation program shall have overall plans and resources to assure a reasonable concentration of experience.

(c) A hospital shall have on staff and available a gastroenterologist who is either certified by or who has attained preboard certification status with the American Board of Gastroenterology or an equivalent Board. The gastroenterologist shall have at least 2 years experience in hepatology. The gastroenterologist may also serve as the transplant physician.

(d) The pathologist shall be specifically trained in liver pathology.

Cross References

This section cited in 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.34. Lung and heart/lung transplantation programs.

(a) The general standards in §§ 158.11—158.19 apply to lung and heart/lung transplantation programs. Additionally, the criteria contained in this section apply only to lung and heart/lung transplantation programs.

(b) A lung or heart/lung transplantation program shall have overall plans and resources to assure a reasonable concentration of experience.

(c) A lung or heart/lung transplantation program shall have on staff and available a cardiologist and a pulmonologist who are either certified by or who have attained preboard certification status with the respective appropriate American Board or equivalent Board. Either of these specialists may also serve as the transplant physician.

(d) The hospital shall have a cardiac catheterization service which meets all of the regulatory requirements for this service. The cardiac catheterization laboratory shall be available to perform these procedures on an emergency basis.

(e) The hospital shall have an open heart surgery program and shall meet all of the regulatory requirements for this service.

Cross References

This section cited in 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.35. Pancreas transplantation programs.

(a) The general standards in §§ 158.1—158.19 apply to pancreas transplantation programs. Additionally, the criteria contained in this section applies only to pancreas transplantation programs.

(b) A pancreas transplantation program shall have overall plans and resources to assure a reasonable concentration of experience.

(c) A hospital in which a pancreas transplantation program performs combined kidney/pancreas transplants or sequential kidney and pancreas or sequential pancreas and kidney transplants shall have an active kidney transplantation program.

(d) A hospital which has a pancreas transplantation program shall have a division of endocrinology comprised of at least one endocrinologist currently certified by the American Board of Endocrinology or an equivalent Board. If the endocrinologist serves as the transplant physician, then the endocrinologist shall have at least 1 year of training or 2 years experience in the care of transplant patients.

Cross References

This section cited in 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.36. Other organs.

A facility proposing to establish a program for transplant of an organ other than kidney, heart, liver, lung, heart/lung or pancreas shall:

- (1) Comply with the general criteria contained in this chapter.
- (2) Comply with Organ Procurement Transplant Network criteria applicable to the specific organ.

Cross References

This section cited in 28 Pa. Code § 158.37 (relating to pediatric transplantation programs).

§ 158.37. Pediatric transplantation programs.

(a) A transplantation center that provides a transplantation program to pediatric patients shall do the following:

- (1) Follow the general criteria for transplantation centers and programs in §§ 158.1—158.19.
- (2) Follow the supplementary criteria for the applicable organ transplantation program in §§ 158.31—158.36.
- (3) Follow the criteria in this section in the treatment of pediatric patients.

(b) In those instances where criteria for pediatric transplantation programs differs from supplementary criteria for organ specific transplants, transplantation centers providing services to both adult and to pediatric patients are required to fulfill both the supplementary criteria for the specific organ and the following pediatric transplant criteria. Transplantation centers providing programs exclusively to pediatric patients need only meet the criteria for pediatric transplantation programs.

(c) Those transplantation centers which are exclusively pediatric shall have overall plans and resources to assure a reasonable concentration of experience.

(d) Transplantation centers providing services to pediatric patients shall have on staff and available the following specialists who shall be either certified by or have attained preboard certification status with the appropriate subspecialty board of the American Board of Pediatrics or an equivalent Board:

- (1) Pediatric transplantation programs shall have on staff: a pediatric nephrologist, a pediatric infectious disease specialist and a pediatric internist.
- (2) Pediatric liver transplantation programs shall have on staff: a pediatric gastroenterologist and a pediatric pulmonologist.
- (3) Pediatric heart, lung and combined heart/lung transplantation programs shall have on staff: a pediatric pulmonologist, a pediatric cardiologist and a pediatric cardiac surgeon.

(4) Pediatric pancreas transplantation programs shall have on staff a pediatric endocrinologist.

(e) Transplantation centers providing services to pediatric patients shall have on staff and available the following personnel who are certified or qualified, or both, as follows:

(1) An anesthesiologist who is either certified by or who has attained preboard certification status with the American Board of Anesthesiology or an equivalent Board and has 2 years of experience providing anesthesiology services to pediatric patients.

(2) A dietitian who is registered by the American Dietetic Association or who is a feeding specialist and who has 2 years of experience providing dietetic services to pediatric patients.

(3) A radiologist who is either certified by or who has attained preboard certification status with the American Board of Radiology or an equivalent Board and who has 2 years of experience providing radiology services to pediatric patients.

(4) A physical therapist who has 2 years experience providing services to pediatric patients.

(5) A psychiatrist who is either certified by or who has attained preboard certification status with the American Board of Child Psychiatry or an equivalent Board.

(6) A social worker who has 1 year of experience providing social services to pediatric patients.

(7) A nursing staff that is experienced in providing nursing services to pediatric patients and is of a sufficient complement to meet nursing care goals, standards of nursing practice and nursing care needs of pediatric patients.

(8) An occupational therapist who is registered with the American Occupational Therapy Association and who has 1 year of experience in treating pediatric patients.

(f) A pediatric heart transplantation center shall have cardiac catheterization and open heart surgical services which meet all of the regulatory requirements for pediatric patients.

(g) A pediatric program which provides kidney transplantation services to pediatric patients shall have on staff and available a urologist who is either certified by or who has attained preboard certification status with the American Board of Urology or an equivalent Board and who has 2 years experience providing urology services to pediatric patients.

(h) Transplantation centers that provide transplantation programs to pediatric patients shall have appropriate equipment available to provide the following services to pediatric patients:

- (1) Dialysis.
- (2) Anesthesia.
- (3) Intensive care.
- (4) Operating room.

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