

CHAPTER 136. OPEN HEART SURGICAL SERVICES**GENERAL PROVISIONS**

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Cross References

This chapter cited in 55 Pa. Code § 6100.2 (relating to applicability).

GENERAL PROVISIONS**§ 136.1. Principle.**

Adult open heart surgical services and pediatric open and closed heart surgical services shall be performed only in hospitals and shall be performed in accordance with accepted and prevailing standards of medical practice.

§ 136.2. 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 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).

CABG—Coronary artery bypass graft—A type of open heart procedure wherein a section of a blood vessel is taken from another part of the body to create an alternative path for blood to flow around a narrow or blocked portion of a coronary artery.

Cardiac intensive care service—Service provided to an open heart surgery patient immediately after surgery. This service is provided in a specially equipped area in a facility wherein the highest level of medical care is available. This area shall be equipped to provide invasive monitoring, including arterial pressure, Swan-Ganz catheters and intra-aortic balloon pumps.

Cardiac surgical service—Those personnel involved in the preparation, operation and postoperative care of patients receiving cardiac surgery.

Onsite—In the physical structure at which open heart surgical services are being offered or in an adjoining structure.

Open heart surgery—A surgical procedure to repair acquired or congenital diseases of the heart. The procedure shall do one of the following:

- (i) Include the use of an extracorporeal pump oxygenator (heart lung machine) to perform the functions of the circulatory system during the surgery.
- (ii) Employ minimally invasive procedures, which do not routinely involve the use of the extracorporeal pump oxygenator to perform the same types of surgical procedures, although its presence is required because, in a certain number of cases, this approach may have to be abandoned in favor of the other method.

Open heart surgery program—A service established by a hospital to evaluate, operate on and provide postoperative care to individuals with cardiovascular illness who require surgical intervention. Adult open heart surgery programs may perform any open or closed heart surgery not defined as pediatric heart surgery.

Operating room—The room wherein the open heart surgery is performed.

Pediatric heart surgery—Includes both open heart and closed heart procedures for patients under 18 years of age except for those whose physical development, in the judgment of the patient's physician, allows the patient to receive treatment safely and appropriately in hospitals which do not have a pediatric heart program.

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.

Surgical suite—That area of the hospital wherein the patient is brought for open heart surgery and which is dedicated to the preparation of the surgical team and the patient for open heart surgery and to the actual performance of that surgery.

Twenty-four hours per day—Refers to the availability or onsite presence of specific personnel, support services or equipment on a 24-hour-per-day, 7-days-a-week basis.

PROGRAM, SERVICE AND PERSONNEL REQUIREMENTS

§ 136.11. Director.

(a) The Director of the open heart surgery program shall be a Board certified thoracic surgeon. The director of a pediatric heart surgery program shall be a Board certified pediatric and thoracic surgeon.

(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. If the exception is granted, the Department will specify the maximum period of time for which the interim director shall be appointed.

§ 136.12. Medical staff.

Supporting medical staff of the service shall include:

(1) Thoracic surgeons who are either Board certified or who have attained preboard certification status. There shall be a sufficient number of surgeons within the service to allow for 24-hour-per-day continuous coverage. In a pediatric service, the medical staff shall include pediatric and thoracic surgeons who are either Board certified or who have attained preboard certification status.

(2) A Board certified medical cardiologist with subspecialty certification in cardiovascular disease or who has demonstrated competence as determined by peer review. A pediatric open heart surgery program shall include a board certified pediatric cardiologist.

(3) A cardiac catheterization team with interventional ability on call 24 hours per day.

(4) A Board certified anesthesiologist experienced in open heart anesthesia. There shall be a sufficient number of anesthesiologists within the service for 24 hour per day continuous coverage. The anesthesiologists in a service performing pediatric surgery shall have experience in pediatric anesthesia.

(5) A physician who is Board certified in anatomic and clinical pathology.

§ 136.13. 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 cardiovascular unit before assuming primary responsibility for the nursing care of open heart 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 cardiovascular 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 open heart surgical services program shall be assigned to duties consistent with their training, experience and scope of practice where applicable.

§ 136.14. Support team in the operating room.

(a) The operating room support team shall include:

(1) A circulating registered professional nurse and additional nursing personnel as required.

(2) A perfusionist. Each open heart procedure shall have a designated perfusionist in attendance. This individual shall meet the requirements for Board certification as established by the American Board of Cardiovascular Perfusion. If the perfusionist is not Board certified, all duties shall be performed under the supervision of a certified perfusionist, cardiologist or cardiac surgeon, until the

perfusionist obtains Board certification. This certification shall be obtained within 2 years of the commencement of the perfusionist's employment at the hospital. The perfusionist's duties shall include the operation of the extracorporeal pump oxygenator (heart-lung machine) in accordance with the requirements of the hospital. The perfusionist shall have immediate access to hospital and surgeon specific procedure manuals for the conduct of cardiopulmonary bypass during all open heart procedures.

(b) There shall be a sufficient number of extracorporeal pump oxygenators and perfusionists to allow 24-hour-per-day coverage.

(c) A back-up extracorporeal pump oxygenator shall be available during all open heart procedures.

§ 136.15. Other support services.

(a) Supportive services within the hospital shall include the following, which shall be provided 24 hours per day and shall be either available or onsite, as noted:

(1) Medicine (cardiology onsite; availability of nuclear cardiology; hematology; pulmonary; nephrology; neurology; and infectious disease).

(2) Anesthesiology—available.

(3) Clinical laboratory services, onsite for blood banking, hematology, blood chemistry and urinalysis. These services shall be under the same direct management and quality assurance programs as the main hospital laboratories.

(4) Diagnostic radiology, including bedside X-rays—onsite.

(5) Cardiac catheterization and interventional angiography laboratory—onsite.

(6) Respiratory care services—available.

(7) Cardiac intensive care service—onsite.

(8) Inpatient service for continuing care after transfer from the intensive care unit.

(9) An advanced cardiac life support certified physician—onsite.

(10) Cardiographic laboratory, including continuous electrocardiogram monitoring—available.

(11) Echocardiography service (this may or may not be a part of the cardiographic laboratory)—available.

(12) Installation of pacemakers—available.

(13) Organized and designated cardiopulmonary resuscitation team—onsite.

(14) Bioengineering service—available.

(15) Peripheral vascular surgery and a noninvasive vascular laboratory—available.

(16) Acute inpatient dialysis—available.

(b) An operating room shall be specifically equipped for cardiac surgery, and the room and support facilities shall be of adequate size, as per Inter-society

Commission on Heart Disease requirements or American College of Cardiology/
American Hospital Association Guidelines.

§ 136.16. Rapid mobilization.

(a) An open heart surgery program shall have the capability for rapid mobilization of the cardiac surgical service and support team members for emergency procedures, 24 hours per day.

(b) There shall be an on-call schedule of physicians established and posted at each patient unit and other areas where cardiac surgical patients are admitted and at the communications center of the hospital to ensure that there is 24-hour-per-day emergency care and peri-operative care available.

§ 136.17. Observation of patients.

A cardiac surgical care service shall include the capability of visual observation of all patients.

§ 136.18. Postoperative care.

(a) An intensive surgical care service shall be available immediately after surgery to provide invasive monitoring, including Swan-Ganz catheter, arterial pressure and intra-aortic balloon pumps.

(b) The cardiac surgical service shall be responsible for postoperative care and involved in discharge planning of patients.

§ 136.19. Education and training.

The staff of the open heart surgical program shall engage in the following activities:

- (1) Ongoing programs of continuing education in cardiovascular care.
- (2) Provision of training and consultation services with other providers of cardiovascular care and others.
- (3) Patient and family education.

§ 136.20. Pediatric heart surgery—supplementary criteria.

(a) A hospital which provides pediatric heart surgery shall meet the standards in this chapter for a cardiovascular surgery program for adults.

(b) In addition, the following criteria shall be met by a pediatric heart surgery program:

- (1) The facility shall be capable of providing definitive diagnostic and therapeutic services for children with all types of cardiovascular disease.
- (2) A diagnostic laboratory with radiographic and cardiac catheterization equipment generally similar to that for adults. Bi-plane cineangiography shall be readily available 24 hours per day, and laboratories (both catheterization and general chemical) shall be equipped for small volume samples.
- (3) Surgical equipment appropriate for newborns, infants and children.

(4) Intensive care facilities for newborns (as defined by current American Academy of Pediatrics/American College of Obstetrics and Gynecology Guidelines for Perinatal Care), infants and children.

(5) All staff responsible for care of the pediatric patient shall have experience and training in pediatrics including both physiological and psychosocial needs of the patient.

§ 136.21. Quality management and improvement.

(a) A hospital performing open heart surgery shall maintain patient data on the following:

- (1) Mortality/morbidity.
- (2) Infections and complications.
- (3) Patient risk factors.
- (4) Volume of procedures performed.

(b) The hospital shall provide this information to the Department on a quarterly basis, on a form prescribed by the Department. This data shall be integrated into the hospital's quality assurance program and used to ensure necessary corrections to improve outcomes.

(c) In lieu of the information listed under subsection (a), a hospital may submit information provided by its thoracic surgeons to the Risk Stratification Program of the Society of Thoracic Surgeons.

(d) The Department will review the information submitted by the hospital and other relevant information which is available to assess the qualitative performance of the hospital's open heart surgery program.

(e) If the Department's review of this information raises concerns with the quality of care in an open heart surgery program, the Department will undertake a review of that program to determine if these concerns are valid. The hospital shall cooperate with the Department in this review.

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