

CHAPTER 138. CARDIAC CATHETERIZATION SERVICES

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GENERAL PROVISIONS

§ 138.1. Principle.

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

§ 138.2. 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).

Cardiac catheterization—A procedure used to diagnose and treat various cardiac and circulatory diseases that involves inserting a thin, pliable catheter, which is viewable by X-ray, into a major blood vessel of the arm or leg, and manipulating the tip of the catheter through veins or arteries to the heart.

Cardiac catheterization area—That portion of the hospital dedicated to the performance of cardiac catheterizations, including the cardiac catheterization laboratory where the invasive procedures are performed by the physician, and preoperative and postoperative recovery units used for treatment of the cardiac catheterization patient.

Electrophysiology study (EPS)—diagnostic—The use of blood vessel access to position electrode catheters in various intra cardiac locations with the help of fluoroscopy for the purpose of recording the timing of electrical events to assess the location and direction of impulse propagation. The term includes procedures designed to induce ventricular or supraventricular tachycardia and activation sequence mapping of cardiac tachyarrhythmias.

Electrophysiology study (EPS)—therapeutic—EPS used as or in combination with a therapeutic procedure, which includes electrode catheter ablative procedures and implantation of antitachyarrhythmia devices and implantable cardioverter defibrillators.

High-risk cardiac catheterization—Cardiac catheterization which presents a high risk of significant cardiac complication. The term includes diagnostic cardiac catheterization procedures that present a high risk of significant cardiac complication, PTCA, pediatric cardiac catheterization and therapeutic electrophysiology except for the implantation of routine permanent pacemakers.

Low-risk cardiac catheterization—Cardiac catheterization which is not high-risk cardiac catheterization.

Onsite—In the physical structure at which cardiac catheterization services are being offered or in an adjoining structure.

PTCA—Percutaneous transluminal coronary angioplasty—A procedure which uses a balloon catheter, plaque removing device, laser device or mechanical stent to re-open collapsed, blocked or partially blocked arteries.

Pediatric cardiac catheterization—The performance of cardiac catheterization on a person who is under 18 years of age except for those patients whose physical development, in the judgment of the patient's physician, allows the patient to receive treatment safely and appropriately in hospitals that do not have pediatric cardiac catheterization programs.

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.

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, PERSONNEL AND AGREEMENT
REQUIREMENTS**

§ 138.11. Director.

(a) The director of the cardiac catheterization service shall be Board certified in cardiology or pediatric cardiology, as appropriate.

(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.

§ 138.12. Medical staff.

(a) There shall be at least two physicians staffing the cardiac catheterization laboratory to perform angiographies.

(b) These physicians shall be either Board certified or shall have attained preboard certification status in cardiovascular diseases with specialized training in invasive procedures.

§ 138.13. Nursing staff; other health care personnel.

(a) There shall be at least one registered nurse assigned to provide nursing care for patients in the cardiac catheterization area at all times who shall have intensive care or coronary care experience and knowledge of cardiovascular medications, and experience with cardiac catheterization patients. In pediatric units, this nurse shall also have experience in pediatric cardiac surgery units.

(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, where applicable.
- (c) In addition to the requirements for the nursing staff in subsections (a) and (b), 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) Catheterization laboratory health care personnel shall be assigned to duties consistent with their training, experience and scope of practice when applicable.
 - (d) The patient's preoperative and postoperative care in the cardiac catheterization area shall be provided by a registered nurse and other nursing staff as required to meet patient care needs. Either nursing personnel or other health care personnel with appropriate education, training and experience shall assist the physician in the performance of the cardiac catheterization procedures in the cardiac catheterization laboratory.

§ 138.14. Programs and services.

- (a) To perform cardiac catheterizations a hospital shall be an acute care facility that:
 - (1) Has inpatient medical and surgical services onsite.
 - (2) Has a coronary care unit onsite with 24-hour per day monitoring capability.
 - (3) Has a peripheral vascular surgical program available.
 - (4) Provides noninvasive cardiac diagnostic modalities including exercise and pharmacologic stress testing, echo cardiography and nuclear cardiology.
 - (5) Has a setting in which ambulatory cardiac catheterization patients can be observed for 4 to 6 hours after the procedure.
 - (6) Has adequate physician coverage to manage postprocedure complications.
- (b) Outpatient diagnostic cardiac catheterization services shall be performed if care is exercised in selecting only appropriate low risk patients as defined in this chapter.
- (c) To allow for continuity of care, mobile cardiac catheterization laboratories may be utilized onsite at a hospital which is already providing cardiac catheter-

ization services while the existing, fixed cardiac catheterization laboratory is being renovated or its equipment upgraded.

§ 138.15. High-risk cardiac catheterizations.

A hospital may perform high-risk cardiac catheterizations only if it has an open heart surgical program onsite.

§ 138.16. Transfer agreements for low-risk cardiac catheterization hospitals.

(a) A hospital that does not have an open heart surgical program onsite may perform low-risk cardiac catheterizations if the hospital has protocols for distinguishing between low and high-risk cardiac catheterization patients and a formal written agreement with at least one hospital that does have an open heart surgical program onsite, which agreement includes the following:

- (1) Protocols addressing indications, contraindications and other criteria for the emergency transfer of patients in a timely manner.
- (2) Assurance of transfer of patients to an open heart surgery program and initiation of open heart surgery in a timely manner.
- (3) Provision for semiannual data exchange on performance between the hospitals party to the agreement.
- (4) Specification of mechanisms for continued substantive communication between the hospitals party to the agreement, and between their sending and receiving physicians.

(b) The agreement shall remain continuously in effect and be reviewed at least annually.

§ 138.17. PTCA.

(a) In a hospital in which elective PTCA is performed, each physician performing PTCAs shall be either Board certified or shall have attained preboard certification status in cardiovascular diseases with specialized and appropriate training in interventional cardiology procedures.

(b) A rigorous mechanism for valid peer review shall be established and ongoing in a hospital offering PTCA services.

(c) If a hospital that does not have an open heart surgery program onsite performs an emergent PTCA, the hospital shall report the circumstances to the Department in writing within 72 hours.

§ 138.18. EPS studies.

(a) In a hospital in which EPS is performed, each physician performing EPS shall be either Board certified or shall have attained preboard certification status in cardiovascular diseases and shall also be either Board certified or have attained preboard certification status in clinical cardiac electrophysiology.

(b) Therapeutic electrophysiology, including ablation and the implantation of automatic implantable cardioverter defibrillators shall be performed in a hospital with an open heart surgery program, and not in another facility. Implantation of routine permanent pacemakers may be performed in hospitals that do not have an open heart surgery program onsite. Pediatric diagnostic electrophysiology procedures also shall only be performed at a hospital with onsite pediatric cardiovascular surgery.

§ 138.19. Pediatric cardiac catheterizations.

A hospital may perform pediatric cardiac catheterizations only if:

- (1) It has a pediatric heart surgical program onsite.
- (2) The physicians and other staff who participate in the pediatric cardiac catheterizations are trained and experienced in the care of the pediatric cardiac patient.
- (3) The equipment used for pediatric cardiac catheterizations is appropriate to meet the needs of the pediatric patient. 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.

§ 138.20. Quality management and improvement.

(a) A hospital providing cardiac catheterization services shall maintain patient data on the following:

- (1) Mortality/morbidity.
- (2) Infections and complications.
- (3) Patient risk factors.
- (4) Volume of procedures performed (including separate volumes for diagnostic visualizations, PTCA and electrophysiology procedures).

(b) The hospital shall provide this information to the Department through the Pennsylvania Cardiac Catheterization Report. This data shall be integrated into the hospital's quality assurance program and used to ensure necessary corrections to improve outcomes.

(c) 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 cardiac catheterization program.

(d) If the Department's review of this information raises concerns with the quality of care in a cardiac catheterization 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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