

Existing Title 22 Cardiac Catheterization Laboratory Service Regulations

§ 70438. Cardiac Catheterization Laboratory Service.

Cardiac catheterization laboratory service shall be organized to perform laboratory procedures for obtaining physiologic, pathologic and angiographic data on patients with cardiovascular disease.

§ 70438.1. Cardiac Catheterization Laboratory Service -General Requirements.

The cardiac catheterization laboratory service may be approved in a general acute care hospital which does not provide cardiac surgery provided the following requirements are met:

- (a) The hospital shall maintain a current written transfer agreement as specified in Section 1255 of the Health and Safety Code, which shall include all of the following:
 - (1) Provisions for emergency and routine transfer of patients.
 - (2) Provisions which specify that cardiac surgery staff and facilities shall be immediately available to the patient upon notification of an emergency.
 - (3) Provisions which specify that the cardiac catheterization laboratory staff shall have responsibility for arranging transportation to the receiving hospitals.
- (b) Only the following diagnostic procedures shall be performed in the catheterization laboratory:
 - (1) Right heart catheterization and angiography.
 - (2) Right and left heart catheterization and angiography.
 - (3) Left heart catheterization and angiography.
 - (4) Coronary angiography.
 - (5) Electrophysiology studies.
 - (6) Myocardial biopsy.
- (c) The hospital shall comply with all of the requirements of Sections 70433(a), (b), (c)(1), (e), (i), (j), 70435a) and 70437(a).

§ 70438.2. Cardiac Catheterization Laboratory Service - Expanded.

- (a) As used in this section, the following definition applies:
 - (1) "Expanded cardiac catheterization laboratory space" means a catheterization laboratory space, as provided for in Section 70439(a), that is located in a building connected to a general acute care hospital, as described in subdivision (b).
 - (b) General acute care hospitals that qualify, pursuant to Section 1255(d)(3) of the Health and Safety Code, to provide cardiac catheterization laboratory service in expanded cardiac catheterization laboratory space, may do so, provided that:
 - (1) There exists an enclosed all-weather passageway that connects the general acute care hospital and the structure in which the expanded cardiac catheterization space is located. Such a passageway shall:
 - (A) be short enough to allow a patient that is undergoing a cardiac catheterization procedure in the expanded cardiac catheterization laboratory space and who needs emergent care to arrive in the appropriate definitive care option in the general acute care hospital within 10 minutes of the time the physician deems that the patient needs to be transported to the definitive care option within the general acute care hospital. The actual transport time of the patient to the definitive care option from the cardiac catheterization laboratory space shall not exceed 5 minutes.

(B) have lighting and emergency lighting and power in accordance with Sections 70851 and 70841, respectively;

(C) have installed heating, air conditioning and ventilating systems;

(D) be equipped with an emergency call feature at each end of the enclosed all-weather passageway. For the purposes of this subdivision, "emergency call feature" is defined as a telephonic connection, or any other means of communication, permanently located within the enclosed all-weather passageway, that allows the medical staff members to communicate with medical staff members in the general acute care hospital;

(E) have access that is restricted to authorized staff and to patients accompanied by authorized staff. Authorized staff shall be determined by the policies and procedures developed, maintained, and implemented by the general acute care hospital; and

(F) be secured by electronic means in accordance with the security policies and procedures developed, maintained, and implemented by the general acute care hospital.

(2) Policies and procedures for expanded cardiac catheterization laboratory space care for both inpatients and outpatients shall be developed, maintained and implemented by the general acute care hospital.

(A) Inpatient care policies and procedures for the expanded cardiac catheterization laboratory space shall include consideration of the acuity of the inpatient and the type of procedure needed by the patient for the purpose of determining whether the placement of an inpatient in the expanded cardiac catheterization laboratory space is medically appropriate.

(3) Inpatients shall have priority for placement on the general acute care hospital's cardiac catheterization laboratory schedule. Inpatients in need of cardiac catheterization laboratory procedures shall not have such procedures performed in the expanded cardiac catheterization laboratory space, unless all of the general acute care hospital cardiac catheterization laboratory space is actively in use.

(4) Pediatric cardiac catheterization, as defined in Health and Safety Code Section 1255.5(e), services shall not be performed in an expanded cardiac catheterization laboratory space, in accordance with Sections 1255.5(d) and (e) of the Health and Safety Code.

(c) Not more than 25 percent of the general acute care hospital's inpatients in need of cardiac catheterization laboratory service may have such procedures performed in the expanded cardiac catheterization laboratory space per calendar year. The general acute care hospital shall maintain records that provide the number of cardiac catheterization procedures performed in the expanded cardiac catheterization laboratory space, and the patient's status as an inpatient or outpatient.

(d) The hospital shall comply with all of the requirements of Sections 70433(a), (b), (c)(1), (e), (i), (j), 70435(a) and 70437(a).

§ 70437. Cardiovascular Surgery Service Equipment and Supplies.

(a) Cardiovascular catheterization laboratory equipment and supplies shall include but not be limited to:

(1) X-ray machine

(2) Image intensifier.

(3) Pulse generator.

(4) Camera.

- (5) Spot film device.
- (6) Videotape viewing equipment of fluoroscopic procedures.
- (7) Magnetic tape recording and playback equipment.
- (8) Motor driven cardiac table.
- (9) Cinefluorography and radiography equipment.
- (10) Monitoring and recording equipment.
- (11) Pressure transducers.
- (12) Equipment for determining cardiac output.
- (13) Equipment for exercising patients during procedures.
- (14) Equipment for determining oxygen saturation, hemoglobin, blood gas analysis and pH.
- (15) Appropriate cardiac catheters and accessory equipment.
- (16) Resuscitation equipment.
- (b) Cardiovascular operating room equipment and supplies shall include but not be limited to:
 - (1) Monitoring and recording equipment for:
 - (A) Electrocardiograms.
 - (B) Pressures.
 - (C) Coronary blood flow.
 - (D) Cardiac output.
 - (E) Patient temperature.
 - (2) Blood gas analyzer.
 - (3) Heart-lung machine with oxygenator.
 - (4) Device for rapid cooling and heating of the patient.
 - (5) DC defibrillator.
 - (6) Magnetic tape recording equipment.
 - (7) Suction outlets, piped in air and oxygen and tanks of gas including mixtures of oxygen and carbon dioxide.
 - (8) All other necessary equipment and supplies as required in an operating room.

§ 70439. Cardiovascular Surgery Service Space.

- (a) Catheterization laboratory space shall include:
 - (1) A minimum floor area of 40 square meters (450 square feet) for the procedure room.
 - (2) A minimum floor area of 9 square meters (100 square feet) for each of the following:
 - (A) Control, monitoring and recording equipment.
 - (B) X-ray power and controls.
 - (C) Work room.
 - (D) Dressing rooms for doctors and nurses.
- (b) Cardiovascular surgery space shall include:
 - (1) Operating rooms that comfortably accommodate 12 persons and all necessary equipment with a minimum floor area of 60 square meters (650 square feet).
 - (2) Work room.
 - (3) Pump work room.
 - (4) Adequate storeroom.