§ 70431. Cardiovascular Surgery Service Definition.
Cardiovascular surgery service means the performance of laboratory procedures for obtaining physiologic, pathologic, and angiographic data on patients, and cardiovascular operative procedures, each supported by appropriate staff, space, equipment and supplies. It is the intent of this definition that the two aspects of this service shall not exist separately.

§ 70433. Cardiovascular Surgery Service General Requirements.
(a) Written policies and procedures shall be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. These policies and procedures shall include provision for at least:

1. Definitions of qualifications of physicians for privileges to perform cardiovascular laboratory catheterization procedures and/or surgery.
2. Regular review of case management, both preoperatively and postoperatively.
3. Collection, processing and retrieval of data on all patients to include at least: diagnosis, procedure performed, pathophysiologic, angiographic, morbidity and mortality data.
4. Recommendations regarding equipment used, procedures performed and staffing patterns in the catheterization laboratory and cardiovascular surgery units.

There exists in the current regulations a core set of required administrative and written policies, such as those found in sub-sections 70433 (a), that pertain to all the supplemental services. CHA would like to recommend that regulations pertaining to administrative policies and procedure requirements be consistent across the supplemental service areas. Drafting a standard set of general requirements relevant to all supplemental services, and including nuanced requirements pertaining to a specific service area under the section pertaining to that service area, will eliminate redundancy, improve consistency, and focus attention to key provisions that are unique to a particular supplemental service.

Or
(a) Written policies and procedures shall be developed, in consultation with cardiovascular surgery clinical staff and administration based on national standards, and maintained.

(b) The responsibility and the accountability of the service to the medical staff and administration shall be defined by the hospital.

(c) An adequate service base shall support the provision of these services. The hospital and its medical staff and other clinicians must ensure quality and adequate volumes. Recommended minimums are 75 cardiovascular procedures requiring extra corporeal bypass per year.

1. 260 cardiac catheterizations per year. Move to new section 70438.2 (b)
2. 150 cardiovascular procedures requiring extra corporeal bypass per year.

(d) The cardiovascular surgical service shall be available at all times for emergencies.

(e) Supportive diagnostic services with trained personnel shall be available and include, where appropriate, electrocardiography, vectorcardiography, exercise stress testing, cardiac pacemaker station, and echocardiography, phonocardiography and pulse tracings. A cardiac catheterization laboratory service shall be available to support
the cardiovascular surgery service based on the program and the patients served to meet the needs of the patients.

(f) An intensive care service with respiratory care capabilities shall be provided by the hospital with the appropriate trained personnel shall be available to support the cardiovascular surgery service.

(g) An animal laboratory is recommended as support for the cardiovascular surgery service.

(h) A cardiac rehabilitation program should be integrated with available to the cardiovascular surgery service for early identification of the patient who can profit thereby, post-operative rehabilitation of appropriate patients.

(i) All persons operating or supervising the operation of X-ray radiology equipment machines shall comply with the requirements of the Radiologic Technology Regulations, Subchapter 4.5, Chapter 5, Title 17, California Administrative Code.

(j) Periodically, an appropriate committee of the medical staff shall evaluate the services provided and make appropriate recommendations to the executive committee of the medical staff and administration move to general requirements section in Title 22, Article 6 pertaining to all supplemental services.

(k) Transesophageal Echocardiogram should be available to the operating room and staffed by the appropriately trained professionals.

§ 70435. Cardiovascular Surgery Service Staff.

(a) Cardiovascular catheterization laboratory.

(1) A physician shall have overall responsibility for the service. This physician shall be certified or eligible for certification in cardiology by either the American Board of Internal Medicine or the American Board of Pediatrics or have equivalent experience and training. He shall be responsible for:

(A) Implementing established policies and procedures.

(B) Supervision and training of all personnel, including in-service training and continuing education.

(C) Assuring proper safety, function, maintenance and calibration of all equipment.

(D) Maintaining a record of all angiographic procedures performed.

(2) A physician who is certified or eligible for certification by the American Board of Radiology with special training or experience in cardiovascular radiology shall be available to the cardiovascular surgery service staff.

(3) Two persons (registered nurses or cardiovascular technicians) shall assist during the performance of all cardiac catheterization procedures. These personnel shall be trained in the use of all instruments and equipment and shall be supervised by a physician.

(4) A biomedical engineer shall be available for consultation as required.

(5) An electronic technician shall be available where required.

(b) Cardiovascular operative service.

(1) A physician shall have overall responsibility for the service. This physician shall be certified or eligible for certification by the American Board of Thoracic Surgery or the American Board of Surgery with training and experience in cardiovascular surgery. S/He shall be responsible for:

(A) Implementing established policies and procedures.

(B) Training and supervising the nurses and technicians in special techniques.

(C) Training and supervising the clinical perfusionists.
Based on national standards, a minimum number of licensed personnel, including a surgeon of three two surgeons, which may include a resident or fellow, and a nurse practitioner or physician’s assistant or medical student shall constitute a surgical team for the performance of all cardiovascular operative procedures which require extracorporeal bypass. At least one surgeon must meet the requirements outlined in subparagraph (b) (1) above.

Anesthesia for cardiovascular procedures surgery requiring extracorporeal bypass shall be administered by a physician Licensed anesthesia providers, working within their scope or practice, and privileged by the medical staff to provide anesthesia who is certified or eligible for certification by the American Board of Anesthesiology.

A physician who is certified or eligible for certification in cardiology by the American Board of Internal Medicine should be a member of the surgical team and should assist in monitoring the patient.

A nationally board certified clinical perfusionist shall operate the extracorporeal equipment under the immediate supervision of the cardiovascular surgeon or cardiologist.

§ 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.
   (6) Resuscitation equipment. Move Cath Lab equipment to new section 70438.4

(b) Cardiovascular operating room equipment and supplies shall be based on national standards and the procedures performed and the patients served by the cardiovascular surgery service. include but not be limited to:
(c) Monitoring and recording equipment for:
(d) Electrocardiograms.
(e) Monitoring of PP pressures with digital display visible to the operating team.
(f) Coronary blood flow.
(g) Cardiac output. Equipment to monitor cardiac output.
(h) Patient temperature.
(i) Access to blood gas analyzer and rapid-response labs in the operating room.
(j) — Heart-lung machine with oxygenator.
(k) — Device for rapid cooling and heating of the patient.
(l) — DC defibrillator.
(m) — Magnetic tape recording equipment.
(n)(b) — Suction outlets, piped in air and oxygen and tanks of gas including mixtures of oxygen and carbon dioxide.
(o) — All other necessary equipment and supplies as required in an operating room.

§ 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 or suspected of having cardiovascular disease and to perform diagnostic, therapeutic and interventional procedures on patients with or suspected of having cardiovascular disease.

§ 70438.1. Cardiac Catheterization Laboratory Service—General Requirements for Cardiac Catheterization Laboratories—Laboratory Service in a Hospital that does Not provide—maintain a Cardiovascular Surgery Service.
The cardiac catheterization laboratory service may be approved in a general acute care hospital which does not provide—maintain a cardiovascular surgery service is limited to providing certain diagnostic cardiac catheterization services provided the following requirements in subsection (a) are met. The cardiac catheterization laboratory space may be used for additional cardiovascular diagnostic and non-cardiac interventional procedures, provided the hospital requests and is granted program flexibility in accordance with the procedures required by the department.

(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 cardiac catheterization procedures shall be performed in the catheterization laboratory space:
   (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.
   (7) Permanent insertion of cardiac rhythm management in-plants
   (8) Non-cardiac percutaneous angiography and intervention
   (9) Lead extraction
   (10) Such other procedures as authorized by statute or by flexibility granted by the Department under the procedures provided in Section 70129.
   (11) Pacemaker insertion, insertion of pacemaker leads, other pacemaker related intervention.

(c) The hospital shall comply with all of the requirements of Sections 70433(a), (b), (c)(1), (e), (i), (j), 70435a) and 70437(a).
(c) The hospital shall comply with all of the requirements of Sections 70438.2 (b) (d) and (h) and 70438.3 (1) and 70438.4 (a).

(d) The cardiac catheterization laboratory space may be used for additional cardiovascular diagnostic procedures and non-cardiovascular diagnostic and interventional procedures.

§ 70438.2-General Requirements for Cardiac Catheterization Laboratories which Maintain a Cardiovascular Surgery Service. Separated out from Sections 70433 pertaining to Cardiovascular Surgery Service.

Cardiac catheterization laboratories may perform cardiac and non-cardiac procedures based on national standards and approved by the hospital medical staff. The following cardiac and non-cardiac procedures shall be performed in the cardiac catheterization laboratory space of a hospital with Cardiovascular Surgery Service:

- Right heart catheterization and angiography.
- Right and left heart catheterization and angiography.
- Left heart catheterization and angiography.
- Coronary angiography.
- Electrophysiology studies and/or ablation.
- Myocardial biopsy.
- Carotid stenting.
- Non-Cardiac angiography and intervention.
- Placement of cardioverter defibrillator.
- Placement of pacemaker and cardiac resynchronization device.
- Percutaneous coronary intervention.
- Insertion of balloon pump or left ventricular assist device.
- Septal repair.
- Percutaneous valve replacement.
- Valvuloplasty.
- Fractional flow reserve.
- Intravascular ultrasound.
- Optical coherence tomography.
- Rotational and direct atherectomy.
- Intracardiac ultrasound.
- Mechanical and rheolytic thrombectomy.
- Percardiocentesis.
- Transesophageal Echocardiogram.
- Acute stroke diagnostic and therapeutic procedures.
- Such other procedures as authorized by statute or by flexibility granted by the Department under the procedures provided in Section 70129.

(b) The hospital, the hospital medical staff, and other clinicians must ensure quality and adequate volumes of cardiac catheterization laboratory procedures.

(b) An adequate service base shall support the provision of these services. Recommended minimums are 260 cardiac catheterizations per year for a mature program (i.e., a cardiac catheterization laboratory that has been operational for at least three years); however, the Department may approve programs with lesser volumes in the case of new programs that are reasonably expected to achieve these
minimums within three years, or that otherwise have demonstrated that patient safety can be achieved and maintained at lesser volumes.

(c) The cardiac catheterization laboratory service shall be available at all times for emergencies.

(d) Supportive diagnostic services with trained personnel shall be available and include, where appropriate, electrocardiography, vectorcardiography, exercise stress testing, cardiac device/pacemaker station, implantation and echocardiography, phonocardiography and pulse tracings for the services provided in the cardiac catheterization laboratory.

(e) An intensive care service with respiratory care capabilities shall be provided by the hospital to support the cardiac catheterization laboratory service.

(f) All persons operating or supervising the operation of X-ray radiological machines shall comply with the requirements of the Radiologic Technology Regulations, Subchapter 4.5, Chapter 5, Title 17, California Administrative Code.

§ 70438.3 Cardiac Catheterization Laboratory Service Staff. Separated out from Sections 70435 pertaining to Cardiovascular Surgery Service.

(a) Cardiovascular catheterization laboratory staff:

(1) A physician shall have overall responsibility for the service. This physician shall be certified or eligible for certification in cardiology by either the American Board of Internal Medicine or the American Board of Pediatrics or have equivalent experience and training. He shall be responsible for: The physician will work with leadership and management team to:

(A) Implementing established policies and procedures.
(B) Supervising and training of all personnel, including in-service training and continuing education.
(C) Assuring proper safety, function, maintenance and calibration of all equipment.
(D) Maintaining a record of all angiographic procedures performed.

(2) A physician who is certified or eligible for certification by the American Board of Radiology with special training or experience in cardiovascular radiology shall be available to the cardiovascular surgery service staff.

Cardiovascular Surgery Service Only

(3) Two persons (registered nurses or cardiovascular technicians) shall assist during the performance of all cardiac catheterization procedures. These personnel shall be trained in the use of all instruments and equipment and shall be supervised by a physician.

(4) A biomedical engineer shall be available for consultation as required.

(5) An electronic technician shall be available where required.

§ 70438.4 Cardiac Catheterization Laboratory Service Equipment and Supplies. Separated out from Sections 70437 pertaining to Cardiovascular Surgery Service.

(a) There shall be adequate and appropriate equipment for the delivery of cardiac catheterization laboratory services, based on national standards for the services provided. Cardiovascular service equipment and supplies shall include but not be limited to:
(1) X-ray machine. Radiological equipment pertinent to the procedures being performed.
(1) Image intensifier.
(1) Pulse generator.
(1) Camera (tube and rotor)
(1) Spot film device
(1) Videotape viewing equipment of fluoroscopic procedures.
(1) Magnetic tape recording and playback equipment.
(1) Motor driven cardiac table.
(1) Cinefluorography and radiography equipment.
(1) Monitoring and recording equipment, including equipment for determining oxygen saturation.
(1) Pressure transducers.
(1) Equipment for determining cardiac output.
(1) Equipment for exercising patients during procedures.
(1) Equipment for determining oxygen saturation, hemoglobin, blood gas analysis and pH.
(1) Appropriate cardiac supplies and accessory equipment.
(1) Resuscitation equipment.

§ 70439. Cardiovascular Surgery Service Space. Move to Title 24
(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.