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AFL 11-04 Revision Date February 16, 2011				(Supercedes AFL10-13 and AFL 10-08)		
General Acute Care Hospitals: Use of Cardiac Catheterization Laboratory Space: Program Flexibility						
	If GACHs wish to provide services other than those permitted for catheterization laboratory space, they must first obtain program flexibility approval from their CDPH District Office as described in this AFL.					
Title 22	Description	Evidence of Completion	Person Responsible	Due Date	Action Taken	% Completed
§70431-39, 70805 and 70129	Cardiovascular surgery service is defined in Title 22 CCR Section 70431 as "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."					
§70438	The use of cardiac catheterization laboratory space is defined in Title 22 CCR Section 70438. This regulation requires cardiac catheterization laboratory service to be "organized to perform laboratory procedures for obtaining physiologic, pathologic and angiographic data on patients with cardiovascular disease."					
	GACHs that do not provide cardiac surgery service					
	GACHs that have been issued special permits to operate cardiac catheterization laboratories under H&S Code Section 1255(h), but have not been issued a special permit to offer cardiac surgery under H&S Code Section 1255(g), are permitted to conduct only minimally invasive diagnostic procedures in these spaces. Those procedures are delineated at Title 22 of the CCR, Section 70438.1(b), which allows only the following diagnostic procedures to 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.					

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Title 22	Description	Evidence of Completion	Person Responsible	Due Date	Action Taken	% Completed
	(5) Electrophysiology studies.					
	(6) Myocardial biopsy.					
§70805	Section 70805 addresses space conversion and states: "Spaces approved for specific uses at the time of licensure shall not be converted to other uses without the written approval of the Department."					
	Use of cardiovascular surgery space or cardiac catheterization laboratory space for purposes other than permitted by existing law requires program flexibility be approved by the Department prior to the alternative use of the space.					
	GACHs should direct program flexibility requests and supporting documentation to their local CDPH District Office. In order to consider a program flexibility request, CDPH's Licensing and Certification Program (L&C) requests the following information be provided:					
	1. A list of procedures to be performed in the catheterization laboratory with a listing of the anatomic location of the exact procedures proposed.					
	2. Policy and procedures for conscious sedation and type of sedation used. Identify who will administer the conscious sedation, including the competency of all staff administering conscious sedation.					

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Title 22	Description	Evidence of Completion	Person Responsible	Due Date	Action Taken	% Completed
	3. Policies and procedures describing how the hospital will ensure that patients who require emergency cardiac catheterization will receive immediate priority in the cardiac catheterization laboratory in the event that the cardiac catheterization laboratory is occupied by a non-emergent case.					
	4. For operative procedures, surgical and anesthesia staffing and competencies.					
	5. The mechanism for inclusion in Quality Assessment and Performance Improvement.					
	6. Documentation and all policies and procedures for radiation protection and monitoring of radiation exposure, including monitoring of apron effectiveness and primary radiation barriers.					
	7. Policies and procedures for time-out procedures.					
	8. Policies and procedures for patient transfer to the recovery room or ICU/Medical Surgical Unit.					
	9. Policies that identify in-patient versus out-patient procedures, patient holding areas and recovery areas.					
	10. Documentation of transfer agreements and availability of cardiovascular surgery if emergent transfer is required.					
	11. Dress code in the catheterization laboratory.					
	12. Temperature and humidity logs.					
	13. Policies and procedures for fires in the catheterization laboratory.					
	14. Moderate sedation policy.					
	15. Policies and procedures on the cleaning of the catheterization laboratory.					
	16. Infection control policies and procedures.					

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Title 22 Division 5						
§70351. Special Permit Required						
§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.						
Title 22	Description	Evidence of Compliance	Person Responsible	Due Date	Action Taken	% Completed
§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.					

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Cardiac Catheterization Lab Licensing Requirements

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Title 22	Description	Evidence of Compliance	Person Responsible	Due Date	Action Taken	% Completed
	(b) The responsibility and the accountability of the service to the medical staff and administration shall be defined.					
	(c) An adequate service base shall support the provision of these services. Recommended minimums are:					
	(1) 260 cardiac catheterizations per year.					
	(e) Supportive diagnostic services with trained personnel shall be available and include, where appropriate, electrocardiography, vectorcardiography, exercise stress testing, cardiac pacemaker station, echocardiography, phonocardiography and pulse tracings.					
	(f) An intensive care service with respiratory care capabilities shall be provided by the hospital.					
	(h) A cardiac rehabilitation program should be integrated with the cardiovascular surgery service for early identification of the patient who can profit thereby.					
	(i) All persons operating or supervising the operation of X-ray 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.					

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Title 22	Description	Evidence of Compliance	Person Responsible	Due Date	Action Taken	% Completed
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.					

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Title 22	Description	Evidence of Compliance	Person Responsible	Due Date	Action Taken	% Completed
§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) Video tape viewing equipment of fluoroscopic procedures.					
	(7) Magnetic tape recording and play back equipment.					
	(8) Motor driven cardiac table					
	(9) Cine-fluorography 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.					
§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.					

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Title 22	Description	Evidence of Compliance	Person Responsible	Due Date	Action Taken	% Completed
	(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), 70435(a) and 70437(a).					
§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.					