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EDMUND G. BROWN JR.
Governor

AFL REVISION NOTICE

Subject: General Acute Care Hospitals: Use of Cardiac Catheterization
Laboratory Space; Program Flexibility

Revision To: AFL 10-13

Revision Date: February 16, 2011

Attachments: AFL 11-04

This notice is to inform you that the California Department of Public Health has revised All Facilities Letter (AFL) 10-13 with the attached AFL 11-04, which supersedes AFL 10-13 and AFL 10-08.

The revised AFL has been updated to provide clarification, uniformity and consistency in processing program flexibility requests for use of cardiac catheterization laboratory space in General Acute Care Hospitals.

Please review the AFL and contact your local district office if you have further questions.



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AFL 11-04
(Supersedes AFLs 10-08 & 10-13)

TO: General Acute Care Hospitals

SUBJECT: Use of Cardiac Catheterization Laboratory Space

AUTHORITY: Title 22 California Code of Regulations (CCR)
Sections 70431-39, 70805 and 70129.

Health and Safety (H&S) Code Section 1255, 1276.05

The California Department of Public Health (CDPH) has recently received questions about what services may be provided in cardiac catheterization laboratory space in General Acute Care Hospitals (GACH). This All Facilities Letter (AFL) has been updated to provide clarification, uniformity and consistency in processing program flexibility requests for use of cardiac catheterization laboratory space in GACHs. This AFL supersedes AFLs 10-08 and 10-13 and provides important information for all GACHs regarding the authorized use of cardiac catheterization laboratory space and procedures governing program flexibility requests for alternative use of this space.

GACHs that provide cardiovascular surgery service

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.”

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.”

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.

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.
- (5) Electrophysiology studies.
- (6) Myocardial biopsy.

In addition, Title 22 CCR 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.

Title 22 CCR Section 70129 allows the Department to approve alternate concepts, methods, procedures, techniques, equipment, personnel qualifications or the conducting of pilot projects provided such exceptions are carried out with the provisions for safe and adequate care and with the prior written approval of the Department. Such approval shall provide for the terms and conditions under which the exception is granted after a written request plus supporting evidence is submitted to the Department.

In some cases, the alternative use of catheterization laboratory space may require inspection and approval by the Office of Statewide Health Planning and Development such as a change of use involving surgical procedures requiring installation of a scrub sink and additional infection control measures.

Procedure for requesting program flexibility

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:

- A list of procedures to be performed in the catheterization laboratory with a listing of the anatomic location of the exact procedures proposed.

- 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.
- 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.
- For operative procedures, surgical and anesthesia staffing and competencies.
- The mechanism for inclusion in Quality Assessment and Performance Improvement.

L&C may request additional information after receipt of the initial program flexibility request if needed in the review and decision-making process. Additional information requested may include, but is not limited to, the following:

- Documentation and all policies and procedures for radiation protection and monitoring of radiation exposure, including monitoring of apron effectiveness and primary radiation barriers.
- Policies and procedures for time-out procedures.
- Policies and procedures for patient transfer to the recovery room or ICU/Medical Surgical Unit.
- Policies that identify in-patient versus out-patient procedures, patient holding areas and recovery areas.
- Documentation of transfer agreements and availability of cardiovascular surgery if emergent transfer is required.
- Dress code in the catheterization laboratory.
- Temperature and humidity logs.
- Policies and procedures for fires in the catheterization laboratory.
- Moderate sedation policy.
- Policies and procedures on the cleaning of the catheterization laboratory.
- Infection control policies and procedures.

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L&C may conduct an on site inspection, in addition to reviewing any documentation, while considering whether to approve the program flexibility.

Facilities are responsible for following all applicable laws. CDPH's failure to expressly notify facilities of legislative or statutory requirements does not relieve facilities of their responsibility for following all laws and regulations. Facilities should refer to the full text of all applicable sections of the H&S Code and Title 22 of the CCR to ensure compliance.

Sincerely,

Original Signed by Pamela Dickfoss

Pamela Dickfoss
Acting Deputy Director
Center for Health Care Quality