State of California—Health and Human Services Agency
California Department of Public Health

RON CHAPMAN, MD, MSPH
Director

EDMUND G. BROWN JR.
Governor

AFL REVISION NOTICE

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

Revision To: AFL 11-04

Revision Date: November 2, 2011

Attachments: AFL 11-30

This notice is to inform you that the California Department of Public Health has revised All Facilities Letter (AFL) 11-04 with the attached AFL 11-30, which supersedes AFL 11-04.

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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November 2, 2011

AFL 11-30
(Supersedes AFLs 10-08, 10-13, and 11-04)

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 the types of services and procedures that may appropriately be provided in cardiac catheterization laboratory (CCL) space in General Acute Care Hospitals (GACH). This All Facilities Letter (AFL) has been updated to provide consistency for expanded use of CCL space, and streamlines the program flexibility submittal and review process. This AFL supersedes all other AFLs addressing cardiac catheterization laboratory space (specifically AFLs 10-08, 10-13, and 11-04).

<u>GACHs licensed for a cardiac catheterization laboratory service without cardiovascular surgery service</u>

GACHs that are licensed to operate CCLs without cardiovascular surgery service are permitted to only conduct the following diagnostic procedures pursuant to Title 22 CCR Section 70438.1(b):

(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.

GACHs that operate CCL Service without cardiovascular surgery service may request program flexibility for additional cardiovascular <u>diagnostic</u> procedures, as well as

program flexibility for non-cardiac interventional procedures. No program flexibility can be provided for cardiac interventional procedures for these facilities.

GACHs licensed for a cardiovascular surgery service

Cardiovascular surgery service is defined in Title 22 CCR Section 70438 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." This regulation specifies that the two aspects of this service – diagnostic and therapeutic – shall not exist separately.

The CCL service is described in Section 70438 as a diagnostic service. This regulation requires CCL services to be "organized to perform laboratory procedures for obtaining physiologic, pathologic and angiographic data on patients with cardiovascular disease."

GACHs that operate CCLs with cardiovascular surgery service may request program flexibility for additional cardiovascular diagnostic and therapeutic procedures, as well as program flexibility for alternate use of the CCL space for non-cardiac interventional procedures.

Program Flexibility

The use of the CCL space for purposes other than what is permitted by existing regulations requires program flexibility approval by CDPH prior to the alternative use of the space. To facilitate the utilization of the CCL space, CDPH is allowing program flexibility under Title 22 CCR Section 70129 to permit expanded use in these spaces.

Section 70129 allows CDPH 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 CDPH. Such written approval shall provide the terms and conditions under which the exception is granted. All GACHs requesting to perform expanded procedures in a CCL must submit in writing a program flexibility request and supporting evidence as needed.

Procedure for requesting program flexibility

GACHs should direct program flexibility requests and supporting documentation to their local CDPH, Licensing and Certification (L&C) Program District Office. To facilitate consistent handling of program flexibility requests, L&C has developed an electronic form that can be used for submitting the program flexibility request. A copy of the form is attached to this AFL. L&C encourages electronic submission of the request and supporting documentation.

When requesting program flexibility, please submit the appropriate request form and the following additional items:

a. Policies and procedures for conscious sedation
b. Policies and procedures for infection control practices in the CCL
c. Verification that the radiologic equipment in the CCL space has immediate emergency power
d. Policies and procedures that ensure that patients requiring emergency cardiac catheterization will receive immediate priority in the CCL in the event that the CCL space is already occupied by a non-emergent case, including transfer agreements if appropriate
e. Include the CCL space in the hospital's quality assurance program
f. Documentation and all policies/procedures for radiation protection and monitoring of radiation exposure, to include monitoring of apron effectiveness and primary radiation barriers
g. Credentialing and privileging of practitioners utilizing CCL space
h. In hospitals with no cardiac surgical services, transfer agreements and policies addressing triage, evaluation, and transfer of patients requiring invasive therapeutic procedures that are non-emergent (do not qualify under STEMI protocol) to hospitals with cardiac surgical services

Once the program flexibility request packet has been received and is complete, the local district office will forward the packet to L&C's designated medical consultant for review and approval. The consultant will notify the district office if further supporting evidence is required. Once the review is completed, the medical consultant will forward a list of approved and denied flexibility requests to the district office. Any denied procedures shall be explained with the rationale for denial. The district office will respond to the requesting hospital in writing with the approved and denied procedure requests, with a copy sent to L&C Headquarters. Every effort will be made to complete the review within two weeks; however, some packets may take longer to complete. Headquarters will maintain a database to include all approved and denied procedures for any hospital requesting program flexibility for their CCL space.

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 California Health and Safety Code and Title 22 of the CCR to ensure compliance.

Additional Considerations for Expanded Use of CCL Space

For expanded procedures involving a surgical component, the CCL space, regardless of the availability of cardiac surgical services, must also meet applicable Title 24 building

and safety code requirements for a CCL/operating room space. Please attest on the attached form that your facilities are compliant with all applicable Title 22 and Title 24 regulations governing operating rooms for alternate use of the CCL space.

If you have any questions about Title 24 compliance, please contact the Office of Statewide Health, Planning and Development for guidance.

Hospitals that have had program flexibility requests for alternate use of the CCL space for interventional radiology and/or non-cardiovascular procedures previously denied should resubmit program flexibility requests to their local L&C district office.

Sincerely,

Original Signed by Pamela Dickfoss

Pamela Dickfoss
Acting Deputy Director
Center for Health Care Quality

Attachment: Program Flexibility Request for Cardiac Catheterization Laboratories