

**DEPARTMENT OF PUBLIC HEALTH  
INITIAL STATEMENT OF REASONS**

**California Code of Regulations, title 22, division 5**

**Chapter 1. General Acute Care Hospitals**

**Article 6. Supplemental Services**

SUBJECT MATTER OF PROPOSED REGULATIONS:

Expanded Cardiac Catheterization Laboratory Space

SECTIONS AFFECTED:

Adopt section 70438.2

SPECIFIC PURPOSE OF EACH ADOPTION, AMENDMENT, OR REPEAL:

The California Department of Public Health (the "Department") proposes to adopt section 70438.2 of Article 6, Chapter 1, Division 5 of Title 22 of the California Code of Regulations to establish certain standards for the limited expansion of cardiac catheterization laboratory service.

On September 29, 2012, the Governor signed Assembly Bill 491 (Chapter 772, statutes of 2012) (the "Law"), amending Health and Safety Code Section 1255. Pursuant to the Law, the Department is authorized to adopt regulations that allow a general acute care hospital that satisfies the Law's requirements to provide cardiac catheterization services in an expanded cardiac catheterization laboratory space. Prior to the enactment of the Law, cardiac catheterization could be performed only within a licensed general acute care hospital.

In compliance with the Law, the Department proposes to adopt section 70438.2 to provide guidance for certain qualified general acute care hospitals that want to create expanded cardiac catheterization laboratory space. The proposed regulations include, in part, a definition of the term "expanded cardiac catheterization laboratory space," requirements for a mandated all-weather enclosed passageway, and standards for general acute care hospital inpatient usage of the expanded cardiac catheterization laboratory space. The Department believes this proposal would benefit California in

that it will provide additional access to cardiac catheterization laboratory space, specifically, and improve the public health and safety, generally.

Based on an initial evaluation, the Department has reviewed existing state and federal regulations and does not believe that the proposed regulations are inconsistent or incompatible with existing state or federal regulations.

PROBLEMS INTENDED TO ADDRESS:

The proposed regulation would address the potential problem of reduced access to cardiac catheterization laboratory space due to greater demand for cardiac catheterization procedures as a result of the passage of the federal Affordable Care Act (“ACA”).

STATEMENT OF FACTUAL BASIS AND RATIONALE:

Existing law provides for the licensure and regulation of health facilities, including general acute care hospitals, administered by the Department. The Department is authorized under existing law to approve a general acute care hospital to offer specified special services, including, but not limited to, cardiac catheterization laboratory services, in addition to the basic services offered under the general acute care hospital’s license. Current law requires a cardiac catheterization laboratory to be located within a general acute care hospital and prohibits, except as provided, cardiac catheterizations to be performed outside a general acute care hospital or a multispecialty clinic, as defined.

Existing regulations require that cardiac catheterization laboratory services may be approved in a general acute care hospital that is not authorized to deliver cardiac surgery service, provided that the general acute care hospital maintains a written transfer agreement. The type of cardiac catheterization laboratory procedures a general acute care hospital without cardiac surgery facilities may provide is limited by existing regulations to certain diagnostic procedures.

Cardiac catheterization is a critically important diagnostic and treatment tool for heart disease. The procedure involves insertion of a thin flexible catheter into a large blood vessel in the patient’s arm, leg, or neck and extending the catheter to or into the blood vessels of the patient’s heart. The catheter may be equipped with a camera which will provide the cardiologist with an immediate and direct view of the patient’s heart. In 2010, an estimated 1,029,000 inpatient diagnostic cardiac catheterizations were performed in the United States (American Heart Association, AHA Statistical Update:

Heart Disease and Stroke Statistics – 2013 (2013) Coronary Heart Disease, Acute Coronary Syndrome, and Angina Pectoris -- Operations and Procedures, p. e184.)

As the author of the Law wrote, with the enactment of the ACA, utilization of all forms of medical diagnosis and treatment, including cardiac catheterization procedures are expected to increase as people who previously had no health insurance become covered. Allowing for cardiac catheterization in an expanded cardiac catheterization laboratory space is one approach to meeting this increased need on a cost-efficient and urgent-need basis. In order for expanded cardiac catheterization laboratory space to be constructed and operated in time to be able to meet the increased demand that will result from full enactment of the ACA, construction and operating standards must be established immediately.

Full implementation of the ACA will occur on January 1, 2014. Establishing the necessary regulatory standards is critical to providing health facilities adequate lead time to ensure that their expanded cardiac catheterization laboratory space can both meet state standards and be fully operational as soon as possible. This is especially true with respect to the construction of new expanded cardiac catheterization laboratory space, which may take many months to build and equip.

The effect of these regulations will be to establish certain standards for the limited expansion of cardiac catheterization laboratory service. Expanded cardiac catheterization service will allow for cardiac catheterization laboratory service outside of a general acute care hospital, so long as the service is performed in a facility that is connected to the general acute care hospital by an enclosed all-weather passageway. These regulations provide the two qualifying general acute care hospitals to expand cardiac catheterization laboratory service with standards relating to the enclosed all-weather passageway. In addition, these regulations provide certain limitations on cardiac catheterization procedures performed on general acute care hospital inpatients.

The broader objective of these regulations is to provide additional capacity for cardiac catheterization procedures for those patients who are in need of such care. Under these regulations, patients receiving expanded cardiac catheterization laboratory service will have access to a similar level of care and expertise available to them at the general acute care hospital.

The Department proposes to adopt Section 70438.2 to implement the regulations required under the Law regarding expanded cardiac catheterization laboratory space, as follows:

*Adopt subsection (a)(1)* which adds the term “expanded cardiac catheterization laboratory space” to clarify its use within the section.

*Adopt subsection (b)(1)(A)* which provides that this passageway be short enough to enable a patient that is in need of emergent care to be transported to a definitive care option in a reasonable amount of time. The Department’s review of relevant scientific literature found no recommended transportation time from a cardiac catheterization laboratory in an attached setting to a cardiovascular surgical space, or other such definitive care option. However, given the nature of such medical emergencies, transporting a patient to the suggested treatment as quickly as possible should reduce negative health outcomes, including, but not limited to, death of the patient. The Department did rely on timed simulations provided by the Cedars-Sinai Health System (“Cedars-Sinai”), one of the affected general acute care hospitals. These simulations suggest that the estimated maximum transportation time from its planned expanded cardiac catheterization laboratory space to surgical suites within the hospital is roughly 8.5 minutes. Cedars-Sinai’s simulations are based on certain assumptions, including that there will be response team members located on specific floors within the general acute care hospital, that a dedicated patient gurney will be available in the expanded cardiac catheterization laboratory space, and that elevators for transport to operating rooms may not be immediately available. The simulations consider three separate routes to two operating rooms within the general acute care hospital and include the physical distance that separate the expanded cardiac catheterization laboratory space and the operating room. Each simulation takes into account the response time to initial emergency page, the time to reach the expanded cardiac catheterization laboratory space, as well as the return time with gurney and patient. According to the time simulations provided by Cedars-Sinai, the longest potential route to an operating room is 865 feet. The time simulations suggest it would take medical staff an estimated four minutes 16 seconds to reach the expanded cardiac catheterization laboratory space and another four minutes 35 seconds to reach the operating room. Cedars-Sinai also indicates that it expects that response times to be shorter than estimated due in part to the likelihood of medical staff being available within the expanded cardiac catheterization laboratory space, cutting down on time to reach the patient in need. Given this, it is the Department’s position that allowing for 10 minutes to transport a

patient is reasonable. Furthermore, while most emergent care needs will be resolved through cardiovascular surgery, there may be other current or future treatment options available and thus the Department uses the term “definitive care option” as it is commonly understood within the healthcare industry.

*Adopt subsection (b)(1)(B)-(F)* which provides additional requirements for the enclosed all-weather passageway connecting the general acute care hospital and the expanded cardiac catheterization laboratory space. The Department proposes in subparagraph (B) that at a minimum, the passageway features electric lighting as well as emergency lighting and power, as required within the general acute care hospital. In subparagraph (C) the Department proposes the passageway be climate-controlled, featuring heating, air conditioning and ventilating systems for patient safety and comfort. Under the proposed regulations, the Department calls for both ends of the passageway to be equipped with an emergency call feature. For the purposes of subparagraph (D), an emergency call feature may mean a telephone connection, or any other means of communication that is located in the passageway that allows medical staff in the passageway to communicate with medical staff in the general acute care hospital, should the need arise. In subparagraph (E) the Department proposes limiting access to the passageway to the appropriate medical staff, as defined by the policies and procedures of the general acute care hospital, and the patients that are in need of medical treatment. While the Law provides that the passageway shall be “accessible by staff and patients” it does not expressly limit access to authorized staff and patients, which is necessary to better provide for patient health and safety by explicitly limiting unauthorized personnel or other individuals from entering the passageway. Subparagraph (F) requires that the passageway be secured from unauthorized personnel or other individuals. To provide such security, the proposed regulations require the entrances to the passageway to be secured by electronic means, such as an electronic passkey, that conforms to existing security policies and procedures of the general acute care hospital. The Department proposes this regulation text to provide for patient safety and to enable patients to be transported through the passageway as easily and as quickly as possible.

*Adopt subsection (b)(2)* to require the general acute care hospital to create policies and procedures for the expanded cardiac catheterization laboratory space that are consistent with existing hospital protocols as well as industry standards for adequate quality of patient care. Because the expanded cardiac catheterization laboratory space is expected to provide services to both inpatients and outpatients, the proposed

regulations call for the general acute care hospital to develop, maintain and implement such policies and procedures with both distinct populations and their respective needs in mind.

*Adopt subsection (b)(2)(A)* as cardiac catheterization inpatients are generally at greater health risks than outpatients. In determining the policies and procedures for the expanded cardiac catheterization laboratory space setting, it is important for the general acute care hospital to consider the severity of the inpatient's condition, as well as the type of procedure the inpatient is to undergo.

*Adopt subsection (b)(3)* because, as stated above, inpatient cardiac catheterization populations generally are more at-risk than outpatients needing such procedures. This subsection limits procedures performed on inpatients in the expanded cardiac catheterization laboratory space to only those instances when the general acute care hospital's cardiac catheterization laboratory space schedule has reached its maximum capacity. Thus, an inpatient would have first priority for the general acute care hospital's cardiac catheterization laboratory space schedule. If, however, that schedule has reached capacity, the proposed regulation text would permit the inpatient to undergo a cardiac catheterization procedure in the expanded cardiac catheterization laboratory space. The proposed regulation would potentially reduce transportation times for the higher risk inpatients, should the inpatient experience an emergent event. Providing inpatients with first priority for placement in the general acute care hospital's cardiac catheterization laboratory space schedule benefits this more at-risk population because these procedures when performed closer to the cardiovascular surgical suites inside the general acute care hospital could decrease potential transportation times in the event of an emergent situation.

*Adopt subsection (b)(4)* which prohibits cardiac catheterization procedures to be performed on children in the expanded cardiac catheterization laboratory space, in accordance with Health and Safety Code Sections 1255.5 (d) and (e). Under these sections, cardiac catheterization procedures are permitted on children so long as they are performed in a general acute care hospital. This proposed regulation subsection is included to expressly state that for the purposes of pediatric cardiac catheterization laboratory services, the expanded cardiac catheterization laboratory space shall not be considered a part of the general acute care hospital, where such procedures are authorized.

*Adopt subsection (c)* which restates the Law's requirement that no more than 25% of the general acute care hospital's inpatients in need of cardiac catheterization laboratory services may have such procedures performed in the expanded cardiac catheterization laboratory space, but also provides that the hospital must maintain records demonstrating compliance with this requirement. Such a condition is consistent with existing practices where hospitals maintain records to demonstrate compliance with regulatory requirements and this subsection merely codifies this expressly for the expanded cardiac catheterization laboratory space.

*Adopt subsection (d)* because the Law requires that the same standards and regulations prescribed by the Department for cardiac catheterization laboratories located inside general acute care hospitals apply to the expanded cardiac catheterization laboratory space. The sections provided for within the proposed regulations make up the existing regulatory framework with which the cardiac catheterization laboratories must comply.

TECHNICAL, THEORETICAL, AND EMPIRICAL STUDY, REPORT, OR SIMILAR DOCUMENTATION:  
Cedars-Sinai Health Systems. "AHSP Simulation Code Blue Team and RRT Responses Plus Travel Times with Gurneys/Elevator Transitions." 2012. Microsoft Word file.

American Heart Association. "AHA Statistical Update: Heart Disease and Stroke Statistics – 2013." 2013.

SPECIFIC TECHNOLOGIES OR EQUIPMENT:

This regulation does not mandate the use of specific technologies or equipment.

CONSIDERATION OF REASONABLE ALTERNATIVES:

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Department would either be more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to affected private persons than the proposed regulations.

REASONABLE ALTERNATIVES THE DEPARTMENT HAS IDENTIFIED THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES:

The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals,

including the ability of California businesses to compete with businesses in other states. Thus, there will be no significant adverse economic impact on California businesses.

BENEFITS:

Anticipated benefits, including nonmonetary benefits to the protection of public health and safety, worker safety, the environment, the prevention of discrimination, or the promotion of fairness or social equity, from this proposed regulatory action are:

- Additional cardiac catheterization laboratory space will provide greater access for patients to these potentially life-saving procedures.
- Increased access to cardiac catheterization procedures to both patients with emergent needs and those seeking diagnostic services.
- Patients seeking diagnostic services will receive the diagnostic services they need before their health issues worsen.
- Positive patient outcomes.

FACTS, EVIDENCE, DOCUMENTS, TESTIMONY, OR OTHER EVIDENCE OF NO SIGNIFICANT ADVERSE IMPACT ON BUSINESS:

No facts, evidence, documents, testimony, or other evidence of any significant adverse economic impact on business have been identified.

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS:

This proposal does not duplicate or conflict with Federal regulations.