

FINDING OF EMERGENCY

The director of the California Department of Public Health (the "Department") finds that an emergency exists and that the proposed emergency regulation, as required by the legislature, is necessary to address a situation that calls for immediate action to avoid serious harm to the public peace, health, safety or general welfare.

INTRODUCTION

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, a hospital which satisfies the Law's requirements may 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.

Cardiac catheterization has become a critically important diagnostic and treatment tool for heart disease. The procedure involves insertion of 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.

SPECIFIC FACTS SHOWING THE NEED FOR IMMEDIATE ACTION

The Legislature, in approving the Law, demonstrated a clear intent that the bill should be implemented with all possible speed, specifically indicating that this implementation should be through emergency regulation. Section 3 of the Law provides that "[t]his act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect." As section 8(d) of Article IV of the California Constitution states, "[a] statement of facts constituting the necessity shall be set forth in one section of the bill." The Law provides such a statement of facts in section 3, indicating that the Law should take effect immediately "[i]n order to improve access to health care for patients requiring cardiac catheterization services at the earliest possible time."

The need for immediate action is further supported by the requirement of Section 1255(d)(3)(D) of the Health and Safety Code, which makes adoption of emergency regulations a precondition for the March 1, 2013 effective date of the bill. The adoption of the Law as urgency legislation combined with the express condition that it must be implemented through emergency regulation constitutes clear evidence of the Legislature's intent that the Law be implemented through emergency regulation in order to effectuate the law with minimal delay.

With the enactment of the federal Affordable Care Act (“ACA”), utilization of all forms of medical diagnosis and treatment are expected to increase as people who previously had no health insurance become covered allowing hospitals to perform diagnostic cardiac catheterization procedures in an expanded cardiac catheterization laboratory space. 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.

There is at least one large California hospital that should be able to provide expanded cardiac catheterization laboratory service on March 1, 2013 as the Law contemplated, but this can only occur if the standards implementing Health and Safety Code Section 1255 are adopted immediately as emergency regulations. They must be adopted immediately as emergency regulations so that the benefits of having expanded cardiac catheterization laboratory space can be made available to the public in a timely manner.

The potential delay in providing the services that the Legislature authorized via the Law is a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, or general welfare. It is therefore appropriate that the proposed regulations, which address that situation, be adopted as emergency regulations.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

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.

Purpose

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 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.

Objective

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.

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.

Evaluation as to whether the proposed regulations are inconsistent or incompatible with existing state regulations

The regulations are consistent and compatible with existing state regulations that pertain to cardiac catheterization laboratories in that they do not create competing or contradictory standards. Cardiac catheterization laboratories within general acute care hospitals and those covered in the proposed regulation text must comply with the same existing regulatory framework.

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 subsection.

Adopt subsection (b)(1)(A) which provides the relevant general acute care hospitals guidance relating to the enclosed all-weather passageway that connects the hospital to the expanded cardiac catheterization laboratory space. This subsection provides that this passageway be short enough to enable a patient that is in need of emergent care be transported to a definitive care option in a reasonable amount of time. The Department's review of the 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 is obviously of the utmost importance. The Department did rely on timed simulations provided by the Cedars-Sinai Health System, 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. 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 treatment options available and thus the Department uses the term "definitive care option" in accordance with industry standards.

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. Under the proposed emergency 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) patient safety is best served by 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 staff and patients, which is necessary to better provide for patient health and safety. 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.

Adopt subsection (b)(2) to give to the general acute care hospital the authority and responsibility 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 inpatient access to the expanded cardiac catheterization laboratory space, except when the general acute care hospital's cardiac catheterization laboratory space has reached its maximum capacity. The proposed regulation would potentially reduce transportation times for the higher risk inpatients to a definitive care option, should the inpatient experience an emergent event. Similarly, providing inpatients with first priority for placement within the general acute care hospital's cardiac catheterization laboratory space benefits this more at-risk population by performing these procedures closer to the cardiovascular surgical suites inside the general acute care hospital, which decreases 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 expressly states that for the purposes of pediatric cardiac catheterization laboratory services, the expanded cardiac catheterization laboratory space is not considered a part of the general acute care hospital.

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 emergency regulations make up the existing regulatory framework with which the cardiac catheterization laboratories must comply.

AUTHORITY AND REFERENCE CITATIONS

The Department is proposing to adopt, amend, or repeal the regulation sections identified under the authority provided in sections 1255, 131050, 131051, and 131200, of the Health and Safety Code. This proposal implements, interprets and makes specific section 1255, of the Health and Safety Code.

TECHNICAL STUDIES RELIED UPON

AHSP Simulation Code Blue Team and RRT Responses Plus Travel Times with Gurneys/Elevator Transitions. Cedars-Sinai Health Systems.

FISCAL IMPACT ESTIMATE

- A. FISCAL IMPACT ON LOCAL GOVERNMENT: None
- B. FISCAL IMPACT ON STATE GOVERNMENT: None
- C. FISCAL IMPACT ON FEDERAL FUNDING OF STATE PROGRAMS: None
- D. FISCAL IMPACT ON PRIVATE PERSONS OR BUSINESSES DIRECTLY AFFECTED: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.
- E. OTHER NONDISCRETIONARY COST OR SAVINGS IMPOSED ON LOCAL AGENCIES: There are no known costs or savings in connection with this regulation package.

MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS

The Department has determined that this regulation imposes a mandate on local agencies or school districts as it expands the definition of a crime. No reimbursement is required under Section 1255 of the Health and Safety because the only costs that may be incurred by a local agency or school district will be incurred because it creates a new crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.