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Director & State Health Officer

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



EDMUND G. BROWN JR.
Governor

ACTION: Notice of Emergency Rulemaking
Title 22, California Code of Regulations

SUBJECT: Cardiac Catheterization Laboratory, DPH-12-006E

The California Department of Public Health has adopted the regulations described in this notice on an emergency basis, and they are now in effect.

Public Proceedings

Notice is hereby given that the California Department of Public Health will conduct a written comment period during which time any interested person or such person's duly authorized representative may submit statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice. No hearing has been scheduled; however any interested person or his or her duly authorized representative may request in writing, no later than 15 days prior to the close of the written comment period, a public hearing pursuant to Government Code Section 11346.8. For individuals with disabilities, should a public hearing be scheduled, the Department will provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, or onto audiocassette or computer disk. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

Comments

Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by 5 p.m. on July 29, 2013, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.

Written comments may be submitted as follows:

1. By email to regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH-12-006E" in the subject line to facilitate timely identification and review of the comment; or
2. By fax transmission: (916) 440-5747; or

3. By mail to: Office of Regulations, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377; or hand-delivered to: 1616 Capitol Avenue, Sacramento, CA, 95814. It is requested but not required that written comments sent by mail or hand-delivered be submitted in triplicate.

All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

Inquiries

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Keith Van Wagner, Office of Legal Services, at (916) 445-2012.

All other inquiries concerning the action described in this notice may be directed to Linda M. Cortez, Office of Regulations, at (916) 440-7807.

CONTACTS: In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-12-006E.

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.

Authority and Reference

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

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 establishes the transportation time from a cardiac catheterization laboratory in an attached setting to a cardiovascular surgical space, or other such definitive care option of a patient that is in need of emergent. 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. 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 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.

Adopt subsection (b)(2)(A) as cardiac catheterization inpatients are generally at greater health risks than outpatients.

Adopt subsection (b)(3) to limit 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. 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.

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). 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.

Forms Incorporated by Reference N/A

Mandated by Federal Law or Regulations N/A

Other Statutory Requirements N/A

Mandate on Local Agencies or School Districts

The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

Fiscal Impact Estimate

- A. Fiscal Effect on Local Government: None
- B. Fiscal Effect on State Government: None
- C. Fiscal Effect on Federal Funding of State Programs: None
- D. Fiscal Effect on Private Persons or Business 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: None
- F. Fiscal Effect on Small Businesses: These proposed regulations will not affect small businesses because General Acute Care Hospitals are not small businesses.

Recordkeeping Requirement

The proposed regulations contain a reporting requirement that was determined to be necessary for the health, safety, or welfare of the people of California. The proposed regulations provide that the general acute care hospital's inpatients in need of cardiac catheterization laboratory service may have certain procedures performed in the expanded cardiac catheterization laboratory space. The general acute care hospital shall maintain records that provide the number of cardiac catheterization procedures

performed in the expanded cardiac catheterization laboratory space, and the patient's status as an inpatient or outpatient. The reporting requirement, expressly for the expanded cardiac catheterization laboratory space is consistent with existing practices where hospitals maintain records to demonstrate compliance with regulatory requirements.

Significant Statewide Adverse Economic Impact Directly Affecting Business, Including the Ability to Compete

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.

Result of Economic Impact Analysis

The Department has determined that the regulations would not significantly affect the following:

- (A) The creation or elimination of jobs within the State of California.
- (B) The creation of new businesses or the elimination of existing businesses within the State of California.
- (C) The expansion of businesses currently doing business within the State of California.
- (D) The benefits of the regulation to the health and welfare of California residents, worker safety, and the state environment. Please see "Benefits" discussion under the Informative Digest/Policy Statement Overview.

Statewide Effect on Housing Costs

The Department has determined that the regulations will have no impact on housing costs.

Alternatives Considered

In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons or equally effective in implementing the statutory policy or other provisions of law.

Availability of Proposed Regulation Text, Statement of Reasons and Rulemaking File

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations

(rulemaking file). In addition, a copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) are available via the Internet may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation, Regulations, Proposed.

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440-7807 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377. Upon specific request, these documents will be made available in Braille, large print, and audiocassette or computer disk.

Availability of Changed or Modified Text

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DPH-12-006E

Date:



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Director & State Health Officer