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SB-1464 Health facilities: cardiac catheterization laboratory services. (2023-2024)

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Senate Bill No. 1464

CHAPTER 136

An act to amend Sections 1255 and 1256.01 of the Health and Safety Code, relating to health facilities.

[Approved by Governor July 15, 2024. Filed with Secretary of State July 15, 2024.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1464, Ashby. Health facilities: cardiac catheterization laboratory services.

Existing law provides for the licensure and regulation of health facilities, including general acute care hospitals, administered by the State Department of Public Health. A violation of these provisions is a misdemeanor.

Existing law authorizes the department to approve, as prescribed, 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 facility's license. Existing law authorizes the expansion of a cardiac catheterization laboratory service if specified requirements are met, including that the department, at a minimum, adopt standards and regulations that specify that only diagnostic services, and what diagnostic services, may be offered by a general acute care hospital or a multispecialty clinic.

This bill would remove the requirement that the department adopt standards and regulations that specify that only diagnostic services may be offered and instead require the department to adopt standards and regulations that specify the type of servicing, including diagnostic servicing, that may be offered by a general acute care hospital or a multispecialty clinic.

Existing law creates the Elective Percutaneous Coronary Intervention (PCI) Program in the State Department of Public Health to certify general acute care hospitals that are licensed to provide urgent and emergent cardiac catheterization laboratory service in California, and that meet prescribed, additional criteria, to perform scheduled, elective PCI.

This bill would remove the specification that the described certified general acute care hospitals are licensed to provide urgent and emergent cardiac catheterization laboratory service, and instead license general acute care hospitals that do not offer cardiac surgery services but are licensed to provide cardiac catheterization service.

Because this bill would expand the definition of a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1255 of the Health and Safety Code is amended to read:

1255. (a) In addition to the basic services offered under the license, a general acute care hospital may be approved in accordance with subdivision (c) of Section 1277 to offer special services, including, but not limited to, the following:

- (1) Radiation therapy department.
- (2) Burn center.
- (3) Emergency center.
- (4) Hemodialysis center (or unit).
- (5) Psychiatric.
- (6) Intensive care newborn nursery.
- (7) Cardiac surgery.
- (8) Cardiac catheterization laboratory.
- (9) Renal transplant.
- (10) Other special services as the department may prescribe by regulation.

(b) A general acute care hospital that exclusively provides acute medical rehabilitation center services may be approved in accordance with subdivision (b) of Section 1277 to offer special services not requiring surgical facilities.

(c) The department shall adopt standards for special services and other regulations as may be necessary to implement this section.

(d) (1) For cardiac catheterization laboratory service, the department shall, at a minimum, adopt standards and regulations that specify the type of services, including diagnostic services, that may be offered by a general acute care hospital or a multispecialty clinic as defined in subdivision (l) of Section 1206 that is approved to provide cardiac catheterization laboratory service but is not also approved to provide cardiac surgery service, together with the conditions under which the cardiac catheterization laboratory service may be offered.

(2) Except as provided in paragraph (3), a cardiac catheterization laboratory service shall be located in a general acute care hospital that is either licensed to perform cardiovascular procedures requiring extracorporeal coronary artery bypass that meets all of the applicable licensing requirements relating to staff, equipment, and space for service, or shall, at a minimum, have a licensed intensive care service and coronary care service and maintain a written agreement for the transfer of patients to a general acute care hospital that is licensed for cardiac surgery or shall be located in a multispecialty clinic as defined in subdivision (l) of Section 1206. The transfer agreement shall include protocols that will minimize the need for duplicative cardiac catheterizations at the hospital in which the cardiac surgery is to be performed.

(3) Commencing March 1, 2013, a general acute care hospital that has applied for program flexibility on or before July 1, 2012, to expand cardiac catheterization laboratory services may utilize cardiac catheterization space that is in conformance with applicable building code standards, including those promulgated by the Office of Statewide Health Planning and Development, now known as the Department of Health Care Access and Information, provided that all of the following conditions are met:

(A) The expanded laboratory space is located in the building so that the space is connected to the general acute care hospital by an enclosed all-weather passageway that is accessible by staff and patients who are accompanied by staff.

(B) The service performs cardiac catheterization services on no more than 25 percent of the hospital's inpatients who need cardiac catheterizations.

(C) The service complies with the same policies and procedures approved by hospital medical staff for cardiac catheterization laboratories that are located within the general acute care hospital, and the same standards and regulations prescribed by the department for cardiac catheterization laboratories located inside general acute care hospitals, including, but not limited to, appropriate nurse-to-patient ratios under Section 1276.4, and with all standards and regulations prescribed by the Office of Statewide Health Planning and Development, now known as the Department of Health Care Access and Information. Emergency regulations allowing a general acute care hospital to operate a cardiac catheterization laboratory service shall be adopted by the department and by the Office of Statewide Health Planning and Development by February 28, 2013.

(D) Emergency regulations implementing this paragraph have been adopted by the department and by the Office of Statewide Health Planning and Development by February 28, 2013.

(E) This paragraph shall not apply to more than two general acute care hospitals.

(4) After March 1, 2014, an acute care hospital may only operate a cardiac catheterization laboratory service pursuant to paragraph (3) if the department and the Office of Statewide Health Planning and Development, now known as the Department of Health Care Access and Information, have adopted regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that provide adequate protection to patient health and safety including, but not limited to, building standards contained in Part 2.5 (commencing with Section 18901) of Division 13.

(5) Notwithstanding Section 129885, cardiac catheterization laboratory services expanded in accordance with paragraph (3) shall be subject to all applicable building standards. The Office of Statewide Health Planning and Development, now known as the Department of Health Care Access and Information, shall review the services for compliance with the OSHPD 3 requirements of the most recent version of the California Building Standards Code.

(e) For purposes of this section, "multispecialty clinic," as defined in subdivision (l) of Section 1206, includes an entity in which the multispecialty clinic holds at least a 50-percent general partner interest and maintains responsibility for the management of the service, if all of the following requirements are met:

(1) The multispecialty clinic existed as of March 1, 1983.

(2) Prior to March 1, 1985, the multispecialty clinic did not offer cardiac catheterization services, dynamic multiplane imaging, or other types of coronary or similar angiography.

(3) The multispecialty clinic creates only one entity that operates its service at one site.

(4) These entities shall have the equipment and procedures necessary for the stabilization of patients in emergency situations prior to transfer and patient transfer arrangements in emergency situations that shall be in accordance with the standards established by the Emergency Medical Services Authority, including the availability of comprehensive care and the qualifications of any general acute care hospital expected to provide emergency treatment.

(f) Except as provided in this section and in Sections 100921 and 100922, cardiac catheterizations shall not be performed outside of a general acute care hospital or a multispecialty clinic, as defined in subdivision (l) of Section 1206, that qualifies for this definition as of March 1, 1983.

SEC. 2. Section 1256.01 of the Health and Safety Code is amended to read:

1256.01. (a) The Elective Percutaneous Coronary Intervention (PCI) Program is hereby established in the department. The purpose of the program is to allow the department to certify general acute care hospitals that do not offer cardiac surgery services but are licensed to provide cardiac catheterization laboratory service in California, and that meet the requirements of this section, to perform scheduled, elective percutaneous transluminal coronary angioplasty and stent placement for eligible patients.

(b) For purposes of this section, the following terms have the following meanings:

(1) "Certified hospital" means an eligible hospital that is certified by the department to participate in the Elective Percutaneous Coronary Intervention (PCI) Program established by this section.

(2) "Elective Percutaneous Coronary Intervention (elective PCI)" means scheduled percutaneous transluminal coronary angioplasty and stent placement. Elective PCI does not include urgent or emergent PCI that is scheduled on an ad hoc basis.

(3) "Eligible hospital" means a general acute care hospital that has an approved cardiac catheterization laboratory, does not have onsite cardiac surgery, and is in substantial compliance with all applicable state and federal licensing laws and regulations.

(4) "Interventionalist" means a licensed cardiologist who meets the requirements for performing elective PCI.

(c) To participate in the Elective PCI Program, an eligible hospital shall obtain certification from the department and shall meet all of the following requirements:

(1) Demonstrate that it complies with the recommendations of the Society for Cardiovascular Angiography and Interventions (SCAI), the American College of Cardiology Foundation, and the American Heart Association, for performance of PCI without onsite cardiac surgery, as those recommendations may evolve over time.

(2) Provide evidence showing the full support from hospital administration in fulfilling the necessary institutional requirements, including, but not limited to, appropriate support services such as respiratory care and blood banking.

(3) Participate in, and provide timely submission of data to, the American College of Cardiology-National Cardiovascular Data Registry.

(4) Confer rights to transfer the data submitted pursuant to paragraph (3) to the Office of Statewide Health Planning and Development, now known as the Department of Health Care Access and Information.

(5) Any additional requirements the department deems necessary to protect patient safety or ensure quality of care.

(d) An eligible hospital shall submit an application to the department pursuant to Section 1265 to obtain certification to participate in the Elective PCI Program. The application shall include sufficient information to demonstrate compliance with the standards set forth in this section, and shall also include the effective date for initiating elective PCI service, the general service area, a description of the population to be served, a description of the services to be provided, a description of backup emergency services, the availability of comprehensive care, and the qualifications of the eligible hospital. The department may require that additional information be submitted with the application. Failure to submit any required criteria or additional information shall disqualify the applicant from the application process and from consideration for participation in the program. The department may deny an Elective PCI Program applicant pursuant to Article 2 (commencing with Section 1265).

(e) An eligible hospital that, as of December 31, 2014, was participating in the Elective Percutaneous Coronary Intervention Pilot Program established under Chapter 295 of the Statutes of 2008, as amended by Chapter 202 of the Statutes of 2013, may continue to perform elective PCI and shall be considered a certified hospital until January 1, 2016. On and after January 1, 2016, a hospital described in this subdivision shall not be considered a certified hospital unless the hospital has obtained a certification under this section.

(f) The Office of Statewide Health Planning and Development, now known as the Department of Health Care Access and Information, shall, using the data transferred pursuant to paragraph (4) of subdivision (c), annually develop and make available to the public a report regarding each certified hospital's performance on mortality, stroke rate, and emergency coronary artery bypass graft rate.

(g) The department may establish an advisory oversight committee composed of two interventionalists from certified hospitals, two interventionalists from general acute care hospitals that are not certified hospitals, and a representative of the department, for the purpose of analyzing the report issued under subdivision (f) and making recommendations for changing the data to be included in future reports issued under subdivision (f).

(h) If at any time a certified hospital fails to meet the criteria set forth in this section for being a certified hospital or fails to safeguard patient safety, as determined by the department, the department may suspend or revoke, pursuant to Section 70309 of Title 22 of the California Code of Regulations, the certification issued to that hospital under this section. A hospital whose certification is revoked pursuant to this subdivision may request an appeal with the department and is not precluded from reapplying for certification under this section.

(i) The department may charge certified hospitals a supplemental licensing fee, the amount of which shall not exceed the reasonable cost to the department of overseeing the program.

(j) The department may contract with a professional entity with medical program knowledge to meet the requirements of this section.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a 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.