AMENDED IN ASSEMBLY JUNE 14, 2013

AMENDED IN SENATE APRIL 4, 2013

SENATE BILL No. 357

Introduced by Senator Correa

February 20, 2013

An act to amend Section 1256.01 of the Health and Safety Code, relating to health facilities, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 357, as amended, Correa. Elective Percutaneous Coronary Intervention (PCI) Pilot Program.

Existing law establishes, until January 1, 2014, the Elective Percutaneous Coronary Intervention Pilot Program in the State Department of Public Health, which authorizes up to 6 eligible acute care hospitals that are licensed to provide cardiac catheterization laboratory service in California, and that meet prescribed, additional criteria to perform scheduled, elective primary percutaneous coronary intervention (PCI), as defined, for eligible patients. Existing law establishes an advisory oversight committee to oversee, monitor, and make recommendations to the department concerning the pilot program. Existing law also imposes various reporting requirements on the advisory oversight committee and the department, including recommendations as to whether the pilot program should be continued or terminated and whether elective PCI without onsite cardiac surgery should be continued in California.

This bill would extend the pilot program until January 1, 2015, and would require the oversight committee to conduct its final report by ~~July 31, 2013.~~ *November 30, 2013.* The bill would require the

department, within 90 days of receiving the final report from the oversight committee, to prepare and submit its report to the Legislature on the initial results of the Elective PCI Pilot Program.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: 2/3. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1256.01 of the Health and Safety Code is amended to read:

1256.01. (a) The Elective Percutaneous Coronary Intervention (PCI) Pilot Program is hereby established in the department. The purpose of the pilot program is to allow the department to authorize up to six general acute care hospitals that 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) "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.

(2) "Eligible hospital" means a general acute care hospital that has a licensed cardiac catheterization laboratory and is in compliance with all applicable state and federal licensing laws and regulations.

(3) "Interventionalist" means a licensed cardiologist who meets the requirements for performing elective PCI at a pilot hospital.

(4) "Pilot hospital" means a hospital participating in the Elective Percutaneous Coronary Intervention (PCI) Pilot Program established by this section.

(5) "Primary percutaneous coronary intervention (primary PCI)" means percutaneous transluminal coronary angioplasty and stent placement that is emergent in nature for acute myocardial infarction and that is performed before administration of thrombolytic agents.

(6) "Receiving hospital" means a licensed general acute care hospital with cardiac surgery services that has entered into a transfer agreement with a pilot hospital.

(7) "STEMI" means ST segment elevation myocardial infarction, a type of heart attack, or myocardial infarction, that is caused by a prolonged period of blocked blood supply, which affects a large area of the heart muscle, and causes changes on an electrocardiogram and in the blood levels of key chemical markers.

(8) "Transfer agreement" means an agreement between the eligible hospital and the receiving hospital that meets all of the requirements of this section.

(c) To participate in the pilot program, an eligible hospital shall demonstrate that it complies with the recommendations of the ~~SCAI~~ *Society for Cardiovascular Angiography and Interventions (SCAI)* for performance of PCI without onsite cardiac surgery, as those recommendations may evolve over time, and meets all of the following criteria:

(1) Performs at least 36 primary PCI procedures annually, has the capacity to perform at least 200 primary and elective PCI procedures annually, and by year two of participation in the pilot program, actually performs at least 200 primary and elective procedures, including at least 36 primary PCI procedures.

(2) Has an on-call schedule with operation of the cardiac catheterization laboratory 24 hours per day, 365 days per year.

(3) Performs primary PCI as the treatment of first choice for STEMI, and has policies and procedures that require the tracking of door-to-balloon times, with a goal of 90 minutes or less, and requires that outlier cases be carefully reviewed for process improvement opportunities.

(4) Permits only interventionists who meet the following requirements to perform elective PCI under the pilot program:

(A) Perform at least 100 total PCI procedures per year, including at least 18 primary PCI per year.

(B) Have lifetime experience of at least 500 total PCI procedures as primary operator.

(C) Have complication rates and outcomes equivalent or superior to national benchmarks established by the American College of Cardiology.

(D) Hold board certification by the American Board of Internal Medicine in Interventional Cardiology and Cardiovascular Diseases.

(E) Actively participate in the eligible hospital's quality improvement program.

(5) Employs experienced nursing and technical laboratory staff with training in interventional laboratories. Cardiac catheterization laboratory personnel ~~must~~ *shall* have demonstrated competency treating acutely ill patients with hemodynamic and electrical instability.

(6) Employs experienced intensive care unit nursing staff who have demonstrated competency with invasive hemodynamic monitoring, temporary pacemaker operation, and intraaortic balloon pump management. Nursing personnel ~~must~~ *shall* be capable of managing endotracheal intubation and ventilator management both onsite and during transfer, if necessary. The eligible hospital shall demonstrate sufficient staffing capacity in the intensive care unit to provide posttreatment care for patients undergoing elective PCI.

(7) Has a well-equipped and maintained cardiac catheterization laboratory with high resolution digital imaging capability and intraaortic balloon pump support compatible with transport vehicles. The ability for the real-time transfer of images and hemodynamic data via T-1 transmission line as well as audio and video images to review terminals for consultation at the receiving hospital is ideal.

(8) Has an appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes, throbectomy and distal protection devices, covered stents, temporary pacemakers, and pericardiocentesis trays. Pressure wire devices and intravascular ultrasound equipment are optimal, but not mandatory.

(9) Provides 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.

(10) Has a written transfer agreement for the emergency transfer of patients to a facility with cardiac surgery services. Transport protocols shall be developed and tested a minimum of twice per year, and ~~must~~ *shall* ensure the immediate and efficient transfer of patients, within 60 minutes, 24 hours per day, seven days per

week, from the eligible hospital to the receiving hospital. The time for transfer of patients shall be calculated from the time it is determined that transfer of a patient for emergency cardiac surgery is necessary at the eligible hospital, to the time that the patient arrives at the receiving hospital.

(11) Has onsite rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.

(12) Participates in the American College of Cardiology-National Cardiovascular Data Registry.

(13) Provides evidence in its application that demonstrates the use of rigorous case selection for patients undergoing elective PCI. Patient selection criteria will meet all of the following requirements, or otherwise be consistent with the recommendations of the SCAI, as those recommendations may evolve.

(A) Patient selection shall be based on the interventionalist's professional medical judgment, which may include, but is not limited to, consideration of the patient's risk, the patient's lesion risk, and the patient's overall health status.

(B) For purposes of this section, "patient risk" means the expected clinical risk in case of occlusion or other serious complication caused by the procedure. "High patient risk" may include, but is not limited to, patients with any of the following features: decompensated congestive heart failure (Killip class III) without evidence for active ischemia, recent cardiovascular attack, advanced malignancy, or known clotting disorders; left ventricular ejection fraction less than or equal to 25 percent; left main stenosis greater than or equal to 50 percent or three-vessel disease unprotected by prior bypass surgery greater than 70 percent stenosis in the proximal segment of all major epicardial coronary arteries; or a single target lesion that jeopardizes over 50 percent of remaining viable myocardium.

(C) For purposes of this section, "lesion risk" means the probability that the procedure will cause acute vessel occlusion or other serious complication. "High lesion risk" may include, but is not limited to, lesions in open vessels with any of the following characteristics: diffuse disease (greater than ~~2 cm~~ *two centimeters* in length) and excessive tortuosity of proximal segments; more than moderate calcification of a stenosis or proximal segments; location in an extremely angulated segment (greater than 90

percent); inability to protect major side branches; degenerated older vein grafts with friable lesions; substantial thrombus in the vessel or at the lesion site; and any other feature that may, in the interventionalist's judgment, impede stent deployment.

(D) In evaluating patient risk and lesion risk to determine patient eligibility for inclusion in the pilot program, the interventionalist shall apply the strategy set forth by the SCAI as set forth below, or as it may otherwise evolve:

(i) A high-risk patient with a high-risk lesion shall not be included in the pilot program.

(ii) A high-risk patient with a not high-risk lesion may be included in the pilot program upon confirmation that a cardiac surgeon and an operating room are immediately available if necessary.

(iii) A not high-risk patient with a high-risk lesion may be included in the pilot program.

(iv) A not high-risk patient with a not high-risk lesion may be included in the pilot program.

(14) Will include evidence of institutional review board (IRB) approval of its participation in the pilot program for as long as ACC/AHA/SCAI guidelines categorize elective PCI with offsite cardiac surgery as a Class III indication.

(15) Shall demonstrate evidence of the process for obtaining written informed consent from patients prior to undergoing elective PCI. The application shall include a copy of the eligible hospital's informed consent form applicable to elective PCI. Evidence of IRB approval of the informed consent form will also be provided for as long as ACC/AHA/SCAI guidelines categorize elective PCI with offsite cardiac surgery a Class III indication.

(d) Consistent with this section, the department shall invite eligible hospitals to submit an application to participate in the Elective PCI Pilot Program. The applications shall include sufficient information to demonstrate compliance with the standards set forth in this section, and additionally 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 general acute care hospital providing the emergency treatment. The department may require that additional

information be submitted with the application. Failure to include any required criteria or additional information shall disqualify the applicant from the application process and from consideration for participation in the pilot program. The department may select up to six general acute care hospitals for participation in the Elective PCI Pilot Program based on the applicant's ability to meet or exceed the criteria described in this section.

(e) An advisory oversight committee comprised of one interventionalist from each pilot hospital, an equal number of cardiologists from nonpilot hospitals, and a representative of the department shall be created to oversee, monitor, and make recommendations to the department concerning the pilot program. In designating the cardiologists from nonpilot hospitals to the committee, the department shall consider the recommendations of the California Chapter of the American College of Cardiology. The advisory oversight committee shall submit at least two reports to the department during the pilot period. The oversight committee shall conduct a final report by ~~July 31, 2013,~~ *November 30, 2013,* including recommendations for the continuation or termination of the pilot program.

(f) If at any time a pilot hospital fails to meet the criteria set forth in this section for being a pilot hospital or fails to safeguard patient safety, as determined by the department, that pilot hospital shall be removed from participation in the pilot program by the department.

(g) Each pilot hospital shall provide quarterly reports to the department and the oversight committee that include statistical data and patient information relating to the number of elective PCI procedures performed, the interventionalists performing elective PCI procedures, and the outcomes of those procedures. In addition, pilot hospitals shall include in the report recommendations, if any, for modifications to the pilot program and any other information the pilot hospitals deem relevant for evaluating the success of the pilot program in delivering improved patient care. The department and the oversight committee may make site visits to any pilot hospital at any time.

(h) Notwithstanding Section 10231.5 of the Government Code, within 90 days of receiving the final report of the oversight committee, the department shall prepare and submit a report to the Legislature, pursuant to Section 9795 of the Government Code,

on the initial results of the Elective PCI Pilot Program. The report shall include, but not be limited to, an evaluation of the pilot program's cost, safety, and quality of care. The report shall also include a comparison of elective PCI performed in connection with the Elective PCI Pilot Program, and elective PCI performed in hospitals with onsite cardiac surgery services. The report shall further recommend whether elective PCI without onsite cardiac surgery should be continued in California, and if so, under what conditions.

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

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

(k) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

SEC. 2. This 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. The facts constituting the necessity are:

In order to ensure continued operation of a successful program that is saving lives, it is necessary that this act take effect immediately.

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