

Introduced by Senator CorreaFebruary 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 introduced, 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 require the oversight committee to conduct its final report by July 31, 2013, and 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 PCI pilot program. The bill would provide that the department may

continue to implement the pilot program until the Legislature enacts subsequent legislation to permanently authorize or end the pilot program.

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

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes.

State-mandated local program: no.

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

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

3 1256.01. (a) The Elective Percutaneous Coronary Intervention
4 (PCI) Pilot Program is hereby established in the department. The
5 purpose of the pilot program is to allow the department to authorize
6 up to six general acute care hospitals that are licensed to provide
7 cardiac catheterization laboratory service in California, and that
8 meet the requirements of this section, to perform scheduled,
9 elective percutaneous transluminal coronary angioplasty and stent
10 placement for eligible patients.

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

13 (1) “Elective Percutaneous Coronary Intervention (elective
14 PCI)” means scheduled percutaneous transluminal coronary
15 angioplasty and stent placement. Elective PCI does not include
16 urgent or emergent PCI that is scheduled on an ad hoc basis.

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

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

23 (4) “Pilot hospital” means a hospital participating in the Elective
24 Percutaneous Coronary Intervention (PCI) Pilot Program
25 established by this section.

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

1 (6) “Receiving hospital” means a licensed general acute care
2 hospital with cardiac surgery services that has entered into a
3 transfer agreement with a pilot hospital.

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

9 (8) “Transfer agreement” means an agreement between the
10 eligible hospital and the receiving hospital that meets all of the
11 requirements of this section.

12 (c) To participate in the pilot program, an eligible hospital shall
13 demonstrate that it complies with the recommendations of the
14 SCAI for performance of PCI without onsite cardiac surgery, as
15 those recommendations may evolve over time, and meets all of
16 the following criteria:

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

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

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

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

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

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

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

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

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

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

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

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

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

28 (9) Provides evidence showing the full support from hospital
29 administration in fulfilling the necessary institutional requirements,
30 including, but not limited to, appropriate support services such as
31 respiratory care and blood banking.

32 (10) Has a written transfer agreement for the emergency transfer
33 of patients to a facility with cardiac surgery services. Transport
34 protocols shall be developed and tested a minimum of twice per
35 year, and must ensure the immediate and efficient transfer of
36 patients, within 60 minutes, 24 hours per day, seven days per week,
37 from the eligible hospital to the receiving hospital. The time for
38 transfer of patients shall be calculated from the time it is
39 determined that transfer of a patient for emergency cardiac surgery

1 is necessary at the eligible hospital, to the time that the patient
2 arrives at the receiving hospital.

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

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

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

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

17 (B) For purposes of this section, "patient risk" means the
18 expected clinical risk in case of occlusion or other serious
19 complication caused by the procedure. "High patient risk" may
20 include, but is not limited to, patients with any of the following
21 features: decompensated congestive heart failure (Killip class 3)
22 without evidence for active ischemia, recent cardiovascular attack,
23 advanced malignancy, known clotting disorders; left ventricular
24 ejection fraction less than or equal to 25 percent; left main stenosis
25 greater than or equal to 50 percent or three-vessel disease
26 unprotected by prior bypass surgery greater than 70 percent stenosis
27 in the proximal segment of all major epicardial coronary arteries;
28 single target lesion that jeopardizes over 50 percent of remaining
29 viable myocardium.

30 (C) For purposes of this section, "lesion risk" means the
31 probability that the procedure will cause acute vessel occlusion or
32 other serious complication. "High lesion risk" may include, but is
33 not limited to, lesions in open vessels with any of the following
34 characteristics: diffuse disease (greater than 2 cm in length) and
35 excessive tortuosity of proximal segments; more than moderate
36 calcification of a stenosis or proximal segments; location in an
37 extremely angulated segment (greater than 90 percent); inability
38 to protect major side branches; degenerated older vein grafts with
39 friable lesions; substantial thrombus in the vessel or at the lesion

1 site; and any other feature that may, in the interventionalist's
2 judgment, impede stent deployment.

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

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

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

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

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

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

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

28 (d) Consistent with this section, the department shall invite
29 eligible hospitals to submit an application to participate in the
30 Elective PCI Pilot Program. The applications shall include
31 sufficient information to demonstrate compliance with the
32 standards set forth in this section, and additionally include the
33 effective date for initiating elective PCI service, the general service
34 area, a description of the population to be served, a description of
35 the services to be provided, a description of backup emergency
36 services, the availability of comprehensive care, and the
37 qualifications of the general acute care hospital providing the
38 emergency treatment. The department may require that additional
39 information be submitted with the application. Failure to include
40 any required criteria or additional information shall disqualify the

1 applicant from the application process and from consideration for
2 participation in the pilot program. The department may select up
3 to six general acute care hospitals for participation in the Elective
4 PCI Pilot Program based on the applicant's ability to meet or
5 exceed the criteria described in this section.

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

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

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

35 (h) ~~The Notwithstanding Section 10231.5 of the Government~~
36 ~~Code, within 90 days of receiving the final report of the oversight~~
37 ~~committee, the department shall prepare and submit a report to the~~
38 ~~Legislature, pursuant to Section 9795 of the Government Code,~~
39 ~~on the initial results of the Elective PCI Pilot Program. The report~~
40 ~~shall be submitted no later than 90 days after termination of~~

1 *department may continue to implement the pilot program until the*
2 *Legislature enacts subsequent legislation to permanently authorize*
3 *or end the pilot program.* The report shall include, but not be
4 limited to, an evaluation of the pilot program's cost, safety, and
5 quality of care. The report shall also include a comparison of
6 elective PCI performed in connection with the Elective PCI Pilot
7 Program, and elective PCI performed in hospitals with onsite
8 cardiac surgery services. The report shall further recommend
9 whether elective PCI without onsite cardiac surgery should be
10 continued in California, and if so, under what conditions.

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

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

17 ~~(k) This section shall remain in effect only until January 1, 2014,~~
18 ~~allowing up to two years for implementation and at least three~~
19 ~~years during which the pilot program will be operational. As of~~
20 ~~January 1, 2014, this section is repealed, unless a later enacted~~
21 ~~statute, that is enacted before January 1, 2014, deletes or extends~~
22 ~~that date.~~

23 (k) *It is the intent of the Legislature to enact subsequent*
24 *legislation to act upon the recommendations of the department*
25 *submitted to the Legislature pursuant to subdivision (h).*

26 SEC. 2. This act is an urgency statute necessary for the
27 immediate preservation of the public peace, health, or safety within
28 the meaning of Article IV of the Constitution and shall go into
29 immediate effect. The facts constituting the necessity are:

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