

AMENDED IN ASSEMBLY JUNE 26, 2008
AMENDED IN SENATE JANUARY 16, 2008
AMENDED IN SENATE JANUARY 7, 2008
AMENDED IN SENATE APRIL 16, 2007

SENATE BILL

No. 891

Introduced by Senator Correa

February 23, 2007

An act to add and repeal Section 1256.01 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 891, as amended, Correa. Health facilities: Elective Percutaneous Coronary Intervention (PCI) Pilot Program.

Existing law provides for the licensure and regulation of health facilities by the State Department of Public Health. Existing law authorizes health facilities to engage in various types of cardiac intervention and surgery.

This bill, until January 1, 2014, would establish the Elective Percutaneous Coronary Intervention Pilot Program in the department, which would authorize 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.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

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

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) Hospitals in California with cardiac catheterization laboratory
4 service and without cardiac surgery services are currently limited
5 to performing certain diagnostic and unscheduled interventional
6 procedures. These parameters were established by the Legislature
7 over 20 years ago, when interventional cardiology was in its
8 infancy, as a precautionary measure against complications.

9 (b) Technological and methodological advances in interventional
10 cardiology have greatly improved patient outcomes.

11 (c) Multiple studies have demonstrated that performance of
12 primary and elective percutaneous coronary intervention (PCI) in
13 hospital-based cardiac catheterization laboratories, with offsite
14 cardiac surgery backup, results in numerous benefits to patients,
15 including all of the following:

16 (1) Improved patient outcomes due to the correlation between
17 the volume of procedures performed and the outcome. For example,
18 as patient volume increases, patient outcomes improve.

19 (2) Provision of diagnosis and therapeutic treatment in one
20 procedure at one hospital, instead of two procedures at two different
21 hospitals.

22 (3) Improved access to care and continuity of care since patients
23 may undergo interventional cardiology procedures closer to home.

24 (4) Reduction of pressure to create and maintain low-volume
25 cardiac surgery centers primarily to support interventional
26 cardiology, thus allowing for a better allocation of resources.

27 (d) Economic benefits associated with shorter hospital stays
28 and reduced numbers of discharges and transfers indicate that
29 elective PCI at hospitals with offsite cardiac surgery backup is a
30 cost-effective alternative to limiting elective PCI to hospitals with
31 onsite cardiac surgery.

32 (e) Primary PCI is the treatment of choice for ST segment
33 elevation myocardial infarction (STEMI) patients, however it
34 should be performed within a 90-minute window of time. Upon
35 arrival in many emergency rooms, STEMI patients often do not
36 receive primary PCI because it is not available in that hospital,
37 and hospital-to-hospital transfer cannot be accomplished within
38 the optimal 90-minute door-to-balloon time. Among the factors

1 affecting achievement of this benchmark is the experience level
2 of the hospital and its staff, and the difficulty of providing coverage
3 24 hours per day, 365 days per year. One strategy for overcoming
4 these factors, and thus improving access to lifesaving PCI, is to
5 permit hospitals capable of performing PCI to perform both
6 primary and elective PCI. Higher total PCI volumes will increase
7 the experience and capabilities of the facility, interventional
8 cardiologists, and personnel, resulting in improved outcomes.

9 (f) The American College of Cardiology (ACC), the American
10 Heart Association (AHA), and the Society for Cardiovascular
11 Angiography and Interventions (SCAI) issued a report titled “2005
12 Guidelines Update for Percutaneous Coronary Intervention.” The
13 ACC/AHA/SCAI guidelines acknowledge that several centers with
14 offsite cardiac surgery backup have reported satisfactory results
15 in performing elective PCI based on careful case selection and
16 well-defined arrangements for immediate transfer to a surgical
17 program if needed. Nevertheless, the ACC/AHA/SCAI guidelines
18 do not recommend elective PCI without onsite cardiac surgery,
19 but note that this recommendation may be subject to revision as
20 clinical data and experience increase.

21 (g) After publication of the ACC/AHA/SCAI guidelines, the
22 SCAI issued recommendations for performing elective and primary
23 PCI in hospitals without onsite cardiac surgery in recognition of
24 the reality that elective PCI without onsite cardiac surgery is
25 already performed in 28 states and around the world without regard
26 to whether cardiac surgery backup is available onsite or offsite.

27 (h) Due to the unique demographics and distribution of
28 California’s population, the Legislature finds that it is appropriate
29 to gather clinical data and experience regarding elective PCI in
30 hospitals with offsite cardiac surgery backup in order to enable
31 California licensed health care facilities and physicians to maintain
32 the highest standard of health care for Californians. For the
33 foregoing reasons, it is the intent of the Legislature to establish
34 the Elective Percutaneous Coronary Intervention (PCI) Pilot
35 Program to allow general acute care hospitals that are licensed to
36 perform cardiac catheterization laboratory service in California,
37 and that meet additional rigorous requirements, to also perform
38 scheduled, elective percutaneous transluminal coronary angioplasty
39 and stent placement for eligible patients.

1 SEC. 2. Section 1256.01 is added to the Health and Safety
2 Code, 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.

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

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

38 (8) “Transfer agreement” means an agreement between the
39 eligible hospital and the receiving hospital that meets all of the
40 requirements of this section.

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

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

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

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

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

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

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

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

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

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

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

36 (6) Employs experienced intensive care unit nursing staff who
37 have demonstrated competency with invasive hemodynamic
38 monitoring, temporary pacemaker operation, and intraaortic balloon
39 pump management. Nursing personnel must be capable of
40 managing endotracheal intubation and ventilator management both

1 onsite and during transfer, if necessary. The eligible hospital shall
2 demonstrate sufficient staffing capacity in the intensive care unit
3 to provide posttreatment care for patients undergoing elective PCI.

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

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

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

21 (10) Has a written transfer agreement for the emergency transfer
22 of patients to a facility with cardiac surgery services. Transport
23 protocols shall be developed and tested a minimum of twice per
24 year, and must ensure the immediate and efficient transfer of
25 patients, within 60 minutes, 24 hours per day, seven days per week,
26 from the eligible hospital to the receiving hospital. The time for
27 transfer of patients shall be calculated from the time it is
28 determined that transfer of a patient for emergency cardiac surgery
29 is necessary at the eligible hospital, to the time that the patient
30 arrives at the receiving hospital.

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

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

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

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

5 (B) For purposes of this section, “patient risk” means the
6 expected clinical risk in case of occlusion or other serious
7 complication caused by the procedure. “High patient risk” may
8 include, but is not limited to, patients with any of the following
9 features: decompensated congestive heart failure (Killip class 3)
10 without evidence for active ischemia, recent cardiovascular attack,
11 advanced malignancy, known clotting disorders; left ventricular
12 ejection fraction less than or equal to 25 percent; left main stenosis
13 greater than or equal to 50 percent or three-vessel disease
14 unprotected by prior bypass surgery greater than 70 percent stenosis
15 in the proximal segment of all major epicardial coronary arteries;
16 single target lesion that jeopardizes over 50 percent of remaining
17 viable myocardium.

18 (C) For purposes of this section, “lesion risk” means the
19 probability that the procedure will cause acute vessel occlusion or
20 other serious complication. “High lesion risk” may include, but is
21 not limited to, lesions in open vessels with any of the following
22 characteristics: diffuse disease (greater than 2 cm in length) and
23 excessive tortuosity of proximal segments; more than moderate
24 calcification of a stenosis or proximal segments; location in an
25 extremely angulated segment (greater than 90 percent); inability
26 to protect major side branches; degenerated older vein grafts with
27 friable lesions; substantial thrombus in the vessel or at the lesion
28 site; and any other feature that may, in the interventionalist’s
29 judgment, impede stent deployment.

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

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

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

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

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

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

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

16 (d) Consistent with this section, the department shall invite
17 eligible hospitals to submit an application to participate in the
18 Elective PCI Pilot Program. The applications shall include
19 sufficient information to demonstrate compliance with the
20 standards set forth in this section, and additionally include the
21 effective date for initiating elective PCI service, the general service
22 area, a description of the population to be served, a description of
23 the services to be provided, a description of backup emergency
24 services, the availability of comprehensive care, and the
25 qualifications of the general acute care hospital providing the
26 emergency treatment. The department may require that additional
27 information be submitted with the application. Failure to include
28 any required criteria or additional information shall disqualify the
29 applicant from the application process and from consideration for
30 participation in the pilot program. The department may select up
31 to six general acute care hospitals for participation in the Elective
32 PCI Pilot Program based on the applicant's ability to meet or
33 exceed the criteria described in this section.

34 (e) An advisory oversight committee comprised of one
35 interventionalist from each pilot hospital, an equal number of
36 cardiologists from nonpilot hospitals, and a representative of the
37 department shall be created to oversee, monitor, and make
38 recommendations to the department concerning the pilot program.
39 In designating the cardiologists from nonpilot hospitals to the
40 committee, the department shall consider the recommendations of

1 the California Chapter of the American College of Cardiology.
2 The advisory oversight committee shall submit at least two reports
3 to the department during the pilot period. The oversight committee
4 shall conduct a final report at the conclusion of the pilot program,
5 including recommendations for the continuation or termination of
6 the pilot program.

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

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

23 (h) The department shall prepare and submit ~~two reports~~ *a report*
24 to the Legislature on the results of the Elective PCI Pilot Program.
25 ~~The first report shall be submitted by July 1, 2012, and the second~~
26 ~~and last report shall be submitted no later than 90 days after~~
27 ~~termination of the pilot program. The reports~~ *report* shall include,
28 but not be limited to, an evaluation of the pilot program's cost,
29 safety, and quality of care. ~~The reports~~ *report* shall also include a
30 comparison of elective PCI performed in connection with the
31 ~~elective PCI pilot program~~ *Elective PCI Pilot Program*, and
32 elective PCI performed in hospitals with onsite cardiac surgery
33 services. ~~The reports~~ *report* shall further recommend whether
34 elective PCI without onsite cardiac surgery should be continued
35 in California, and if so, under what conditions.

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

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

4 (j)

5 (k) This section shall remain in effect only until January 1, 2014,
6 allowing up to two years for implementation and at least three
7 years during which the pilot program will be operational. As of
8 January 1, 2014, this section is repealed, unless a later enacted
9 statute, that is enacted before January 1, 2014, deletes or extends
10 that date.

O