

**Introduced by Senator Correa**

February 23, 2007

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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, 2011, would establish the Elective Percutaneous Coronary Intervention Pilot Program in the department, which would authorize certain eligible acute care hospitals *that are* licensed to provide cardiac catheterization laboratory service in California, *and* that meet prescribed, *additional* criteria to perform ~~elective~~ and scheduled, *elective* primary percutaneous coronary intervention (PCI), as defined, for patients at low to medium risk ~~at offsite surgical clinics that meet specified requirements~~.

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:

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

7 (b) Technological and methodological advances in interventional  
8 cardiology have greatly improved patient outcomes, and have  
9 greatly reduced the incidences of emergency cardiac surgery.

10 (c) Multiple studies have demonstrated that removing the link  
11 between certain interventional cardiology procedures and cardiac  
12 surgery to allow therapeutic procedures to be performed for patients  
13 at low and medium risk in hospital-based cardiac catheterization  
14 laboratories, with offsite cardiac surgery facilities, results in  
15 numerous benefits to patients, including all of the following:

16 (1) Provision of diagnosis and therapeutic treatment in one  
17 procedure at one hospital, instead of two procedures at two different  
18 hospitals.

19 (2) Improved access to care and continuity of care since patients  
20 may undergo interventional cardiology procedures closer to home.

21 (3) Improved patient outcomes due to the correlation between  
22 the volume of procedures performed and the outcome (i.e., as  
23 volume increases patient outcomes improve).

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

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

32 (e) The American College of Cardiology and American Heart  
33 Association ~~acknowledged~~ *currently categorizes elective PCI at*  
34 *hospitals without cardiac surgery as a class III recommendation,*  
35 *which pertains to a condition for which there is evidence, or*  
36 *general agreement, or both, that a procedure or treatment is not*  
37 *useful or effective, and, in some cases, may be harmful based on*  
38 *the consensus opinion among experts, case studies, and*  
39 *standard-of-care guidelines. However, it also notes in its report*  
40 ~~entitled~~ *titled* "2005 Guidelines Update for Percutaneous Coronary

1 Intervention,” that several studies of elective PCI with offsite  
2 cardiac surgery have reported satisfactory results based on careful  
3 case selection and well-defined arrangements for immediate  
4 transfer to a surgical program if needed. *The Society for*  
5 *Cardiovascular Angiography and Interventions* recently issued  
6 *recommendations for performing elective and primary PCI without*  
7 *onsite cardiac surgery.*

8 (f) The Legislature finds that clinical data and experience  
9 relating to elective PCI at hospitals with offsite cardiac surgery  
10 need to be gathered in order to ensure that California licensed  
11 health care facilities and physicians will achieve satisfactory results  
12 and maintain a high standard of care for patients. For the foregoing  
13 reasons, it is the intent of the Legislature to establish the elective  
14 Percutaneous Coronary Intervention (elective PCI) Pilot Program  
15 to allow certain general acute care hospitals that are licensed to  
16 perform cardiac catheterization laboratory service in California to  
17 also perform scheduled elective percutaneous transluminal coronary  
18 angioplasty (PTCA) and stent placement for patients at low and  
19 medium risk ~~at offsite cardiac clinics if those clinics if those~~  
20 *hospitals* have adequate surgical backup.

21 SEC. 2. Section 1256.01 is added to the Health and Safety  
22 Code, to read:

23 1256.01. (a) The Elective Percutaneous Coronary Intervention  
24 (PCI) Pilot Program is hereby established in the department. The  
25 purpose of the pilot program is to allow the department to authorize  
26 six general acute care hospitals *that are* licensed to provide cardiac  
27 catheterization laboratory service in California ~~to perform elective~~  
28 ~~and scheduled~~ *and that meet the requirements of this section to*  
29 *perform scheduled, elective* percutaneous coronary intervention  
30 and stent placement for low- to medium-risk patients ~~at offsite~~  
31 ~~cardiac clinics that meet the requirements of this section.~~

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

34 (1) “Elective Percutaneous Coronary Intervention (elective  
35 PCI)” means scheduled percutaneous transluminal coronary  
36 angioplasty (PTCA) and stent placement. *Elective PCI does not*  
37 *include urgent or emergent PCI that is scheduled on an ad hoc*  
38 *basis.*

39 (2) “Eligible hospital” means a general acute care hospital  
40 without cardiac surgery services that has a licensed cardiac

1 catheterization laboratory and is in compliance with all applicable  
2 state and federal licensing laws and regulations.

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

5 (4) “Pilot hospital” means a hospital participating in the Elective  
6 PCI Pilot Program established by this section.

7 (5) “Primary Percutaneous Coronary Intervention (primary  
8 PCI)” means percutaneous transluminal coronary angioplasty  
9 (PTCA) and stent placement that is emergent in nature.

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

13 (7) “Transfer agreement” means an agreement between the  
14 eligible hospital and the receiving hospital that meets all of the  
15 requirements of this section.

16 (c) (1) To participate in the pilot program, an eligible hospital  
17 shall meet all of the following criteria:

18 (A) The eligible hospital has an interventionalist and cardiac  
19 catheterization laboratory staff on-call and available 24 hours a  
20 day, seven days a week.

21 (B) The eligible hospital performs at least 36 primary PCI  
22 procedures and 800 diagnostic cardiac catheterizations annually.

23 (C) The eligible hospital includes in its application evidence of  
24 having primary PCI available 24 hours a day, seven days a week,  
25 including, but not limited to, the following:

26 (i) Cardiac catheterization laboratory policies and procedures.

27 (ii) Emergency room policies and procedures applicable to  
28 transfers to the cardiac catheterization laboratory.

29 (iii) Volume and relevant patient outcome, including, but not  
30 limited to, complication rates of primary PCI procedures performed  
31 annually for the past three years.

32 (iv) Volume and relevant patient outcome, including, but not  
33 limited to, complication rates of diagnostic cardiac catheterizations  
34 performed annually for the past three years.

35 (D) The eligible hospital providing elective PCI, has an  
36 interventionalist on staff who meets both of the following  
37 requirements:

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

1 (ii) Performs a minimum of 125 primary or elective PCI  
2 procedures per year.

3 (E) The eligible hospital includes in its application evidence of  
4 the qualifications of each interventionalist at the hospital who may  
5 perform elective PCI, including, but not limited to, the following:

6 (i) Proof of a valid, unrestricted California license from a  
7 medical board.

8 (ii) The interventionalist's curricula vitae.

9 (iii) The interventionalist maintains valid privileges at the  
10 eligible hospital.

11 (iv) The interventionalist's total volume of PCI procedures, the  
12 annual volume of those procedures for the past three years, and  
13 information regarding any formal investigation or disciplinary  
14 action regarding PCI procedures taken at any hospital where the  
15 interventionalist has been on staff.

16 (F) The eligible hospital designates a program director who is  
17 an interventionalist with career experience of more than 1,000  
18 elective and primary PCI procedures who meets all other  
19 requirements for an interventionalist described in this section.

20 (G) The eligible hospital employs cardiac catheterization  
21 laboratory staff who are experienced and trained in interventional  
22 procedures and equipment, including, but not limited to,  
23 hemodynamic monitoring and intra-aortic balloon pump  
24 management.

25 (H) The cardiac catheterization laboratory staff at an eligible  
26 hospital complies with all of the following:

27 (i) The eligible hospital has policies and procedures in place for  
28 providing quality cardiac care, including, but not limited to,  
29 continuing education requirements and required competencies.

30 (ii) The eligible hospital complies with all existing laws and  
31 regulations pertaining to catheterization laboratory staff, including  
32 applicable licensure and certification.

33 (iii) The eligible hospital demonstrates competency in caring  
34 for and managing arterial sheaths, including, but not limited to,  
35 removal of those sheaths.

36 (I) An eligible hospital shall also provide in its application  
37 evidence of the cardiac catheterization laboratory staff's  
38 competency to assist in performing elective PCI procedures and  
39 care for elective PCI patients, including, but not limited to, the  
40 following:

1 (i) A description of all cardiac catheterization laboratory policies  
2 and procedures, including those addressing the addition of elective  
3 PCI procedures.

4 (ii) A description of all staff positions and principal  
5 accountabilities of all cardiac catheterization staff and the role of  
6 each position in the proposed elective PCI procedures.

7 (iii) Evidence of demonstrated competencies for all cardiac  
8 catheterization staff.

9 (iv) A description of continuing education requirements and  
10 evidence of completion for required education for all cardiac  
11 catheterization staff.

12 (J) An eligible hospital shall ensure that posttreatment nursing  
13 care for patients undergoing elective PCI shall be provided in an  
14 intensive care unit by appropriately trained and experienced nurses.  
15 The eligible hospital shall also demonstrate sufficient capacity in  
16 the intensive care unit to provide posttreatment care for patients  
17 undergoing elective PCI.

18 (K) An eligible hospital shall ensure that posttreatment care in  
19 the intensive care unit by nurses competent in the care and recovery  
20 of patients who have undergone elective PCI, as demonstrated by  
21 factors, including, but not limited to, the following:

22 (i) Compliance with all existing state laws and regulations,  
23 including, but not limited to, registered nurse licensure and Basic  
24 Life Support and Advanced Cardiac Life Support certification.

25 (ii) Experience in hemodynamic monitoring and intra-aortic  
26 balloon pump management.

27 (iii) Compliance with an eligible hospital's policies and  
28 procedures for providing critical care.

29 (iv) All required competencies (eligible hospital, nursing, and  
30 unit specific) and continuing education requirements.

31 (v) Demonstrated competency in caring for and managing  
32 arterial sheaths, including, but not limited to, removal of the sheath.

33 (L) An eligible hospital shall provide in its application evidence  
34 of its proposed posttreatment care, including, but not limited to,  
35 the following:

36 (i) The intensive care unit's policies and procedures applicable  
37 to the care of patients recovering from elective PCI procedures,  
38 including, but not limited to, how the eligible hospital will ensure  
39 sufficient space in the intensive care unit for patients who have  
40 undergone those procedures.

1 (ii) Position descriptions and principal accountabilities of all  
2 intensive care unit staff that will provide posttreatment care to  
3 patients recovering from elective PCI procedures.

4 (iii) Required competencies and continuing education  
5 requirements, as well as proof of completion of these requirements,  
6 for nurses providing posttreatment care to patients recovering from  
7 elective PCI procedures.

8 (M) The eligible hospital shall provide elective PCI in a cardiac  
9 catheterization laboratory using appropriate equipment, including,  
10 but not limited to, imaging systems capable of transferring cardiac  
11 catheterization images to the receiving hospital, resuscitative  
12 equipment, intra-aortic balloon pump support, and the full range  
13 of interventional equipment necessary for performing elective PCI.  
14 An eligible hospital shall further provide in its application evidence  
15 demonstrating that its cardiac catheterization laboratory is  
16 sufficiently equipped to perform elective PCI, including, but not  
17 limited to, the following:

18 (i) Cardiac catheterization laboratory policies and procedures  
19 relating to the performance of elective PCI.

20 (ii) List of equipment available in an eligible hospital's cardiac  
21 catheterization laboratory.

22 (iii) Description and proof that cardiac catheterization laboratory  
23 equipment is appropriately serviced and maintained.

24 (N) The eligible hospital shall provide letters, board resolutions,  
25 or comparable evidence of approval of, and support for,  
26 participation in the elective PCI Pilot Program by the administrative  
27 staff and governing body of both the eligible hospital and the  
28 receiving hospital.

29 (O) The eligible hospital shall have a transfer agreement that  
30 ensures the immediate and efficient transfer of patients, within 60  
31 minutes, 24 hours a day, seven days a week, from the eligible  
32 hospital to the receiving hospital. The time for transfer of patients  
33 shall be calculated from the time it is determined that transfer of  
34 a patient for emergent cardiac surgery is necessary at the eligible  
35 hospital, to the time that the patient arrives at the receiving hospital.

36 (P) The transfer agreement and the transfer policies and  
37 procedures shall include, at a minimum, all of the following:

38 (i) An arrangement with an ambulance company for transport  
39 by ambulance, or other appropriate means, to be onsite at the  
40 eligible hospital during each elective PCI procedure during the

1 first six months the eligible hospital is enrolled in the pilot program  
2 or during the first 20 elective PCI procedures performed at eligible  
3 hospital, whichever is longer. After the first six months or the first  
4 20 elective PCI procedures, whichever time period is longer, the  
5 eligible hospital may remove the requirement that an ambulance,  
6 or other form of transportation, be available onsite so long as the  
7 eligible hospital is still able to ensure that the 60-minute maximum  
8 patient transfer time is achieved 24 hours a day, seven days a week.

9 (ii) A description of how the eligible hospital's cardiac  
10 catheterization laboratory staff are to communicate and coordinate  
11 with the receiving hospital regarding the transfer of a patient.

12 (iii) A requirement that an interventionalist and a qualified  
13 cardiac catheterization laboratory nurse, trained in hemodynamic  
14 monitoring and intra-aortic balloon pump management, accompany  
15 the patient during transportation to the receiving hospital.

16 (iv) A description of how the receiving hospital will  
17 communicate and coordinate with the eligible hospital regarding  
18 the transfer of a patient.

19 (v) A description of how the patient will be cared for at the  
20 receiving hospital if an operating room has not been prepared by  
21 the time the patient arrives at the receiving hospital.

22 (vi) A description of how the receiving hospital will ensure  
23 appropriate postsurgical care for patients who are transferred,  
24 including admission to receiving hospital's intensive care unit.

25 ~~(2) The application shall also include copies~~ (vii) Copies of the  
26 transfer agreement and the transfer policies and procedures from  
27 both the eligible hospital and the receiving hospital.

28 (Q) The eligible hospital shall develop and complete a  
29 performance improvement plan dedicated to monitoring and  
30 evaluating the elective PCI program to ensure patient safety and  
31 efficacy, which shall also include all of the following:

32 (i) Enrollment in the American College of Cardiology National  
33 Cardiovascular Data Registry, or a comparable national  
34 cardiovascular data registry.

35 (ii) A performance improvement plan that includes, but is not  
36 limited to, the following:

37 (I) A system for regularly reviewing and assessing the results  
38 from the eligible hospital's chosen national cardiovascular data  
39 registry.

1 (II) A system for monitoring Interventionalist privileges  
2 including reviewing continuation of interventionalist privileges in  
3 elective PCI, based on outcome rates, at least every two years.

4 (III) A system for performing ongoing quality assessment  
5 comparing results with current benchmarks, and performing risk  
6 stratification of complication rates.

7 (IV) A plan for conducting performance reviews on every  
8 elective PCI procedure, assessing patient complication rates and  
9 root cause analysis of problems associated with complications,  
10 and taking action as necessary in accordance with the eligible  
11 hospital's performance improvement plan.

12 (iii) The receiving hospital shall develop a performance review  
13 plan that addresses how it will monitor the transfer of each patient  
14 to its facility from the eligible hospital.

15 (iv) The eligible hospital and the receiving hospital shall develop  
16 a system that allows each facility to share with the other relevant  
17 performance improvement information regarding the elective PCI  
18 Pilot Program and related peer review information.

19 (v) The application shall include evidence of both the eligible  
20 hospital and the receiving hospital's performance improvement  
21 plans, including, but not limited to, the following:

22 (I) The eligible hospital's performance improvement policies  
23 and procedures.

24 (II) The receiving hospital's performance review policies and  
25 procedures.

26 (R) The eligible hospital shall provide evidence in its application  
27 that demonstrates the use of rigorous case selection for patients  
28 undergoing elective PCI that meets all of the following  
29 requirements:

30 ~~(I) Only patients at low to medium risk may undergo elective  
31 PCI at an eligible hospital.~~

32 (i) *Patients at high clinical and increased lesion risk shall not*  
33 *be eligible for inclusion in the elective PCI Pilot Program.* Patient  
34 selection shall be based on the interventionalist's professional  
35 medical judgment, which may include, but is not limited to,  
36 consideration of the patient's clinical risk, the patient's lesion risk,  
37 and the patient's overall health status.

38 ~~(H)~~

39 (ii) For purposes of this clause, "clinical risk" means the  
40 patient's clinical capacity to compensate in the event of unexpected

1 arterial blockage. “High clinical risk” may include, but is not  
2 limited to, the following features: severe left ventricular heart  
3 function with ejection fraction of 25 percent or less; severe left  
4 main or 3-vessel disease unprotected by prior bypass surgery; or  
5 the target lesion jeopardizes over 50 percent of the remaining viable  
6 heart muscle.

7 ~~(H)~~

8 (iii) For purposes of this clause, “lesion risk” means the  
9 likelihood that elective PCI will cause arterial blockage based on  
10 characteristics, including, but not limited to, length, tortuosity,  
11 location, or other anatomical features. “Increased lesion risk” may  
12 include, but is not limited to: long blockages (> 4 cm length) in  
13 small vessels; excessive tortuosity of calcified arteries; location  
14 in an extremely angulated calcified arteries; inability to protect  
15 major side branch arteries; or degeneration of older vein grafts  
16 with a severe amount of blood clots.

17 ~~(ii) Patients at high clinical and increased lesion risk shall not~~  
18 ~~be eligible for inclusion in the elective PCI Pilot Program.~~

19 ~~(iii)~~

20 (iv) The receiving hospital shall review and approve the eligible  
21 hospital’s patient selection criteria.

22 (S) The eligible hospital shall demonstrate evidence of the  
23 process for obtaining written informed consent from patients prior  
24 to undergoing elective PCI. The application shall include a copy  
25 of the eligible hospital’s informed consent form applicable to  
26 elective PCI.

27 (T) The eligible hospital shall include with its application an  
28 implementation plan describing how the eligible hospital will  
29 implement the pilot program following selection and approval by  
30 the department.

31 (U) Consistent with this section, the department shall invite  
32 eligible hospitals to submit an application to participate in the  
33 elective PCI Pilot Program. The applications shall include sufficient  
34 information to demonstrate compliance with the standards set forth  
35 in this section, and additionally include the effective date for  
36 initiating elective PCI service, the general service area, a  
37 description of the population to be served, a description of the  
38 services to be provided, a description of backup emergency  
39 services, the availability of comprehensive care, and the  
40 qualifications of the general acute care hospital providing the

1 emergency treatment. The department may require that additional  
2 information be submitted with the application. Failure to include  
3 any required criteria or additional information shall disqualify the  
4 applicant from the application process and from consideration for  
5 participation in the pilot program. The department may select up  
6 to six general acute care hospitals for participation in the elective  
7 PCI Pilot Program based on their ability to meet or exceed the  
8 criteria described in this section.

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

22 (ii) If at any time an eligible hospital that participates in the  
23 pilot program fails to meet the criteria for being a pilot hospital or  
24 fails to safeguard patient safety, as determined by the department,  
25 that pilot hospital shall be removed from participation in the pilot  
26 program by the department.

27 (W) An eligible hospital that participates in the pilot program  
28 shall provide annual reports to the department and the oversight  
29 committee that include statistical data and patient information  
30 relating to the number of elective PCI procedures performed, the  
31 interventionalists performing elective PCI procedures, and the  
32 outcomes of those procedures. In addition, eligible hospitals shall  
33 include in the report recommendations, if any, for modifications  
34 to the pilot program and any other information the eligible hospitals  
35 deem relevant for evaluating the success of the pilot program in  
36 delivering improved patient care.

1 (d) This section shall remain in effect only until January 1, 2011,  
2 and as of that date is repealed, unless a later enacted statute, that  
3 is enacted before January 1, 2011, deletes or extends that date.

O