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California Department of Public Health



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AFL 09-06

TO: General Acute Care Hospitals (GACHs)
(Equipped with Cardiac Catheter Laboratories)

SUBJECT: Elective Percutaneous Coronary Intervention Pilot Program

AUTHORITY: Senate Bill (SB) 891 (Correa, Chapter 295, Statutes of 2008)
(Health and Safety Code (HSC) Section 1256.01)

Effective January 1, 2009, Senate Bill 891 established the Elective Percutaneous Coronary Intervention (PCI) Pilot Program within the California Department of Public Health (CDPH).

The purpose of the PCI Pilot Program is to allow the CDPH to authorize up to six (6) general acute care hospitals, that are licensed to provide cardiac catheterization laboratory service in California, and that meet specific requirements, to perform scheduled, elective percutaneous transluminal coronary angioplasty and stent placement for eligible patients.

The new law, Health and Safety Code Section 1256.01, includes the following definitions:

- (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.

To participate in the pilot program, an eligible hospital shall demonstrate that it complies with the recommendations of the 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:
 - Perform at least 100 total PCI procedures per year, including at least 18 primary PCI per year.
 - Have lifetime experience of at least 500 total PCI procedures as primary operator.
 - Have complication rates and outcomes equivalent or superior to national benchmarks established by the American College of Cardiology
 - Hold board certification by the American Board of Internal Medicine in Interventional Cardiology and Cardiovascular Diseases.
 - 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 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 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, thrombectomy 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 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.
 - 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.
 - 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 3) without evidence for active ischemia, recent cardiovascular attack, advanced malignancy, 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; single target lesion that jeopardizes over 50 percent of remaining viable myocardium.

- 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 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.
 - 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.

The five-year research study began January 1, 2009. The first two years are scheduled for implementation, and the remaining three years for the operation and research involving the pilot project. Once an application process is established, CDPH will notify and invite eligible hospitals to submit an application to participate in the PCI Pilot Program. Following the selection process, an oversight committee shall be established, comprised of one interventionalist from each pilot hospital, an equal number of cardiologists from non-pilot hospitals, and a representative of the department.

The information in this AFL is a summary of SB 891 requirements regarding eligibility for participation in the Elective PCI Pilot Program. Eligible and participating facilities are responsible for following the laws applicable to participation in the program. CDPH’s failure to expressly notify facilities of legislative changes does not relieve facilities of their responsibility for following all laws and for being aware of all legislative changes.

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Facilities should refer to the full text of SB 891, or Health and Safety Code Section 1256.01, to ensure compliance.

If you have any questions, please contact the CDPH Liaison for the Elective PCI Pilot Program, Dr. Tammy Morin at tammy.morin@cdph.ca.gov.

Sincerely,

Original Signed by Kathleen Billingsley, R.N.

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