Date of Hearing: May 18, 2020

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
AB 3083 (Arambula) – As Introduced February 21, 2020

SUBJECT: Ambulatory surgical centers.

SUMMARY: Enacts the California Outpatient Cardiology Patient Safety, Cost Reduction and Quality Improvement Act, authorizing the Department of Public Health (DPH), within the Elective Percutaneous Coronary Intervention (PCI) Program, to certify an ambulatory surgical center (ASC) to provide elective cardiac catheterization laboratory services that meet certain requirements, to perform scheduled, elective percutaneous transluminal coronary angioplasty and stent placement for eligible patients. Specifically, **this bill**:

1) Authorizes DPH, within the PCI Program, to certify an ASC to provide elective cardiac catheterization laboratory services, and to perform scheduled, elective percutaneous transluminal coronary angioplasty and stent placement for eligible patients.

2) Requires DPH to certify an eligible ASC that meets all of the following requirements:

    a) Demonstrates that the ASC complies with the recommendations of the Society for Cardiovascular Angiography and Interventions (SCAI), the American College of Cardiology Foundation, and the American Heart Association for the performance of PCI without onsite cardiac surgery, as those recommendations may evolve over time;
    b) Provides evidence showing the full support from the ASC administration in fulfilling the necessary institutional requirements, including, but not limited to, appropriate support services such as respiratory care and blood banking;
    c) Participates in, and provides timely submission of data to, the American College of Cardiology National Cardiovascular Data Registry
    d) Confers rights to transfer the data submitted pursuant to c), above, to the Office of Statewide Health Planning and Development (OSHPD); and,
    e) Any additional requirements DPH deems necessary to protect patient safety or ensure quality of care.

3) Requires an eligible ASC to submit an application to DPH to obtain certification to participate in the Elective PCI Program. Requires the application to include sufficient information, as determined by DPH, to demonstrate compliance with the standards of the PCI Program, and to also 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 eligible ASC. Authorizes DPH to require that additional information be submitted with the application.

4) Specifies that failure to submit any criteria or additional information required by DPH disqualifies the applicant from the application process and from consideration for participation in the PCI Program. Authorizes DPH to deny an ASC PCI Program application pursuant to the requirements of the PCI Program, as described in 2) in Existing Law, below.

5) Requires OSHPD, using the data transferred pursuant to 2) c) above, to annually develop and make available to the public a report regarding each certified ASC's performance on mortality and stroke rates of ASCs certified to participate in the PCI Program.

6) Authorizes DPH to retain experts or establish one or more committees to analyze a report issued pursuant to 5) above, and to advise DPH on recommendations to improve the performance on mortality and stroke rates of certified ASCs.

7) Authorizes DPH to suspend or revoke the certification issued to an ASC, if, at any time, the ASC fails to meet the criteria for being a certified ASC or fails to safeguard patient safety, as determined by DPH. Specifies that an ASC whose certification is revoked may request an appeal and is not precluded from reapplying for certification.

8) Authorizes DPH to charge a certified ASC a fee for the reasonable regulatory costs to the state for issuing licenses and permits, performing investigations, inspections, and audits, and the administrative enforcement and adjudication thereof.

9) Authorizes DPH to contract with a professional entity with medical program knowledge to meet the requirements of this bill.

10) Defines the following for purposes of these provisions:

    a) "Certified ASC" means an eligible ASC that is certified by DPH pursuant to this bill.
    b) "Elective Percutaneous Coronary Intervention (elective PCI)" means scheduled percutaneous transluminal coronary angioplasty and stent placement service approved by the Medicare Program under the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).
    c) "Eligible ASC" means an ASC certified to participate in the Medicare program that does not have onsite cardiac surgery, and is in substantial compliance with all applicable state and federal laws and regulations.
    d) "Interventionist" means a licensed cardiologist who meets all of the requirements for performing an elective PCI.

11) Authorizes an ASC certified to participate in the Medicare program to perform cardiac catheterization laboratory services pursuant to this bill, only if all of the following requirements are met:

    a) The ASC maintains a current written transfer agreement, which includes all of the following:

        i) Provisions for emergency and routine transfer of patients;
        ii) Provisions that specify cardiac surgery staff and facilities shall be immediately available to the patient upon notification of an emergency; and,
        iii) Provisions that specify the cardiac catheterization staff shall have responsibility for arranging transportation to the receiving hospitals.

    b) The ASC complies with certain regulations as they existed on January 1, 2021 that specify how a PCI program must operate, including:

i) Requiring written policies and procedures to be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals;
ii) Recommended minimum of 260 cardiac catheterizations per year;
iii) Requiring supportive diagnostic services with trained personnel to be available;
iv) Require all persons operating or supervising the operation of X-ray machines to comply with Radiologic Technology Regulations; and,
v) Periodically require an appropriate committee of the medial staff to evaluate the services provided and make appropriate recommendations to the executive committee of the medical staff and administration.

c) The ASC has a system for the ongoing evaluation of its operations and the services it provides that includes a written plan for evaluating the efficiency and effectiveness of its health care services describing all of the following:

i) The scope of services provided;
ii) Measurement indictors regarding the processes and outcomes of the services provided;
iii) The assignment of responsibility when the data from the measurement indicators demonstrates the need for action;
iv) A mechanism to ensure follow-up evaluation of the effectiveness of the actions taken; and,
v) An annual evaluation of the plan.

12) Limits an ASC to only performing procedures on adults in an outpatient basis and requires the ASC to define patient characteristics that are appropriate for the safe performance of procedures in the ASC, including evaluation of these criteria in its quality assurance process.

13) Allows only the following diagnostic procedures to be performed in the ASC:

a) Right heart catherization and angiography;
b) Right and left heart catherization and angiography;
c) Left heart catherization and angiography;
d) Coronary angiography;
e) Electrophysiology studies; and,
f) Myocardial biopsy.

14) Makes findings and declarations regarding PCI, including, that SCAI stated that elective, nonemergent percutaneous coronary angioplasty and coronary stenting procedures have relatively low complication rates, are not expected to pose a significant risk to Medicare beneficiaries, and do not typically require inpatient-level care following the procedure.

15) Makes the provisions of this bill effective on January 1, 2021 and specifies that DPH is not required to adopt regulations.

EXISTING LAW:

1) Establishes the PCI Program in DPH, for the purpose of allowing DPH to certify general acute care hospitals (GACHs) that are licensed to provide urgent and emergent cardiac

catheterization laboratory service in California, that meet certain requirements, to perform scheduled, elective percutaneous transluminal coronary angioplasty and stent placement for eligible patients.

2) Requires DPH to, at a minimum, adopt standards and regulations that specify that only diagnostic services, and what diagnostic services, may be offered by a GACH or a multispecialty clinic that is approved to provide cardiac catheterization laboratory service but is not also approved to provide cardiac surgery service. Requires a cardiac catheterization laboratory service to be located in a GACH that is either licensed to perform cardiovascular procedures requiring extracorporeal coronary artery bypass that meets all of the applicable licensing requirements relating to staff, equipment, and space for service, or, at a minimum, have a licensed intensive care service and coronary care service and maintain a written agreement for the transfer of patients to a GACH that is licensed for cardiac surgery.

3) Defines the following terms:

   a) "Certified hospital" means an eligible hospital that is certified by the DPH to participate in the PCI Program.
   b) "Elective PCI" means scheduled percutaneous transluminal coronary angioplasty and stent placement. Excludes from elective urgent or emergent PCI that is scheduled on an ad hoc basis.
   c) "Eligible hospital" means a GACH that has an approved cardiac catheterization laboratory, does not have onsite cardiac surgery, and is in substantial compliance with all applicable state and federal licensing laws and regulations. Defines "GACH" as a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care, including the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services. Includes as a GACH, more than one physical plant maintained and operated on separate premises. States that a GACH that exclusively provides acute medical rehabilitation center services, including at least physical therapy, occupational therapy, and speech therapy, may provide for the required surgical and anesthesia services through a contract with another acute care hospital.
   d) "Interventionalist" means a licensed cardiologist who meets the requirements for performing elective PCI.
   e) "Outpatient setting" means any facility, clinic, unlicensed facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes.

4) Establishes the Medical Board of California (MBC), which, among other functions, adopts standards for accreditation of outpatient settings (including physician owned ASCs), and, in approving accreditation agencies to perform accreditation of outpatient settings, which at a minimum include standards for the following aspects of the settings' operations:

   a) Require outpatient setting allied health staff to be licensed or certified to the extent required by state or federal law;

b) Require outpatient settings to have a system for facility safety and emergency training requirements;
c) Require onsite equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate handling of any medical emergency that may arise in connection with services sought or provided;
d) Require for procedures to be performed, an outpatient setting to do one of the following:

   i) Have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff; or,
   ii) Permit surgery only by a licensee who has admitting privileges at a local accredited or licensed GACH, with the exception that licensees who may be precluded from having admitting privileges by their professional classification or other administrative limitations, must have a written transfer agreement with licensees who have admitting privileges at local accredited or licensed acute care hospitals.

e) Submit for approval by an accrediting agency a detailed procedural plan for handling medical emergencies that must be reviewed at the time of accreditation. Requires that no reasonable plan be disapproved by the accrediting agency.

5) Specifies that certificates of accreditation issued to outpatient settings by an accreditation agency are valid for not more than three years. Requires the MBC to ensure that accreditation agencies inspect outpatient settings no less often than once every three years, and authorizes an accreditation agency that determines an outpatient setting is not in compliance with the standards under which it was approved to do any of the following:

   a) Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the outpatient setting's accreditation;
   b) Issue a reprimand;
   c) Place the outpatient setting on probation, during which time the setting shall successfully institute and complete a plan of correction, approved by the board or the accreditation agency, to correct the deficiencies; or,
   d) Suspend or revoke the outpatient settings certification of accreditation.

6) Requires ASCs to comply with federal certification standards specified in federal regulation.

7) Establishes OSPHD as the single state agency to collect essential data from health facilities. Specifies that the data be collected, to the extent practical, on consolidated, multipurpose report forms for use by all state agencies.

FISCAL EFFECT: This bill has not yet been analyzed by a fiscal committee.

COMMENTS:

1) PURPOSE OF THIS BILL. According to the author, ASCs are becoming an increasingly important healthcare setting for many types of surgical procedures. The author states that for patients who have been screened by their physician as generally low-risk, and for procedures that are minimally invasive and do not require an overnight stay, the ASC setting represents an excellent option that delivers high quality patient care in a highly efficient environment, at

a fraction of the cost incurred in other sites of service. The author notes that, in this era of needing to increase access to care, while also bending the cost-curve of that care and based on a proven track record of safety, California should now at least catch-up to Medicare and allow ASCs to perform diagnostic and interventional therapeutic cardiology procedures. The author concludes that Medicare approved these cardiology procedures because they are not expected to pose a significant risk to patient safety when performed in an ASC.

2) BACKGROUND.

a) PCI. Coronary angioplasty, also called PCI, is a procedure used to open clogged heart arteries. PCI uses a tiny balloon catheter that is inserted in a blocked blood vessel to help widen it and improve blood flow to the heart. PCI is often combined with the placement of a small wire mesh tube called a stent. The stent helps prop the artery open, decreasing its chance of narrowing again. Most stents are coated with medication to help keep the artery open (drug-eluting stents). PCI can improve symptoms of blocked arteries, such as chest pain and shortness of breath. PCI done under emergency circumstances is referred to as "primary" PCI. Other PCI procedures, such as those done to unblock an artery before a heart attack occurs, are referred to as "elective" PCI.

b) ASCs. ASCs are facilities for surgical patients who do not need to be admitted to a hospital and remain on site for less than 24 hours. According to a 2018 California Health Care Foundation (CHCF) report, "California's Ambulatory Surgery Centers: A Black Box of Care," the number of freestanding ASCs in California has increased over the past 11 years from 626 to 791. However, a 2007 court case, "*Capen v. Shewry*" decision was interpreted to mean that ASCs with physician ownership come under the oversight of the MBC, not DPH, thereby removing any requirement for these ASCs to report data to OSHPD. This resulted in a rapid drop-off in the number of licensed ASCs reporting: only 34 in 2016. The CHCF report notes that the vast majority of freestanding ASCs in California and the United States (U.S.) are investor-owned, many by physicians. Only 3% of ASCs in California and the U.S. are nonprofit, and an additional 2% in California and 3% in the US are owned by the government.

In 46 states (including California), ASCs must be licensed under state law. Each state sets forth its own licensure requirements, but typically, they require initial and ongoing inspection and reporting. The states without licensure requirements are Idaho, West Virginia, Wisconsin and Wyoming. In 28 of the 46 states, accreditation by a third party is required as part of licensure. As noted in Existing Law, above, ASCs in California are primarily licensed and regulated by the MBC, which requires ASCs to be accredited by a national organization. The three-accreditation bodies recognized are Accreditation Association for Ambulatory Health Care, American Association for Accreditation of Ambulatory Surgery Facilities, and the Joint Commission on Accreditation of Healthcare Organizations. Twenty-five states (not California) have "certificate of need" laws that apply to ambulatory surgical centers. Under these laws, any party seeking to open an ASCs must demonstrate a need for the new service and construction. These laws are designed to control health care costs by avoiding overbuilding of facilities.

An ASC must be certified under the Medicare program to participate in Medicare. They must demonstrate compliance with state licensure law, and ongoing compliance with Medicare standards designed to ensure patient safety and the quality of services provided.

Medicare also limits the scope of surgical procedures reimbursed to elective procedures with short anesthesia and operating times. DPH is the certifying agency in California for the Medicare program. According to information supplied by the California Ambulatory Surgery Association (CASA), the sponsor of this bill, California is one of only 11 states that explicitly limit the site of service where PCI/cardiology procedures can be performed, including Maine, Massachusetts, New York, Pennsylvania, Ohio, Michigan, Mississippi, and Alabama.

c) **Recent Medicare approval for diagnostic cardiology procedures in ASCs.** The Centers for Medicare and Medicaid Services (CMS) recently approved the addition of total knee replacement, diagnostic cardiology procedures and several interventional therapeutic cardiology procedures such as angioplasties and stents to be performed in the ASC setting. In their final rule, CMS stated that they do not believe these procedures pose a significant risk when performed in an ASC. According to an Ambulatory Surgery Center Association study, "Medicare Cost Savings Tied to ASCs," the Medicare program currently reimburses ASCs at 58% of the Hospital Out Patient Department rate. The study used UC Berkeley analysis of data from 2008 to 2011, which showed that every procedure performed in an ASC saved the Medicare program 40% percent and Medicare beneficiaries 50 to 60% in their co-payments.

d) **SCAI Expert Consensus Document (SCAI recommendations).** In 2007, SCAI, the American College of Cardiology (ACC), and the American Heart Association (AHA) published an Expert Consensus Document titled "The Current Status and Future Direction of Percutaneous Coronary Intervention without On-Site Surgical Backup," which summarized the available data on the performance of PCI without on-site surgery in the US, reviewed the existing literature, examined the recommendations for the performance of PCI in this setting from several professional organizations abroad and from experienced programs in the U.S., defined the best practices for facilities engaged in PCI without onsite surgery and made recommendations for the future role of PCI without on-site surgery. This document was updated in 2012.

According to SCAI, the annual volume of PCI procedures peaked in 2006 and has since declined by over 30 percent. Numerous factors have contributed to this decline, including a reduction in restenosis (the re-occurrence of an artery closing) by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, and, a reduction in the incidence of ST-segment elevation myocardial infarction (also known as heart attacks.) As a result of these factors, many operators and hospitals now have low-volume practices.

The SCAI recommendations also note that hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically underserved populations and allow patients to be cared for in close geographic proximity to their own families and physicians. However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access. SCAI recommends, if the transfer time is 30 minutes, it is reasonable to assume that transfer to the nearest PCI center will provide treatment as rapidly as if it were available at the first hospital. For transport times longer than 30 minutes, performing PCI on-site is likely to be quicker than a transfer. The development of PCI facilities within a 30-minute emergency transfer

time to an established facility is therefore strongly discouraged. SCAI guidelines also suggest that new programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations.

According to DPH there are currently 21 hospitals certified in the Elective PCI Program to perform elective PCIs without onsite surgical backup. A list of these hospitals and their locations follows:

FACILITY NAME	City	Area/Description
Adventist Health Simi Valley	Simi Valley	Southern California/Urban
Chino Valley Medical Center	Chino	Southern California/Urban
Clovis Community Medical Center	Clovis	Central California/Urban
Corona Regional Medical Center	Corona	Southern California/Urban
Emanuel Medical Center	Turlock	Central California/Urban
Highland Hospital	Oakland	Bay Area/Urban
John F. Kennedy Memorial	Indio	Southern California/Urban
Kaiser Foundation Hospital - Orange County - Irvine	Irvine	Southern California/Urban
Kaiser Foundation Oakland/Richmond	Oakland	Bay Area/Urban
Kaiser Foundation Hospital - Roseville	Roseville	Northern California/Urban
Kaiser Foundation Hospital - South Sacramento	Sacramento	Northern California/Urban
Kaiser Foundation Hospital-San Jose	San Jose	Greater Bay Area/Urban
Kaiser Foundation Hospital - Walnut Creek	Walnut Creek	Greater Bay Area/Urban
Kaiser Foundation Hospital & Rehab Center - Vallejo	Vallejo	Northern California/Urban
Los Alamitos Medical Center	Los Alamitos	Greater Los Angeles/Urban
Mercy Medical Center	Sacramento	Northern California/Urban
Sherman Oaks Hospital	Sherman Oaks	Greater Los Angeles/Urban
St. Rose Hospital	Hayward	Bay Area/Urban
Sutter Delta Medical Center	Antioch	Bay Area/Urban
Sutter Roseville Medical Center	Roseville	Bay Area/Urban
Desert Valley Hospital	Victorville	Southern California/Rural

According to DPH there are 820 Medicare-certified ASCs and four licensed-only, for a total of 824 in the DPH database. DPH does not know how many total ASCs are in California, since many are operated under a physician's license and not in DPH's database, but rather under the purview of the Medical Board

3) **SUPPORT.** CASA is the sponsor of this bill and states that the COVID-19 crisis has shut down all elective procedures and has diverted much of their resources. CASA believes there will be immense pent up demand for their services going forward and that cardiac catheterization laboratories will have extreme difficulty in meeting this demand. CASA states that even before COVID-19, cardiology physicians and colleagues were concerned about the access to care for these lifesaving treatments. CASA concludes that this bill will provide significant savings to the California health care system.

The California Chapter of the ACC supports this bill, and states that CMS recently approved the addition of several interventional therapeutic cardiology procedures such as angioplasties and stents to be performed in ASCs. In their final rule, Medicare stated they do not believe these procedures pose a significant risk when performed in an ASC. CA-ACC notes that this

bill would allow those procedures to be done in ASCs in California as long as the ASC follows essentially the same structure as was established in current law, once again following the joint guidelines from ACC, AHA, and SCAI. CA-ACC believes this structure is appropriate for allowing ASCs to perform these cardiac procedures. CA-ACC concludes that this will further create more access to cardiac procedures which will benefit patients with reduced waiting times while not putting them at any greater risk.

4) **OPPOSITION.** The Service Employees International Union (SEIU) is opposed to this bill and states, while SEIU shares the author's interest in expanding access to healthcare, we do not believe that this bill will achieve this laudable goal, and would instead will result in less transparency into cardiac catheterization procedures. We have yet to find data that demonstrates that patients are unable to get elective cardiac catheterization promptly. Further, allowing ASCs to perform cardiac catheterization procedures puts the lives of patients at risk. Issues within ACS in California are well documented, including not having a physician on duty and not having the appropriate emergency supplies and equipment. SEIU notes that in 2019, CMS expressed concern that ASCs are not the appropriate care setting for many patients requiring cardiac catheterization. CMS acknowledged that: "[A] majority of Medicare beneficiaries may not be suitable candidates to receive these procedures in an ASC setting due to factors such as age and comorbidities." SEIU concludes that many ASCs in California are partially or wholly owned by physicians who may refer patients to their own facility, and while the physician is required to disclose this financial relationship to patients, that disclosure is not adequate to ensure the patient is given care in the appropriate setting.

5) **PREVIOUS LEGISLATION.**

   a) SB 906 (Correa), Chapter 368, Statutes of 2014**,** creates the PCI Program in DPH to certify an unlimited number of GACHs licensed to provide cardiac catheterization laboratory service in California, and that meet prescribed, additional criteria, to perform scheduled, elective PCI. SB 906 also authorizes a hospital that was participating in the Elective PCI Pilot Program as of December 31, 2014, to continue to perform elective PCI but required the hospital to obtain a certification, as specified, by January 1, 2016

   b) SB 357 (Correa), Chapter 202, Statues of 2013, extends the January 1, 2014 sunset date for the PCI Pilot Program to January 1, 2015, and requires the final report by the oversight committee to be completed by November 30, 2013, rather than at the conclusion of the pilot program.

   c) SB 891 (Correa), Chapter 295, Statues of 2008, establishes the PCI Pilot Program, until 2014, which authorizes six acute care hospitals, licensed to provide cardiac catheterization laboratory services, to perform elective PCI without onsite back-up cardiac surgery services.

6) **TECHNICAL AMENDMENTS**. Due to technical drafting errors, the Committee recommends amending this bill as follows:

   a) On page 3, on lines 28 and 33, “and interventional therapeutic” should be inserted after “diagnostic.”

b) On page 9, line 39, "2021" should read "2020."

c) On page 10, lines 4-7, the two references to "Title 2" should be "Title 22."

7) SUGGESTED AMENDMENTS.

a) As currently drafted, this bill places no limits on the number of ASCs that can be certified to perform PCI; however, the SCAI recommendations note that hospitals are more likely to introduce new invasive cardiac services when neighboring hospitals already offer such services and that the increase in the number of hospitals offering invasive cardiac services has not led to a corresponding increase in geographic access. The Committee may wish to amend this bill to prohibit DPH from certifying ASCs to perform PCI within 30 minutes of another facility providing PCI without on-site surgery.

b) As currently drafted, this bill requires DPH to certify that an eligible ASC complies with the SCAI recommendations for patient care. However, the bill also requires the ASC to define patient characteristics that are appropriate for the safe performance of procedures in the ASC. The Committee may wish to amend this bill to clarify that the ASC must follow the SCAI guidelines, which define patient characteristics for the safe performance of PCI without on-site cardiac surgery.

REGISTERED SUPPORT / OPPOSITION:

Support

California Ambulatory Surgery Association (sponsor)
Amsurg
California Chapter American College of Cardiology
California Medical Association
Campus Surgery Center
Philips Electronics North America
Premier Outpatient Surgery Center
Society for Cardiovascular Angiography and Interventions
Surgical Care Affiliates
Surgical Care Affilitates North Coast Surgery Center

Opposition

California State Council of Service Employees International Union
Sharp HealthCare

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