

**Date:** December 15, 2023

**CALIFORNIA CHILDREN'S SERVICES PROGRAM**  
CHAPTER 3.13 – Pediatric Cardiac Special Care Center Standards

All California Children's Services (CCS) Pediatric Cardiac Special Care Centers (SCC) are required to comply with the specialty and subspecialty requirements outlined in this standard, and with CCS Chapter 3.37.1 CCS SCC Core Standards.<sup>1</sup>

This Standard has five sections: A. General and Cardiac Clinic; B. Pediatric Cardiac Catheterization Laboratory; C. Interventional Electrophysiology; D. Cardiothoracic Surgery; and E. Pediatric (Cardiac) Intensive Care Unit.

**A. General and Cardiac Clinic SCC Overview**

In addition to Chapter 3.37.1/Section A requirements, the SCC must adhere to the following: <sup>2</sup>

1. Cardiac Special Care Center Overview

- a. The Cardiac SCC provides diagnostic and treatment services to infants, children, adolescents, and young adults under 21 years of age with congenital and acquired heart disease.<sup>3, 4, 5</sup> The SCC must provide family-centered, coordinated, multidisciplinary, multispecialty, equitable, and culturally and linguistically appropriate care.<sup>6</sup>
- b. The Cardiac SCC provides clinical evaluation and management for individuals with congenital or acquired cardiac conditions.<sup>7, 8, 9</sup>
- c. All cardiac SCCs must provide the following essential cardiac services:<sup>10</sup>
  - i. Transthoracic and Transesophageal Echocardiography;
  - ii. Ambulatory rhythm monitoring;
  - iii. Cardiopulmonary exercise testing;
  - iv. Cardiothoracic surgery as defined by the Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery (STAT);<sup>11, 12</sup>
  - v. Pediatric cardiac anesthesiology;

- vi. Diagnostic and interventional cardiac catheterization as per Section B of this document;
  - vii. Electrophysiology studies and interventions including but not limited to ablation and insertion or revision of pacemakers, defibrillators, and other devices;
  - viii. Nitric oxide;
  - ix. Single ventricle home monitoring program;
  - x. Extra Corporeal Membrane Oxygenation (ECMO), also known as Extra Corporeal Life Support (ECLS); and
  - xi. Dedicated cardiovascular intensive care unit (CICU) or mixed pediatric intensive care unit (PICU/CICU).
- d. Centers may provide the following services as indicated on the CCS application:<sup>13</sup>
- i. Cardiac imaging (Magnetic Resonance Imaging [MRI]/Computerized Tomography [CT]);
  - ii. Heart transplant/ventricular assist device (VAD). Note: Heart and/or combined heart-lung transplantation must only be performed in a CCS-approved Cardiac SCC that has been approved by Centers for Medicare and Medicaid Services and the Medi-Cal program for transplant of the specific organ(s) in the pediatric population;
  - iii. Neurodevelopmental follow-up program;
  - iv. Adult congenital cardiac heart disease (ACHD) program;
  - v. Pulmonary hypertension program.
- e. A Cardiac SCC with multiple cardiac services must have the capability to provide support to other Cardiac SCCs, including ongoing consultation and professional education.
- f. An identified Cardiac SCC multidisciplinary core team must consist of CCS-paneled providers described in this Section A.3.<sup>14</sup>

## 2. CCS Program Requirements

In addition to Chapter 3.37.1/Section B requirements, a Cardiac SCC must:<sup>15</sup>

- a. Offer the essential services listed above in A.1.c. and selected services listed in Section A.1.d; the selected services must be listed on the CCS Application.<sup>16, 17</sup>
- b. Have the SCC core team, including the physician, evaluate each patient in-person during the initial team visit and at least annually.
- c. Be located on a campus with all the following:
  - i. A CCS-approved tertiary hospital or in a CCS-approved community hospital that is equipped to accommodate all aspects of the medical and surgical care of the patient.<sup>18, 19, 20</sup>
  - ii. A hospital with a CCS-approved Regional or Community Neonatal Intensive Care Unit (NICU).<sup>21, 22</sup>
  - iii. A hospital with CCS-approved PICU and a CICU with personnel specifically trained in congenital heart surgery, including physicians, nurses, respiratory therapists, and ancillary staff. Such a unit may be either a separate CICU or a dedicated component within a PICU or NICU.<sup>23</sup>
  - iv. A campus with a Cardiac Catheterization Laboratory a Cardiothoracic Surgery Service and an electrophysiology laboratory which may be co-located with the cardiac catheterization laboratory.
- d. Meet these additional requirements:
  - i. Affiliation

Have an accredited Adult Congenital Heart Clinic (ACHC) that has a physician clinic director with skills and expertise in treating adults with congenital heart disease and that is listed by the Adult Congenital Heart Association (ACHA) or have a written agreement with a hospital with an accredited ACHC.<sup>24</sup>
  - ii. Volume
    - (1) General Cardiology: Perform procedure volume sufficient to maintain proficiency in the following procedures: echocardiography, ambulatory rhythm monitoring, and cardiopulmonary exercise testing.

(2) Subspecialty cardiac procedures: Meet volume requirements as described in Section B.2.d. and B.3.a.iv., Section C.2.g., and Section D.2.d.

(3) The Department of Health Care Services (DHCS), Integrated Systems of Care Division (ISCD) may conduct a review of centers with procedure volume below the specialty-specific minimum.

iii. Echocardiography

Have pediatric echocardiography accredited by the Intersocietal Accreditation Commission (IAC) prior to their initial or subsequent program review, covering pediatric Transthoracic Echoes (TTE) and Trans Esophageal Echoes (TEE).<sup>25</sup>

iv. Subspecialty

(1) Meet all pediatric catheterization requirements described in Section B of this document.

(2) Meet all pediatric cardiac electrophysiology (EP) requirements described in Section C of this document.

(3) Meet all requirements for cardiothoracic surgery described in Section D of this document.

(4) Meet all requirements for pediatric cardiac intensive care described in Section E of this document.

v. Reporting Requirements

Submit annually to ISCD:

(1) The number of patients/operations completed and an analysis of discharge mortality and complexity information, by year (See Section A.6 of this document).

(2) All outcome data corresponding to services provided at the Cardiac SCC in the past 12 months, as described in the subspecialty-specific Sections B, C, D, and E of this document.

vi. Have a CCS-approved heart transplant center or an agreement with a CCS-approved heart transplant center.

- vii. Conduct systems-based quality improvement meetings focused on program structure and processes no less than every three months.

### 3. Cardiac SCC Core Team Members and Specialty Consultants

In addition to Chapter 3.37.1/Section C requirements, the Cardiac SCC team must comply with the following:<sup>26</sup>

- a. The Cardiac SCC multidisciplinary core team must consist of at least the following CCS-paneled providers:
  - i. Medical director who is a pediatric cardiologist and must:<sup>27, 28, 29, 30</sup>
    - (1) Be board-certified in pediatric cardiology;
    - (2) Be responsible for the overall care provided by the Cardiac SCC including:
      - (a) Coordination of inpatient and outpatient cardiac care;
      - (b) Participation in multidisciplinary meetings with at least the cardiologist, cardiac interventionist, intensivist, cardiothoracic surgeon, anesthesiologist, and radiologist available for consult;
      - (c) Ensuring 24-hour availability of a CCS-paneled cardiologist, including back-up coverage for patient transfer to a CCS-approved Regional Cardiac SCC;<sup>31, 32, 33</sup>
      - (d) Maintenance of the Cardiac SCC database and/or vital statistics;
      - (e) Ensuring that all cardiologists performing cardiac catheterization and EP studies are board-certified in cardiology, with advanced fellowship training in the subspecialty;
      - (f) Ensuring that all staff maintain competency in resuscitation techniques;
      - (g) Ensuring that all staff performing procedures at the Cardiac SCC are on staff at the facility; and
      - (h) Not be a medical director of more than one Cardiac SCC;
  - ii. Cardiothoracic surgeon who meets criteria in this document Section D.3.a. who must participate when cases may require surgery;<sup>34, 35, 36, 37</sup>

- iii. Pediatric electrophysiologist who is board-certified in cardiology and must meet or exceed the requirements outlined by one or both tracks outlined in this document Section C.3.b below;<sup>38, 39, 40</sup>
- iv. SCC Coordinator as described in Chapter 3.37.1/Section C.8.c.<sup>41</sup>
- v. Registered nurse as described in Chapter 3.37.1/Section C.8.d;<sup>42, 43, 44</sup>
- vi. Medical social worker as described in Chapter 3.37.1/Section C.8.e;<sup>45, 46</sup>
- vii. Registered dietitian as described Chapter 3.37.1/Section C.8.f;<sup>47, 48, 49</sup>
- viii. Physical therapist and/or occupational therapist, when appropriate;<sup>50, 51</sup> and
- ix. Speech-language pathologist, when appropriate.<sup>52</sup>

b. Required Staff in Diagnostic Laboratories

- i. The echocardiography laboratory must have, at a minimum, the staff needed to obtain IAC pediatric echocardiography certification.<sup>53</sup>
- ii. The ambulatory rhythm monitoring laboratory must have a Cardiac CCS-paneled pediatric cardiologist who must interpret the final report.
- iii. The cardiopulmonary exercise laboratory must have at a minimum:
  - (1) A CCS-paneled board-certified pediatric cardiologist;
  - (2) Basic Life Support (BLS) certified personnel; and
  - (3) Pediatric Advanced Life Support (PALS) trained personnel in the lab at all times during testing.
- iv. The Cardiac Catheterization Laboratory must have staff as described in Section B.3 of this document.
- viii. The Cardiac Interventional EP Laboratory must have staff as described in Section C.3 of this document.

4. SCC Facilities and Equipment

In addition to Chapter 3.37.1/Section D requirements, the Cardiac SCC must adhere to the following:<sup>54, 55</sup>

a. Echocardiology Laboratory

Each Cardiac SCC must meet the criteria for IAC pediatric and transesophageal echocardiography certification.<sup>56</sup>

b. Cardiopulmonary Exercise Laboratory<sup>57</sup>

- i. Each Cardiac SCC must have access to a metabolic exercise laboratory in which oxygen utilization, the anaerobic threshold, and pulmonary function can be determined as an adjunct to detecting early failing cardiopulmonary function.

- ii. Each Cardiac SCC must have the following equipment and documentation:<sup>58</sup>

- (1) Gurney and/or examination table;
- (2) Age- and size-appropriate treadmill and/or cycle ergometer;
- (3) Age- and size-appropriate blood pressure cuffs;
- (4) Age- and size-appropriate facemask and mouthpieces;
- (5) Age- and size-appropriate oxygen saturation monitors;
- (6) Age- and size-appropriate ECG recording equipment;
- (7) Pediatric and adult emergency resuscitation carts that include emergency drugs including those to treat exercise induced asthma, such as bronchodilators and epinephrine, defibrillator, supplemental oxygen, and a portable suction unit;
- (8) A log demonstrating periodic testing of the defibrillator and oxygen supply, and periodic inspection of emergency drug expiration dates; and
- (9) An exercise lab that includes a remote “code” button and telephone.

c. Cardiac Catheterization Laboratory

For equipment and facility requirements for the Cardiovascular Catheterization Laboratory, refer to Section B.4 of this document.

d. The Cardiac Interventional EP Laboratory

For equipment and facility requirements for the Cardiac Interventional EP Laboratory, refer to Section C.4 of this document.

e. Cardiothoracic Surgery

For equipment and facility requirements for the Cardiothoracic Surgery, refer to Section D.4 of this document.

5. SCC Patient Care Policies and Procedures

In addition to Chapter 3.37.1/Section E requirements, the SCC must have patient care policies and procedures addressing the following: <sup>59, 60, 61, 62, 63</sup>

- a. The Cardiac SCC must establish and adhere to policies and procedures in the areas of patient intake, ongoing treatment, follow-up, multidisciplinary team assessments, and transition to adulthood, including the cardiac transition policy described in the 2022 American Heart Association scientific statement, and as described in the Chapter 3.37.1 SCC Core Standards. <sup>64, 65</sup>
- b. The Cardiac SCC must establish and adhere to policies and procedures related to consent and privacy protection, in accordance with the CCS Standards for tertiary hospitals.

6. Quality Assurance (QA) and Quality Improvement (QI)

In addition to Chapter 3.37.1/Section F requirements, the SCC must perform the following: <sup>66, 67</sup>

- a. The Cardiac SCC must adhere to general cardiac quality measures, including admission type, length of stay, and follow up.
- b. Annually, the Cardiac SCC must provide to DHCS summary reports that were submitted to national cardiac quality registries within the previous year, including Society for Thoracic Surgeons (STS), Improving Pediatric and Adult Congenital Treatment (IMPACT), Virtual Pediatric Systems (VPS), or Pediatric Cardiac Critical Care Consortium (PC<sup>4</sup>) as specified in Sections B, C, D and E of this document. <sup>68, 69, 70, 71</sup>
- c. The Cardiac SCC must have regular cardiac morbidity and mortality conferences (M&M) and systems-based QI meetings at least quarterly where complications, adverse events, and incorrect or partial diagnoses are discussed and quality improvement actions, such as root cause analyses and/or process improvement are performed and must maintain records of these meetings.



## **B. Pediatric Cardiac Catheterization Laboratory**

### **1. Pediatric Cardiac Catheterization Laboratory Overview**

- a. CCS requirements for the Pediatric Cardiac Catheterization Laboratory (PCCL) must be the same for all Cardiac SCCs.
- b. The PCCL must follow the recommendations of the American College of Cardiology/Society for Cardiac Angiography and Interventions (ACC/SCAI) Expert Consensus Document, including having an active systems-based process-oriented QI program.<sup>72, 73</sup>
- c. Participation in at least one national or international registry/QI program related to pediatric and/or adult congenital cardiac catheterization is desirable.

### **2. CCS Program Requirements**

- a. A facility performing pediatric cardiovascular catheterization procedures must provide the appropriately credentialed staff, equipment, and policies and procedures as described in this document.
- b. All personnel using equipment associated with cardiovascular catheterization must be able to demonstrate familiarity and proficiency with the setup, operation, and characteristics of the equipment employed at their site.
- c. A facility performing pediatric cardiovascular catheterization procedures that routinely require the performance of trans-esophageal echocardiography, must do so in an IAC echocardiography-accredited facility.<sup>74</sup>
- d. Pediatric Cardiac Catheterization Laboratory Volume Requirements
  - i. Annually, a minimum of 150 pediatric cardiac catheterizations must be performed at the PCCL.
  - ii. PCCLs used for pediatrics and adults must have total 150 cases with at least 100 pediatric cases.
  - iii. Documentation for each case must include:
    - (1) Facility name;
    - (2) Date of service;
    - (3) Patient age;

- (4) Diagnosis;
- (5) Indication for catheterization;
- (6) Procedure performed (diagnostic or interventional);
- (7) The immediate outcome of the catheterization; and
- (8) Complications.

e. Practitioner Requirements<sup>75, 76, 77</sup>

- i. The pediatric interventional cardiologist must be a pediatric cardiology board-certified physician, whose primary clinical practice is dedicated to pediatric catheterizations.
- ii. The minimum annual number of pediatric cardiac catheterizations performed by each pediatric interventional cardiologist, in primary, or assistant role, in a facility requesting to participate as a CCS PCCL is 50 per year. At least half of these must be interventional catheterizations.
- iii. For electrophysiology practitioner requirements, refer to this document, Secton.C.2.g.

Note that ISCD must conduct a facility review of cardiac SCCs with procedure volume below the specialty-specific minimum.

f. Records and Storage Requirements

- i. PCCLs must have a catheterization reporting system suitable for reporting congenital cardiac defects.
- ii. PCCLs must have permanent record of angiograms and hemodynamic data including, at a minimum, video, disk, chart, or digital/electronic recordings.
- iii. Cardiac catheterization reports must be completed and signed by the primary interventional cardiologist.
- iv. Medical records must be retained for a period of no less than seven years in a secure locked area.

g. The PCCL must have a technical manager, technician, or registered nurse (RN) who is a Registered Cardiovascular Invasive Specialist (RCIS), or a Registered Radiologic Technologist (RT) certified by The American Registry

of Radiologic Technologists with a credential in cardiovascular interventional radiography and/or cardiac interventional radiography. <sup>78, 79, 80, 81, 82</sup>

### 3. PCCL Core Team Members and Specialty Consultants

#### a. Medical Director of the PCCL: <sup>83, 84, 85, 86</sup>

- i. The medical director must be a pediatric interventional cardiology specialist who is board-certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics, and who has completed advanced fellowship training (4<sup>th</sup> year) in pediatric interventional cardiology or who meets the practice requirements described in Track 2 below. <sup>87</sup>
- ii. The medical director must have a primary clinical practice dedicated to pediatric diagnostic/interventional catheterization activities in the Cardiac Catheterization Laboratory.
- iii. The medical director must have responsibility for oversight of medical practice in the laboratory, including data collection and quality improvement and must participate in multidisciplinary team meetings related to laboratory matters.
- iv. The medical director must meet requirements of either Track 1 or Track 2 as follows:
  - (1) Track 1: Pediatric interventional cardiologist with training completed after July 1, 2005 must have:
    - (a) Successful completion of a pediatric cardiology fellowship program and board certification in Pediatric Cardiology by the American Board of Pediatrics; <sup>88</sup>
    - (b) Successful completion of a 12-month advanced fellowship in interventional pediatric cardiology; and
    - (c) At least five years of active pediatric interventional cardiology experience, in which the cardiologist's primary clinical interest is pediatric catheterization. The cardiologist must be actively involved in the management and care of pediatric patients treated using catheterization and meet the practitioner requirements specified in Section B.2.e. of this document.
  - (2) Track 2: Pediatric interventional cardiologist with training completed before July 1, 2005:

- (a) May qualify by meeting the requirements in Track 1, or by being board-certified in pediatric cardiology and meeting a minimum level of practice experience consisting of at least 5 years of active catheterization and interventional experience in which the applicant's primary clinical interest is pediatric cardiac catheterizations (diagnostic and interventional).
  - (b) The applicant is generally expected to have a lifetime case volume of at least 250 cases, of which 150 are interventional procedures with 25 of the interventional procedures in neonates (<30 days of age).
- b. In addition to the interventional cardiologist described above, the Cardiac SCC staff must include a pediatric and/or neonatal intensivist (depending on the age of the patient), pediatric anesthesiologist, and a pediatric/congenital heart surgeon, who have board certification or equivalent and advanced training in the cardiovascular aspects of their specialty. Each specialist must be immediately available within the facility or in close proximity (within 30 minutes of the center) for consultation, assistance, emergency, and elective surgical procedures, and peri-operative care.<sup>89, 90, 91, 92</sup>
- c. The PCCL nurse must meet all the following requirements:
  - i. Be a registered nurse, nurse practitioner, or clinical specialist;<sup>93, 94, 95</sup>
  - ii. Have successfully completed an education program or a standardized assessment designed to evaluate their clinical competency and experience in pediatrics and cardiac care;
  - iii. Have training in cardiovascular diagnostic and interventional techniques; pre-catheterization evaluation and instruction; and post-catheterization and discharge teaching;
  - iv. Have current American Heart Association (AHA) PALS certification;<sup>96</sup>
  - v. Have completed at least 15 hours of accredited continuing education relevant to acquired or congenital heart disease in the past 3 years that includes content related to performance of cardiovascular catheterization procedures, acquired and/or congenital heart disease, coronary artery disease, cardiovascular assessment, with at least 1 hour on radiation safety; and
  - vi. At least six months post-training experience in a Cardiac Catheterization Laboratory.

- d. A board-certified physician assistant (PA-C) with pediatric experience and certification in cardiac catheterization procedures may take the place of the PCCL nurse if the PA-C possesses all the requirements required by the licensed RN or advanced practice nurse as outlined above in Section B.3.c.<sup>97</sup>
- e. There must be a social worker or another professional capable of performing medical social worker functions who may be the same person as the Cardiac Social Worker as described in Section A.3.a.v.<sup>98, 99</sup>
- f. The PCCL team must have a Radiologic Technologist(s) who:<sup>100</sup>
  - i. Has training in cardiovascular techniques and in the care of pediatric patients;
  - ii. Must function under the direction of a cardiologist with a fluoroscopy supervisor or operator permit issued by DHCS Licensing and Certification Division;<sup>101</sup>
  - iii. Is RCIS credentialed by the Cardiovascular Credentialing International<sup>102</sup> and licensed by the State of California under relevant clinical laboratory law, when applicable; and
  - iv. Has documentation of successful completion and maintenance of the AHA-approved Basic Cardiac Life Support program (BCLS).<sup>103</sup>
- g. A board-certified pediatric anesthesiologist (cardiac trained) must be available to assist in providing sedation or anesthesia, as needed.<sup>104, 105, 106</sup>
- h. All personnel utilizing fluoroscopy must have a fluoroscopy license issued by the California Department of Public Health (CDPH)<sup>107</sup>.

#### 4. Pediatric Cardiac Catheterization Laboratory Facilities and Equipment

- a. The PCCL must have a dedicated cardiac catheterization suite with all the following:<sup>108</sup>
  - i. Cineangiography system capable of cine frame rates from 7.5-25 frames per second;
  - ii. Positive airflow, high-flow O<sub>2</sub>, sub-sterile scrub area, post-procedure care area, surgical lighting, backup power, pediatric basic supplies, catheters, and resuscitation equipment;
  - iii. Biplane, flat panel fluoroscopic, and digital imaging equipment;

- iv. Adequate hemodynamic monitoring and recording equipment;
  - v. Leaded wall/viewing window, if contiguous with procedure room;
  - vi. A sub-sterile scrub area, post-procedure care area, surgical lighting, back-up power, pediatric basic supplies, catheters, and resuscitation equipment;
  - vii. Radiation shielded barriers that meet both state and federal requirements
  - viii. A full complement of interventional devices (including retrieval and bail-out devices), and resuscitative equipment;
  - ix. A control room with duplex intercom system, desk space for fluoroscopy monitors and recording system, and storage space; and
  - x. All standard interventional supplies, including appropriate sheaths, wires, catheters, angioplasty balloons, occlusion devices, stents, transcatheter valves, etc., as well as pericardiocentesis and Pleuronectes's trays and other bailout and retrieval supplies.
- b. The PCCL equipment must have the following capabilities:<sup>109</sup>
- i. Variable pulsed fluoroscopy;
  - ii. Variable exposure time range;
  - iii. Dose measurement capability;
  - iv. Removal of anti-scatter grids with small patients;
  - v. Multiple focal spot sizes;
  - vi. Radiation dose warning system; and
  - vii. Fluoroscopy equipment that allows for digital acquisition or saved fluoroscopy.
- c. The PCCL must have the following electrical safety and radiation protection:<sup>110</sup>
- i. The use of radiation must be consistent with As Low As Reasonably Achievable (ALARA) principles;<sup>111</sup> and

- ii. Electrical safety and radiation protection must be followed in accordance with the manufacturer's recommendations and applicable state and federal regulations.
- d. Each PCCL must have a dedicated trained cardiovascular recorder, who has no other responsibilities during procedures.
- e. Each PCCL must have immediate access to personnel trained in equipment repair and maintenance.

#### 5. Pediatric Cardiac Catheterization Laboratory Patient Care Policies and Procedures

- a. The PCCL must establish and adhere to policies and procedures in the areas of patient intake, ongoing treatment, follow-up, multidisciplinary team assessments, informed consent and privacy protection, and transition to adulthood, as described in Chapter 3.37.1 Core Standards, Section E.<sup>112</sup>
- b. The PCCL must establish and adhere to policies and procedures for transfer of care and hand-over communications from the pre-catheterization area to the catheterization lab, to the recovery room or intensive care unit (ICU), and to the wards.
- c. The PCCL must document and make available for review all regular pre-catheterization and post-catheterization discussions for all patients going to the catheterization lab for diagnostic, interventional, and EP procedures.

#### 6. Pediatric Cardiac Catheterization Laboratory Quality Assurance and Quality Improvement<sup>113</sup>

- a. The PCCL must submit to DHCS annually a report generated from within the previous 12 months with data that was submitted to IMPACT or Congenital Cardiac Catheterization Outcomes Project Quality Improvement (C3PO-QI) for cardiac catheterization.<sup>114</sup>
- b. For centers not submitting to IMPACT or C3PO-QI, the PCCL must submit to the ISCD comparable summary data, specifically the number of catheterization procedures performed, the outcome of those procedures, the complications or re-interventions within 30 days, and deaths attributable to the catheterization.
- c. The PCCL must be responsible for maintaining diagnostic quality and accuracy of catheterization and procedural outcomes, including selecting and examining specific indicators and addressing quality issues when warranted.

### **C. Pediatric Interventional Electrophysiology**

#### **1. Pediatric Interventional Electrophysiology General Criteria**

- a. The Pediatric Interventional EP Laboratory must have:
  - i. An electrophysiology recording system;
  - ii. An electrophysiology cardiac stimulator;
  - iii. A three-dimensional (3D) mapping system; and
  - iv. Cryoablation and radiofrequency ablation delivery systems.
- b. The Pediatric and Congenital Arrhythmia Service must have the ability to provide follow-up for the following Cardiovascular Implantable Electronic Devices (CIEDs) including:
  - i. Pacemaker;
  - ii. Implantable Cardioverter Defibrillator (ICD);
  - iii. Cardiac Resynchronization Therapy (CRT); and
  - iv. Implantable Loop Recorder (ILR).

#### **2. CCS Program Requirements**

##### **a. Laboratory Component**

The Pediatric Interventional EP Laboratory must be co-located within a facility completely equipped to accommodate all aspects of the medical and surgical care of the pediatric patient, including quick access to a PICU (general PICU or pediatric CICU) and NICU.

##### **b. Device Management**

Pacemaker, ICD, CRT, and ILR device follow-up must be performed by combining both in-clinic and remote monitoring. Criteria for intervals for device follow-up must recognize that the complexity of the underlying heart disease dictates the intervals for such surveillance.

- c. Centers must adhere to the following face-to-face and remote device monitoring criteria for antibradycardia devices (pacemakers), ICD, and CRT devices as follows:



- i. At a minimum, the patient must be seen in a pediatric and congenital device clinic within one month of a device implant procedure and again three months later.
  - ii. For generator change procedures (no lead manipulation), the patient must be seen in a pediatric and congenital device clinic within six months of the procedure.
  - iii. Following this initial follow-up schedule, the patient must be seen at least annually in person in a pediatric and congenital device clinic for pacemakers, and at least every six months in person for ICD and CRT devices as long as clinic visits are supplemented by remote monitoring, no less frequently than every three months, and more frequently as may be clinically indicated.
  - iv. The complexity of the issues managed or device-related issues may require a more intensive and frequent monitoring schedule.
  - v. Evaluation of a post-operative surgical site may be performed by a provider in the patient's local community or by video visit at the implanting center, when appropriate.
- d. Permanent record of real time studies performed in the Pediatric Interventional EP Laboratory must include digital/electronic recordings.
- e. Interpretation and final approval of Pediatric Interventional EP study reports must be performed by a physician who is board-certified in pediatric cardiology and meets the standards for a CCS pediatric electrophysiologist, as defined in Section C.3 below.
- f. Medical records must be retained for a period of at least seven years in a secure area, on a secure server, or in the electronic medical record.
- g. Facility and Practitioner Volume
- i. Facility volume standards:
    - (1) DHCS must evaluate Pediatric Interventional EP Laboratories for two separate areas of expertise within a pediatric EP program:
      - (a) EP studies with and without ablations; and
      - (b) CIED procedures.

(2) Initial EP volume:

- (a) To warrant initial inspection, the Pediatric Interventional EP Laboratory is required within the previous year to have completed a minimum of 12 pediatric and congenital EP studies, of which at least 10 included ablation; and
- (b) A minimum of 10 pediatric and congenital CIED procedures.

(3) Continuing EP volume: After initial approval, the minimum number of procedures per Pediatric Interventional EP Laboratory per year are:

- (a) 30 pediatric and congenital EP studies on patients under 21 years of age; and
- (b) 18 of the 30 EP studies must have included ablation;

vi. Practitioner volume standards:

- (1) Pediatric electrophysiologists must be evaluated independently for two separate areas of expertise in a Pediatric Interventional EP Laboratory: EP studies with ablation and CIED procedures.
- (2) Each center must have at least one pediatric electrophysiologist credentialed to perform EP studies/ablations and at least one pediatric electrophysiologist credentialed to perform CIED procedures. This pediatric electrophysiologist may be the same person.
- (3) The minimum number of pediatric EP studies performed by each electrophysiologist in a primary or assistant role is 30 patients under 21 years of age per year, of which at least 18 must include ablation. Other pediatric electrophysiologists at the center who perform less than this number must be assisted by an electrophysiologist who meets this requirement.
- (4) The minimum number of pediatric and congenital CIED procedures performed by each electrophysiologist in a primary or assistant role is 10 per year. Other pediatric electrophysiologists at the center who perform less than this number must be assisted by an electrophysiologist who meets this requirement.

ISCD may conduct a facility review of cardiac SCCs with procedure volume below the specialty-specific minimum.

### 3. Electrophysiology Core Team Members and Specialty Consultants

- a. Physician-in-charge: The physician in charge of the Pediatric Interventional EP Laboratory must be board-certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics and be a pediatric cardiac electrophysiologist with a primary clinical practice dedicated to pediatric EP activities and has passed the International Board of Heart Rhythm Examiners (IBHRE) certification, specifically the Certified Electrophysiology Specialist Pediatric (CEPS-P) examination.<sup>115, 116, 117, 118, 119, 120</sup>
- b. All pediatric electrophysiologists must meet or exceed the requirements outlined by one or both tracks outlined below:<sup>121, 122, 123, 124</sup>
  - i. Track 1: Pediatric Electrophysiology Training completed after July 1, 2005, must have:
    - (1) Successful completion of a pediatric cardiology fellowship program and board-certified in Pediatric Cardiology by the American Board of Pediatrics;
    - (2) Successful completion of a minimum of one additional year of pediatric EP training in a pediatric EP fellowship program. The training program must be a primarily pediatric focused center with over 50% of cases in patients <21 years of age) with a pediatric electrophysiologist as program director and should meet the recommended criteria set forth by the task force in pediatric cardiology training; and<sup>125</sup>
    - (3) Performance of follow-up evaluations on a continuing basis of at least 30 CIED patients under 21 years of age. The pediatric electrophysiologist performing follow-up evaluations is not required to have performed all CIED procedures for these patients.
  - ii. Track 2: Pediatric Electrophysiology training completed before July 1, 2005:
    - (1) May qualify either by satisfying the Track 1 requirements above, or by demonstrating a minimum level of practice experience consisting of at least five years of active pediatric EP experience in which the applicant's primary clinical practice is pediatric EP.
    - (2) The candidate must be actively involved in the management and care of pediatric and congenital arrhythmia patients and must have practiced pediatric EP as the primary clinical practice for at least five of the last ten years; and

- (a) In that five-year span, performance of a minimum of 150 EP studies of which at least 90 included ablations; and<sup>126</sup>
  - (b) Performance of at least ten CIED procedures per year for five years.
- c. Consulting physicians: In the Pediatric Interventional EP Laboratory, an anesthesiologist and a cardiothoracic surgeon, each with advanced training in the cardiovascular aspects of their specialty, must be immediately available within the facility, or in close proximity (within 30 minutes of the center), for consultation, assistance, emergency, and elective surgical procedures, and peri-operative care.<sup>127, 128, 129, 130</sup>
- d. Registered nurse<sup>131, 132</sup>
  - i. Each laboratory must have a RN with special training in cardiovascular techniques and in the care of children, as described in Section B.3.c. in this document (Pediatric Cardiac Catheterization Laboratory).
  - ii. The RN must have training and experience in pre and post-cardiac interventional laboratory evaluation and management but also needs to have a practice focus in electrophysiology-specific patients. In addition, this nurse must have skills in and ability to coordinate patient and family education and instructions pre and post-procedure.
- e. If there is a cardiovascular technician, the technician must have pediatric cardiac training and experience.<sup>133</sup>

#### 4. Electrophysiology Facilities and Equipment<sup>134</sup>

- a. Radiological, electronic, and computer-based systems are integral components of the equipment for the Pediatric Interventional EP Laboratory. These systems all require a program of rigorous maintenance and troubleshooting.
- b. A Pediatric Interventional EP Laboratory must also have the following:
  - i. A multi-channel EP recording system;
  - ii. EP study data submitted annually as described in Section C.6.a.
  - iii. An EP cardiac stimulator;
  - iv. Fluoroscopy equipment with appropriate radiation shielded barriers;
  - v. A cardiopulmonary monitoring system;

- vi. A radiofrequency energy source;
  - vii. A cryoablation energy source; and
  - viii. On-site availability of a pediatric intensive care unit (general PICU or pediatric CICU) and neonatal ICU and cardiac surgical services.
- c. Electrical safety and radiation protection must be utilized in accordance with the manufacturer's recommendations and applicable state and federal statutes and regulations.

#### 5. Electrophysiology Patient Care Policies and Procedures

All pre-procedure and post-procedure documentation for all patients treated in the Pediatric Interventional EP Laboratory (including admission history and physical, consent, and discharge instructions) must be available for review by ISCD Facility Review Team.

#### 6. Electrophysiology Quality Assurance and Quality Improvement<sup>135</sup>

- a. EP centers must submit to DHCS an annual report generated from IMPACT or an equivalent annual summary of the SCC's Pediatric Interventional EP Laboratory procedures, outcomes, and complications. Until cardiovascular implantable electronic devices (CIED) are reported in IMPACT (version 3.0), centers will need to submit CIED data manually.<sup>136</sup>
- b. EP centers must conduct QI conferences at least quarterly to review adverse events and significant complications with an adjudication process and must maintain documentation of these meetings. These QI conferences can be a part of broader catheterization laboratory conference at the institution.
- c. QI meetings must also address areas identified for system process improvement with notes or minutes available for review.

### **D. Cardiothoracic Surgery Standards**

#### 1. Cardiothoracic Surgery General Criteria

The CCS-approved cardiothoracic surgery component of the Cardiac SCC must:

- a. Be located in the same complex as the cardiac catheterization lab and cardiology clinic;

- b. Have access to general pediatric coverage with subspecialty capability 24-hours a day, 7 days a week;<sup>137, 138, 139</sup>
- c. Be part of a system (with documentation) of rapid referral and transportation;
- d. Have an identified core team with at least two board-certified Congenital Heart Surgeons (CHS) or equivalent. If only one heart surgeon is CHS certified, then the second surgeon must be board-certified in cardiothoracic surgery or related specialty;
- e. Have a team skilled in performing intra-operative TEE's continuously available to aid in the pre-, intra-, and post-surgical assessment of operative procedures;
- f. Extra-corporeal life support (ECLS);
- g. Have a rapid response team to provide ECLS; and
- h. Participate in a Cardiac SCC Quality Initiative that includes, at a minimum, the following CCS-paneled, board-certified (or equivalent) participants: pediatric cardiologist, congenital heart surgeon, pediatric interventionist, pediatric anesthesiologist, and pediatric intensivist.

## 2. CCS Program Requirements

- a. The cardiothoracic surgery component of the Cardiac SCC must collaborate in preoperative care, including review of relevant studies and clearance by other pertinent subspecialists.
- b. The cardiothoracic surgery component of the Cardiac SCC must provide post-operative care that is managed jointly with the post-operative cardiovascular team composed of pediatric intensivists, cardiologists, neonatologists, anesthesiologists, and other personnel, as needed.
- c. The involved pediatric cardiothoracic surgeon may transfer primary responsibilities to another member of the team, such as emergency cardiac re-operation, re-exploration, delayed sternal closure, and non-cardiac re-operation (such as diaphragm plication).
- d. Volume requirements:
  - i. The cardiothoracic surgery component of the Cardiac SCC must perform a minimum of 75 heart surgery cases requiring cardiopulmonary bypass per year on patients under 21 years of age.

- ii. Practitioner must perform at least 50 cases or reoperations per year on patients under 21 years of age with up to twenty-five (25) specified STAT Category 4 and 5 cases in which the applicant has materially participated in the critical portion of the case with another congenital cardiac surgeon.
- iii. ISCD must conduct a facility review of cardiac SCCs with procedure volume below the specialty-specific minimum.
- e. Other reporting or general requirements for cardiothoracic surgery are listed in Section A.2.c.(5) of this document.

### 3. Cardiothoracic Surgery Core Team Members and Specialty Consultants

The cardiothoracic surgery component of the Cardiac SCC must have, at a minimum, the following staff:

- a. A surgical director who is a CCS-paneled pediatric cardiothoracic surgeon and is board-certified in Congenital Heart Surgery by the American Board of Thoracic Surgery (ABTS),<sup>140</sup> or its equivalent;<sup>141, 142, 143, 144</sup>
- b. Additional CCS-paneled surgeons, e.g., the associate surgeons and/or assistant surgeons, who are board-certified, board eligible, or the equivalent in the specialty;<sup>145, 146, 147, 148</sup>
- c. Pediatric subspecialists with expertise including (but not limited to) hematology, nephrology, neurology, infectious disease, critical care, pulmonology, gastroenterology, genetics, and pathology must be available for consultation and management of patients with heart disease;<sup>149, 150, 151</sup>
- d. An imager including a technical manager, technician, or registered nurse (RN) who has RCIS certification in cardiac CT and MRI for congenital conditions, and trained in pediatric cardiopulmonary disease;<sup>152, 153</sup>
- e. A CCS-paneled, board-certified (or equivalent) pediatric anesthesiologist with training and experience in open and closed heart surgery pediatric anesthesia;<sup>154, 155, 156</sup>
- f. A respiratory care practitioner with training and experience in short- and long-term ventilatory support in infants and children;<sup>157</sup>
- g. Technologists available 24-hours a day for laboratory and radiology procedures;<sup>158, 159</sup>

- h. A perfusionist certified by the American Board of Cardiovascular Perfusion in the area of cardiovascular perfusion with advanced training in pediatric cardiovascular perfusion;<sup>160</sup>
- i. CCS-paneled RNs trained in preoperative evaluation and instruction of the patient and family, intensive care, and convalescent care;<sup>161, 162</sup>
- j. A CCS-paneled medical social worker;<sup>163</sup>
- k. Personnel with specific training on cardiovascular surgical procedures in children; and
- l. Specialty trained pediatric anesthesia providers with experience caring for patients with congenital heart disease.

#### 4. Cardiothoracic Surgery Facilities and Equipment

Cardiothoracic surgery facilities must have all the following:<sup>164</sup>

- a. A dedicated operating room for cardiac surgery;
- b. Availability of nitric oxide;
- c. An ECMO program; and
- d. A heart-lung machine and backup heart-lung machine.

#### 5. Cardiothoracic Surgery Patient Care Policies and Procedures

- a. Involved staff must maintain on-going communication throughout the patient's hospital course with the patient's primary cardiologist.
- b. Involved staff must provide, at a minimum, the following pre-operative care:
  - i. Dedicated pediatric patient rooms with provision for a parent, relative, or guardian to remain overnight with a hospitalized child;
  - ii. Clear instructions to parents and patient with pre-operative visits to catheterization laboratory, intensive care unit, and other sites as needed, consistent with their ability to comprehend;
  - iii. Care management conferences the CCS approved PICU with between the pediatric cardiologist, pediatric cardiovascular surgeon, and other professional staff as necessary, which must be documented in the patient record; and



- iv. All post-operative care must be managed jointly with, and in support of, the post-operative cardiovascular team composed of pediatric intensivists, cardiologists, neonatologists, anesthesiologists, and other personnel, as needed.

## 6. Cardiothoracic Surgery Quality Assurance and Quality Improvement

In addition to adhering to the QA and QI requirements in Chapter 3.37.1/Section F, Cardiothoracic Surgery must: <sup>165, 166</sup>

- a. Participate in the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database Report for cardiac surgery; <sup>167</sup> and
- b. Submit annually to DHCS all outcome data corresponding to services provided at the SCC that were submitted to the STS Congenital Heart Surgery Database Report including: <sup>168</sup>
  - i. Number of patients/operations performed; and
  - ii. An analysis of discharge mortality, and complexity information, by year.

Note: The required reporting information is contained in STS Forms 1 and 16.

- c. Maintain annual follow-up data on surgical patients as submitted to STS.

## E. Pediatric (Cardiac) Intensive Care Unit Standards

### 1. Pediatric (Cardiac) Intensive Care Unit Overview

The CCS approved PICU or NICU with a dedicated CICU component of the Cardiac SCC must:

- a. Be located in the same complex as the other units of the Cardiac SCC; and
- b. Have access to the surgical operating rooms and a transport team capable of rapid deployment, including intensivist, respiratory therapist, nurses, registered dietician, and medical social worker.

### 2. CCS Program Requirements

The PICU or NICU with dedicated CICU component of the Cardiac SCC must:

- a. Meet the CCS PICU or NICU standards;

- b. Meet minimum cardiac surgical volumes set out in Section D.2.d of this document;
- c. Submit data to a registry which facilitates benchmarking, PC<sup>4</sup>, or VPS;<sup>169, 170</sup> and
- d. Have constant (24/7) attending intensivist or surgeon in-house coverage.<sup>171, 172, 173, 174</sup>

### 3. Pediatric (Cardiac) Intensive Care Unit Core Team Members and Specialty Consultants

The CCS approved PICU or NICU with a dedicated CICU component of the Cardiac SCC must have, at a minimum, all the following:

- a. At least one intensivist who:<sup>175, 176, 177</sup>
  - i. Is double board-certified in Pediatric Critical Care Medicine (or Neonatology) and Pediatric Cardiology;
  - ii. Has completed a categorical fellowship in Pediatric Critical Care Medicine (or Neonatology) and Pediatric Cardiology followed by a fourth year of training in pediatric CICU; or
  - iii. Has over ten years' experience as a primary cardiac intensivist.
- b. RN staff with a core group who are dedicated to pediatric cardiac patients;<sup>178, 179</sup>
- c. A minimum of 80% of the RN's providing direct patient care to the pediatric cardiac patients must have a baccalaureate degree and specialty certification;<sup>180</sup>
- d. Dedicated respiratory care practitioners;<sup>181</sup>
- e. Available social worker, registered dietitian, and pharmacist;<sup>182, 183, 184, 185</sup> and
- f. Access to anesthesiologist and perfusionist.

### 4. Pediatric or Neonatal (Cardiac) Intensive Care Unit Facilities and Equipment

The CCS approved PICU with dedicated CICU component must have, at a minimum, all the following:<sup>186</sup>

- a. The ability to perform ECLS;

- b. Searchable cardiopulmonary telemetry monitoring of all unit patients;
  - c. On-site or immediate access to portable X-ray and echocardiogram;
  - d. On-site or immediate access to a difficult/advanced airway cart/equipment and physicians with advanced airway management skills;
  - e. The ability to appropriately isolate patients to avoid nosocomial infections;
  - f. An on-site defibrillator and external temporary pacing equipment;
  - g. An on-site code cart with appropriately sized equipment for pediatric patients up to 21 years of age;
  - h. An on-site mediastinal “open heart” cart for sternotomy;
  - i. On-site capability for temporary cardiac pacing;
  - j. An on-site pharmacy through either Pyxis or other safety locked mechanism for rapid and easy nursing access to medications; and
  - k. Access to inhaled nitric oxide.
5. Pediatric or Neonatal (Cardiac) Intensive Care Unit Patient Care Policies and Procedures
- a. PICU patient care teams must be in close communication with the cardiac care team, including intensivist, surgeon, cardiologist, RNs, and respiratory therapist.
  - b. The CCS-approved PICU with dedicated CICU component must provide access to pediatric subspecialty services including:<sup>187</sup>
    - i. Neurology/continuous electroencephalogram (EEG) service;
    - ii. Pediatric nephrology with continuous renal replacement therapy services (CRRT)
    - iii. Pediatric neurosurgery services;
    - iv. Pediatric pulmonary services including lower airway bronchoscopy capabilities for neonates); and

- v. Pediatric Otorhinolaryngologist (ENT) services such as upper airway bronchoscopy capabilities for neonates, which report outcomes to either VPS or PC<sup>4</sup>.<sup>188, 189</sup>
  - c. Care management conferences in the CCS-approved PICU between the pediatric cardiac intensivist, cardiologist, pediatric cardiothoracic surgeon, and other professional staff as necessary, which must be documented in the patient record.
- 6. Quality Assurance and Quality Improvement<sup>190</sup>
  - a. The PICU or NICU must provide to DHCS, annually, a summary report containing:
    - i. The volumes of medical and surgical patients admitted to the CICU per year; and
    - ii. Benchmarked outcome data that are submitted to the CICU registry (either VPS or PC<sup>4</sup>) including:<sup>191, 192</sup>
      - (1) Benchmarked mortality (risk adjusted, if available); and
      - (2) Benchmarked outcome measures (risk adjusted, if available) for ECMO, Cardiopulmonary Resuscitation, Continuous Renal Replacement Therapy, and/or Central Line associated Bloodstream Infection.
  - b. The PICU/Cardiac ICU or NICU must make available to DHCS policies and procedures supporting evidence-based quality metrics, including:
    - i. Best practice bundle care for central line insertion and maintenance;
    - ii. Standardized hand-off process during transitions of care;
    - iii. Standardized communication escalation plan; and
    - iv. Standardized incident/safety reporting process.

<sup>1</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards [Provider Standards \(ca.gov\)](#)

<sup>2</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards [Provider Standards \(ca.gov\)](#)

<sup>3</sup> Health & Safety Code § 123805

<sup>4</sup> Cal. Code Regs., tit. 22, § 41518.2

## CHAPTER 3.13 – Pediatric Cardiac Special Care Center Standards

Page 29 of 34

December 15, 2023

<sup>5</sup> Cal. Code Regs., tit. 22, § 41518.8

<sup>6</sup> U.S Department of Health & Human Services, CLAS Standards

[CLAS Standards - Think Cultural Health \(hhs.gov\)](https://www.hhs.gov/ohrt/standards/)

<sup>7</sup> Cal. Code Regs., tit. 22, § 42020

<sup>8</sup> Cal. Code Regs., tit. 22, § 42000

<sup>9</sup> Cal. Code Regs., tit. 22, § 42030

<sup>10</sup> Health & Saf. Code, § 123840

<sup>11</sup> European Society of Thoracic Surgeons

<https://www.ests.org/>

<sup>12</sup> The Society of Thoracic Surgeons -European Association for Cardiothoracic Surgery STAT Score

<https://www.sts.org/sites/default/files/CHSD%20Appendix%20C%20-%20STAT%20Categories.pdf>

<sup>13</sup> Health & Saf. Code, § 123840

<sup>14</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards

[Provider Standards \(ca.gov\)](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/ImzVaccines/Pages/ProviderStandards.aspx)

<sup>15</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards

[Provider Standards \(ca.gov\)](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/ImzVaccines/Pages/ProviderStandards.aspx)

<sup>16</sup> Health & Saf. Code, § 1200

<sup>17</sup> Cal. Code Regs., tit. 22, § 51115.1(a)(2)

<sup>18</sup> Standards for Tertiary Hospitals

<https://www.dhcs.ca.gov/services/ccs/Documents/Tertiary.pdf>

<sup>19</sup> Standards for Pediatric Community Hospitals

<https://www.dhcs.ca.gov/services/ccs/Documents/PedCommunity.pdf>

<sup>20</sup> Cal. Code Regs., tit. 22, § 42115

<sup>21</sup> Regional NICU

<https://www.dhcs.ca.gov/services/ccs/Documents/RegionalNICU.pdf>

<sup>22</sup> Community NICU

<https://www.dhcs.ca.gov/services/ccs/Documents/CommunityNICU.pdf>

<sup>23</sup> Standards for PICU

<https://www.dhcs.ca.gov/services/ccs/Documents/PICU.pdf>

<sup>24</sup> Adult Congenital Heart Association

<https://www.achaheart.org/>

<sup>25</sup> Intersocietal Accreditation Commission

<https://intersocietal.org/>

<sup>26</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards

[Provider Standards \(ca.gov\)](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/ImzVaccines/Pages/ProviderStandards.aspx)

<sup>27</sup> Cal. Code Regs., tit. 22, § 42020

<sup>28</sup> Cal. Code Regs., tit. 22, § 41412

<sup>29</sup> Cal. Code Regs., tit. 22, § 42030

<sup>30</sup> 42 C.F.R § 482.12(c)(3)

<sup>31</sup> 42 C.F.R § 482.12(c)(3)

<sup>32</sup> Cal. Code Regs., tit. 22, § 70225

<sup>33</sup> Cal. Code Regs., tit. 22, § 42030

<sup>34</sup> Cal. Code Regs., tit. 22, § 42020

<sup>35</sup> Cal. Code Regs., tit. 22, § 41412

<sup>36</sup> Cal. Code Regs., tit. 22, § 42030

<sup>37</sup> Cal. Code Regs., tit. 22, § 70225

<sup>38</sup> Cal. Code Regs., tit. 22, § 42020

<sup>39</sup> Cal. Code Regs., tit. 22, § 41412

<sup>40</sup> Cal. Code Regs., tit. 22, § 42030

<sup>41</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards

[Provider Standards \(ca.gov\)](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/ImzVaccines/Pages/ProviderStandards.aspx)

## CHAPTER 3.13 – Pediatric Cardiac Special Care Center Standards

Page 30 of 34

December 15, 2023

<sup>42</sup> Cal. Code Regs., tit. 22, § 76139

<sup>43</sup> Bus. & Prof. Code § 2725

<sup>44</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards  
[Provider Standards \(ca.gov\)](#)

<sup>45</sup> Bus. & Prof. Code § 4996.9

<sup>46</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards  
[Provider Standards \(ca.gov\)](#)

<sup>47</sup> Cal. Code Regs., tit. 22, § 79023

<sup>48</sup> Bus. & Prof. Code §§ 2585-2586

<sup>49</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards  
[Provider Standards \(ca.gov\)](#)

<sup>50</sup> Bus. & Prof. Code § 2620

<sup>51</sup> Bus. & Prof. Code § 2570.3

<sup>52</sup> Cal. Code Regs., tit.5, § 80048.9.

<sup>53</sup> The IAC Standards and Guidelines for Pediatric Echocardiography Accreditation  
<https://intersocietal.org/document/pediatric-echocardiography-accreditation-standards/>

<sup>54</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards  
[Provider Standards \(ca.gov\)](#)

<sup>55</sup> Health & Saf. Code, § 123840(i)

<sup>56</sup> IAC Pediatric and Transesophageal Echocardiography Certification  
<https://intersocietal.org/programs/echocardiography/>

<sup>57</sup> SCAI Expert Consensus Statement for Advanced Training Programs in Pediatric and Congenital Interventional Cardiac Catheterization  
<https://pubmed.ncbi.nlm.nih.gov/24890705/>

<sup>58</sup> Health & Saf. Code, § 123840

<sup>59</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards  
[Provider Standards \(ca.gov\)](#)

<sup>60</sup> Health & Saf. Code, § 1200

<sup>61</sup> Cal. Code Regs. Tit. 22, § 51115.1

<sup>62</sup> Cal. Code Regs. Tit. 22, § 70005

<sup>63</sup> Health & Saf. Code, § 1250

<sup>64</sup> AHA Journals (2022). Managing Transition to Adulthood for Adolescents with CHD  
[Best Practices in Managing Transition to Adulthood for Adolescents with Congenital Heart Disease: The Transition Process and Medical and Psychosocial Issues | Circulation \(ahajournals.org\)](#)

<sup>65</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards  
[Provider Standards \(ca.gov\)](#)

<sup>66</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards  
[Provider Standards \(ca.gov\)](#)

<sup>67</sup> Health & Saf. Code, § 123925

<sup>68</sup> Society for Thoracic Surgeons (STS)  
<https://www.sts.org/>

<sup>69</sup> American Academy of Pediatrics Database: Improving Pediatric and Adult Congenital Treatment  
<https://www.aap.org/en/patient-care/congenital-heart-defects/congenital-heart-defect-chd-databases-for-surveillance-research-and-innovation/>

<sup>70</sup> Virtual Pediatric Systems  
<https://myvps.org/>

<sup>71</sup> Pediatric Cardiac Critical Care Consortium (PC<sup>4</sup>)  
<https://pc4quality.org/>

<sup>72</sup> 2021 ACCF SCAI expert consensus document on cardiac catheterization laboratory standards update.  
<https://www.acc.org/latest-in-cardiology/articles/2021/07/29/17/05/scai-expert-consensus-update-cardiac-catheterization-laboratory>

<sup>73</sup> 2021 ACCF SCAI expert consensus document on cardiac catheterization laboratory standards update.

## CHAPTER 3.13 – Pediatric Cardiac Special Care Center Standards

Page 31 of 34

December 15, 2023

<https://scai.org/publications/clinical-documents/scai-expert-consensus-update-best-practices-cardiac-catheterization>

<sup>74</sup> Intersocietal Accreditation Commission

<https://intersocietal.org/>

<sup>75</sup> Cal. Code Regs., tit. 22, § 42020

<sup>76</sup> Cal. Code Regs., tit. 22, § 41412

<sup>77</sup> Cal. Code Regs., tit. 22, § 42030

<sup>78</sup> Cardiovascular Credentialing International

<https://cci-online.org/credentials/registered-cardiovascular-invasive-specialist/>

<sup>79</sup> Health & Saf. Code, §§ 106955 - 107111

<sup>80</sup> The American Registry of Radiologic Technologists

<https://www.arrt.org/>

<sup>81</sup> Cal. Code Regs., tit. 22, § 76139

<sup>82</sup> Bus. & Prof. Code § 2725

<sup>83</sup> Cal. Code Regs., tit. 22, § 42020

<sup>84</sup> Cal. Code Regs., tit. 22, § 41412

<sup>85</sup> Cal. Code Regs., tit. 22, § 42030

<sup>86</sup> 42 C.F.R. § 482.12(c)(3)

<sup>87</sup> The American Board of Pediatrics, Pediatric Cardiology Subspecialty Certification

[Pediatric Cardiology Certification | The American Board of Pediatrics \(abp.org\)](https://www.abp.org/content/pediatric-cardiology-certification)

<sup>88</sup> American Board of Pediatrics, Pediatric Cardiology Certification

<https://www.abp.org/content/pediatric-cardiology-certification>

<sup>89</sup> Cal. Code Regs., tit. 22, § 42020

<sup>90</sup> Cal. Code Regs., tit. 22, § 41412

<sup>91</sup> Cal. Code Regs., tit. 22, § 42030

<sup>92</sup> Cal. Code Regs., tit. 22, § 70225

<sup>93</sup> Cal. Code Regs., tit. 22, § 76139

<sup>94</sup> Cal. Code Regs., tit. 22, § 51170.3

<sup>95</sup> Bus. & Prof. Code §§ 2838-2838.4

<sup>96</sup> American Heart Association Pediatric Life Support

<https://cpr.heart.org/en/cpr-courses-and-kits/healthcare-professional/pediatric>

<sup>97</sup> Cal. Code Regs., tit. 22, § 51170.1

<sup>98</sup> Bus. & Prof. Code § 4996.9

<sup>99</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards

[Provider Standards \(ca.gov\)](https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/rhb.aspx)

<sup>100</sup> Health & Saf. Code, §§ 106955 - 107111

<sup>101</sup> Cal. Code Regs., tit. 17, § 30463

<sup>102</sup> Cardiovascular Credentialing International

<https://cci-online.org/>

<sup>103</sup> American Heart Association Basic Life Support

[Basic Life Support BLS Training | American Heart Association CPR & First Aid](https://www.heart.org/en/health-topics/heart-disease/prevention-and-risk-management/heart-disease-prevention/basics-of-life-support/basics-of-life-support)

<sup>104</sup> Cal. Code Regs., tit. 22, § 42020

<sup>105</sup> Cal. Code Regs., tit. 22, § 41412

<sup>106</sup> Cal. Code Regs., tit. 22, § 42030

<sup>107</sup> California Department of Public Health, Radiologic Health Branch- Credentialing

<https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/rhb.aspx>

<sup>108</sup> Health & Saf. Code, § 123840

<sup>109</sup> Health & Saf. Code, § 123840

<sup>110</sup> Health & Saf. Code, § 123840

<sup>111</sup> Centers for Disease Control and Prevention, As Low As Reasonably Achievable (ALARA) Principles

<https://www.cdc.gov/nceh/radiation/alara.html>

<sup>112</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards

## CHAPTER 3.13 – Pediatric Cardiac Special Care Center Standards

Page 32 of 34

December 15, 2023

### [Provider Standards \(ca.gov\)](#)

<sup>113</sup> Health & Saf. Code, § 123925

<sup>114</sup> American Academy of Pediatrics Database: Improving Pediatric and Adult Congenital Treatment  
<https://www.aap.org/en/patient-care/congenital-heart-defects/congenital-heart-defect-chd-databases-for-surveillance-research-and-innovation/>

<sup>115</sup> The American Board of Pediatrics, Pediatric Cardiology Subspecialty Certification  
[Pediatric Cardiology Certification | The American Board of Pediatrics \(abp.org\)](#)

<sup>116</sup> The International Board of Heart Rhythm Examiners (IBHRE)  
<https://ibhre.org/>

<sup>117</sup> Physician Certified Electrophysiology Specialist (CEPS) Exams  
<https://ibhre.org/physicians/physician-certified-electrophysiology-specialist-ceps-exams>

<sup>118</sup> Cal. Code Regs., tit. 22, § 42020

<sup>119</sup> Cal. Code Regs., tit. 22, § 41412

<sup>120</sup> Cal. Code Regs., tit. 22, § 42030

<sup>121</sup> International Board of Heart Rhythm Examiners. Eligibility Requirements Policy: IBHRE Board  
Certification Examination in Cardiac Electrophysiology for the Physician

### [Physicians | IBHRE](#)

<sup>122</sup> Cal. Code Regs., tit. 22, § 42020

<sup>123</sup> Cal. Code Regs., tit. 22, § 41412

<sup>124</sup> Cal. Code Regs., tit. 22, § 42030

<sup>125</sup> Walsh et al. Recommendations for Advanced Fellowship Training in Clinical Pediatric and Congenital  
Electrophysiology. 2013. Heart Rhythm;10:775-781.

<sup>126</sup> ACCF/AHA/AAP Recommendations for Training in Pediatric Cardiology. A Report of the American  
College of Cardiology Foundation/American Heart Association/American Committee to Develop Training  
Recommendations for Pediatric Cardiology) College of Physicians Task Force on Clinical Competence  
Circulation.2005;112:2555-2580

<sup>127</sup> Cal. Code Regs., tit. 22, § 42020

<sup>128</sup> Cal. Code Regs., tit. 22, § 41412

<sup>129</sup> Cal. Code Regs., tit. 22, § 42030

<sup>130</sup> Cal. Code Regs., tit. 22, § 70225

<sup>131</sup> Cal. Code Regs., tit. 22, § 76139

<sup>132</sup> Bus. & Prof. Code § 2725

<sup>133</sup> Certified Cardiographic Technician (CCT)

<https://cci-online.org/credentials/certified-cardiographic-technician/>

<sup>134</sup> Health & Saf. Code, § 123840

<sup>135</sup> Health & Saf. Code, § 123925

<sup>136</sup> American Academy of Pediatrics Database: Improving Pediatric and Adult Congenital Treatment  
[Congenital Heart Defect \(CHD\) Databases for Surveillance, Research, and Innovation \(aap.org\)](#)

<sup>137</sup> 42 C.F.R § 482.12(c)(3)

<sup>138</sup> Cal. Code Regs., tit. 22, § 70225

<sup>139</sup> Cal. Code Regs., tit. 22, § 42030

<sup>140</sup> American Board of Thoracic Surgery

<https://www.abts.org/>

<sup>141</sup> Cal. Code Regs., tit. 22, § 42020

<sup>142</sup> Cal. Code Regs., tit. 22, § 41412

<sup>143</sup> Cal. Code Regs., tit. 22, § 42030

<sup>144</sup> Cal. Code Regs., tit. 22, § 70225

<sup>145</sup> Cal. Code Regs., tit. 22, § 42020

<sup>146</sup> Cal. Code Regs., tit. 22, § 41412

<sup>147</sup> Cal. Code Regs., tit. 22, § 42030

<sup>148</sup> Cal. Code Regs., tit. 22, § 70225

<sup>149</sup> Cal. Code Regs., tit. 22, § 42020



## CHAPTER 3.13 – Pediatric Cardiac Special Care Center Standards

Page 33 of 34

December 15, 2023

- <sup>150</sup> Cal. Code Regs., tit. 22, § 41412
- <sup>151</sup> Cal. Code Regs., tit. 22, § 42030
- <sup>152</sup> Cardiovascular Credentialing International  
<https://cci-online.org/credentials/registered-cardiovascular-invasive-specialist/>
- <sup>153</sup> Health & Saf. Code, §§ 106955 - 107111
- <sup>154</sup> Cal. Code Regs., tit. 22, § 42020
- <sup>155</sup> Cal. Code Regs., tit. 22, § 41412
- <sup>156</sup> Cal. Code Regs., tit. 22, § 42030
- <sup>157</sup> Cal. Code Regs., tit. 22, § 51225.5
- <sup>158</sup> Cal. Code Regs., tit. 22, §§ 1029 – 1075
- <sup>159</sup> Health & Saf. Code, §§ 106955 - 107111
- <sup>160</sup> American Board of Cardiovascular Perfusion  
<https://www.abcp.org/>
- <sup>161</sup> Cal. Code Regs., tit. 22, § 76139
- <sup>162</sup> Bus. & Prof. Code § 2725
- <sup>163</sup> Bus. & Prof. Code § 4996.9
- <sup>164</sup> Health & Saf. Code, § 123840(i)
- <sup>165</sup> Chapter 3.37.1 Provider Core Standards, SCC General Information and Core Standards  
[Provider Standards \(ca.gov\)](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Imz/Pages/ProviderStandards.aspx)
- <sup>166</sup> Health & Saf. Code, § 123925
- <sup>167</sup> Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database Report  
<https://www.sts.org/registries/sts-national-database>
- <sup>168</sup> Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database Report  
<https://www.sts.org/registries/sts-national-database>
- <sup>169</sup> Virtual Pediatric Systems  
<https://myvps.org/>
- <sup>170</sup> Pediatric Cardiac Critical Care Consortium (PC<sup>4</sup>)  
<https://pc4quality.org/>
- <sup>171</sup> 42 C.F.R § 482.12(c)(3)
- <sup>172</sup> Cal. Code Regs., tit. 22, § 70225
- <sup>173</sup> Cal. Code Regs., tit. 22, § 42030
- <sup>174</sup> Cal. Code Regs., tit. 22, § 70225
- <sup>175</sup> Cal. Code Regs., tit. 22, § 42020
- <sup>176</sup> Cal. Code Regs., tit. 22, § 41412
- <sup>177</sup> Cal. Code Regs., tit. 22, § 42030
- <sup>178</sup> Cal. Code Regs., tit. 22, § 76139
- <sup>179</sup> Bus. & Prof. Code § 2725
- <sup>180</sup> American Association of Critical-Care Nurses (AACN)  
<https://www.aacn.org/certification/get-certified/ccrn-peds>
- <sup>181</sup> Cal. Code Regs., tit. 22, § 51225.5
- <sup>182</sup> Bus. & Prof. Code § 4996.9
- <sup>183</sup> Cal. Code Regs., tit. 22, § 79023
- <sup>184</sup> Bus. & Prof. Code §§ 2585-2586
- <sup>185</sup> Cal. Code Regs., tit. 22, § 1793.1
- <sup>186</sup> Health & Saf. Code, § 123840(i)
- <sup>187</sup> Health & Saf. Code, § 123840
- <sup>188</sup> Virtual Pediatric Systems  
<https://myvps.org/>
- <sup>189</sup> Pediatric Cardiac Critical Care Consortium (PC<sup>4</sup>)  
<https://pc4quality.org/>
- <sup>190</sup> Health & Saf. Code, § 123925
- <sup>191</sup> Virtual Pediatric Systems

## CHAPTER 3.13 – Pediatric Cardiac Special Care Center Standards

Page 34 of 34

December 15, 2023

<https://myvps.org/>

<sup>192</sup> Pediatric Cardiac Critical Care Consortium (PC<sup>4</sup>)

<https://pc4quality.org/>