Elective Percutaneous Coronary Intervention (PCI) Program Application

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Elective Percutaneous Coronary Intervention (PCI)
Program Application

FOR DEPARTMENTAL USE ONLY

District:

ELMS Facility Number:

TO BE COMPLETED BY APPLICANT

APPLICANT NAME:

Total number of pages including attachments, numbered sequentially, in the application package:

ELECTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI) PROGRAM

PURPOSE

The California Legislature enacted Health and Safety (H&S) Code section 1256.01, which establishes the Elective Percutaneous Coronary Intervention (PCI) Program to be implemented by the California Department of Public Health (CDPH). Previously in the State, only general acute care hospitals (GACHs) with cardiac surgery on site and a licensed cardiac catheterization lab (cath lab) could perform non-emergent, scheduled ("elective") percutaneous coronary interventions (PCI). **With this legislation, the Department is authorized to certify an unlimited number of eligible GACHs, that do not have on-site cardiac surgery support and are licensed to provide cardiac catheterization laboratory service in California, to perform elective PCI**. Each hospital must meet rigorous facility, staffing, patient selection, patient care, data collection, and reporting requirements to be considered for participation.

TIMELINE

This application must be completed correctly and submitted to CDPH. Approved facilities will be notified. Data reporting at approved hospitals will begin with the effective date of service under the Elective PCI Program.

FEES

CDPH will bill each certified hospital an annual supplemental license fee to participate in this program. This fee will reimburse CDPH for the cost to oversee the program. CDPH will retroactively bill the fee, which will be based on the total cost to administer the program and will be divided by the total number of hospitals that are approved to participate in the program.

GOVERNANCE

Facilities selected as Elective PCI Program hospitals must comply with:

1) The recommendations of the Society for Cardiovascular Angiography and Interventions (SCAI), the American College of Cardiology Foundation (ACCF), and the American Heart Association (AHA), for performance of PCI without on-site cardiac surgery, as these recommendations may evolve over time.
2) California H&S Code section 1256.01
3) California Code of Regulations (CCR) Title 22 including, but not limited to, Division 5, Chapter 1, Article 6, Sections 70433, 70435 (a), 70437 (a), 70438, 70438.1, 70439 (a), 70491, 70493, 70495,70497, 70499, 70461, 70463, 70465, 70467, 70469
4) all other existing federal, state, and local laws, rules and regulations
5) all other SCAI/ACCF/AHA guidelines and standards that pertain to cardiac surgery and cardiac catheterization including, but not limited to, PCI, personnel qualifications, and ST elevation MI (STEMI)/unstable angina (UA)/Non-STEMI treatment protocols.

If at any time a certified hospital fails to meet the criteria set forth in H&S Code section 1256.01 for being a certified hospital or fails to safeguard patient safety, as determined by CDPH, the Department may suspend or revoke the certification issued to that hospital under the program. A hospital whose certification is revoked pursuant to this subdivision may request an appeal with the Department and is not precluded from reapplying for certification under the program.

CERTIFICATION

Eligible hospitals will be certified based on each applicant's ability to meet or exceed the criteria set forth in H&S Code section 1256.01, as determined by CDPH. CDPH and/or its subcontractor will evaluate the applications, and perform on-site inspections as necessary to determine whether the eligible hospital meets all applicable criteria. The decision to certify an eligible hospital will be based on data submitted in the application packages, facility compliance history with all state and federal guidelines, and on-site inspections. When evaluating eligible hospitals, CDPH will consider the extent to which each applicant meets the criteria.

ADVISORY OVERSIGHT COMMITTEE

An Advisory Oversight Committee (AOC) may be established consisting of two interventionists from certified hospitals, two interventionists from general acute care hospitals that are not certified hospitals, and a representative of the Department, for the purpose of analyzing the reports issued under the program and making recommendations for changing the data to be included in future reports.

APPLICATION REQUIREMENTS

This application consists of 34 pages of questions and appendices. We recommend reviewing this entire document before completion to ensure your facility meets the requirements. On page two, the applicant is required to document its facility name and the total number of pages being submitted, including attachments. **This section must be completed.**

Many of the questions can be answered in "yes" or "no" format within the application itself. Other questions require detailed explanation, separate attachments, and multiple levels of information. Any omissions will disqualify the candidate from certification.

Each question has an alphanumeric designation (question number). For questions requiring additional explanation or separate attachments, clearly document at the top of the page(s) the question number to which the attachment or explanation pertains. Any explanations without the designated question number will be disregarded and the question considered unanswered.

On each application page, include your facility name and application page number in the lower right corner. Ensure each attachment also includes, in the lower right corner if possible, your facility name, and the page number consecutive to the other attachment and application pages. Appendix A includes a list of the required policy and procedures.

Email addresses must be provided for all contacts in the application.

All policies, procedures, rules, regulations, bylaws, or guidelines submitted in response to this application must include the date the policy became effective, and evidence that the document has been reviewed and accepted by the governing body.

All application materials and attachments must be submitted in electronic format (PDF or Word) and should be organized according to the instructions in each section. We recommend that each facility maintain one complete copy of this application, as submitted, to expedite on-site surveys that may occur as part of the application process.

A hard copy of the 34-page application, without separate attachments, must be submitted to:

Centralized Applications Unit
California Department of Public Health
Licensing & Certification Program
1615 Capitol Avenue, MS 3401
P.O. Box 997377
Sacramento, CA 95899-7377

The electronic copy of the application with all relevant attachments must be submitted to PCI@cdph.ca.gov. **Direct all inquiries regarding the application to PCI@cdph.ca.gov.**

Once submitted, applications cannot be changed. Any discrepancies in data found during on-site inspections and in the application may disqualify the facility from consideration for the program. Please follow the instructions closely.

A. APPLICANT INFORMATION

***All attachments for Section A should be included as one electronic file (PDF or Word), named in the following format: facility name-Section A**

A5. LOCATION OF ELECTIVE PCI PROGRAM:

Address 1:

Address 2:

City: State: Zip Code:

A6. Medicare Provider Number(s): A7. National Provider Identifier:

A8. Is the applicant currently in compliance with Medicare rules and regulations? Yes No
If no, attach an explanation

A9. Has the applicant been placed on a Medicare termination track within the past 5 years? Yes No
If yes, attach an explanation

A10. California Facility License Number:

A11**. Submit a copy of the current facility California hospital license with this application** A12.

Licensee Name:

Address 1:

Address 2:

City: State: Zip Code:

Telephone number: Fax number:

A13. Licensee mailing address, if different from above:

Address 1:

Address 2:

City: State: Zip Code:

A14. Is the applicant in compliance with all local and state laws, rules and regulations? Yes No
If no, attach an explanation

A15. Has the applicant's license been suspended or revoked? Yes No
If yes, attach an explanation

A16. Has the applicant received a CDPH-issued administrative penalty? Yes No
If yes, attach an explanation

A17. Has the applicant received an Immediate Jeopardy finding on either a CDPH or CMS survey or investigation? ◯ Yes ◯ No
If yes, attach an explanation

A18. Owner type (check one):

☐	**a.** Sole proprietorship(Individual)	☐	**g.** City
☐	**b.** Profit corporation	☐	**h.** County
☐	**c.** Nonprofit corporation	☐	**I.** State agency
☐	**d.** Limited Liability Company (LLC)	☐	**j.** Other agency (specify)
☐	**e.** Partnership –General	☐	**k.** Public agency (specify)
☐	**f.** Partnership – Limited		

A19. Is the licensee a **subsidiary** of another organization? ◯ Yes ◯ No
If yes, complete the information below:

Parent Organization Name:

Address:

City, State, & Zip:

A20. Is this facility affiliated with any other GACHs in the State of California not noted in Question A19? If yes, complete the information below:

Facility Name: Relationship:

Address:

City, State, & Zip:

Facility Name: Relationship:

Address: City, State, & Zip:

Facility Name: Relationship:

Address: City, State, & Zip:

Facility Name: Relationship:

Address: City, State, & Zip:

Facility Name: Relationship:

Address: City, State, & Zip:

A21. If any facility listed above has had a license revocation action filed, license placed on probation, suspended, or revoked (whether stayed or not), or had a final Medi-Cal decertification action taken, submit additional information, including all ownership and facility information, date, and final action.

KEY PERSONNEL

A22. Provide a hospital-wide organization chart with department and management names and titles. Provide contact information for key personnel as requested below:

A23. Name of Hospital Administrator: Title:

Professional license number: Expiration date: Date of hire:

Address 1 (if different than facility address):

Address 2:

City: State: Zip Code:

Telephone number: Fax number: Email address:

A24. Name of Director of Nursing: Title:

Professional license number: Expiration date: Date of hire:

Address 1 (if different than facility address):

Address 2:

City: State: Zip Code:

Telephone number: Fax number: Email address:

A25. Name of Chief of Cardiology: Title:

Professional license number: Expiration date: Date of hire:

Address 1 (if different than facility address):

Address 2:

City: State: Zip Code:

Telephone number: Fax number: Email address:

A26. Name of Cardiac Catheterization Lab Director: Title:

Professional license number: Expiration date: Date of hire:

Address 1 (if different than facility address):

Address 2:

City: State: Zip Code:

Telephone number: Fax number: Email address:

A27. Name of Cardiac Catheterization Lab Manager (if any): Title:

Professional license number: Expiration date: Date of hire:

Address 1 (if different than facility address):

Address 2:

City: State: Zip Code:

Telephone number: Fax number: Email address:

A28. Name of person responsible for the elective PCI program: Title:

Professional license number: Expiration date: Date of hire:

Address 1 (if different than facility address):

Address 2:

City: State: Zip Code:

Telephone number: Fax number: Email address:

A29. Name of person completing Elective PCI Program application: Title:

Professional license number: Expiration date: Date of hire:

Address 1 (if different than facility address):

Address 2:

City: State: Zip Code:

Telephone number: Fax number: Email address:

FINANCIAL RESOURCES

To participate in the Elective PCI Program, all facilities must be committed to resource dedication, as well as demonstrate the financial means to do so.

A30. Provide a letter from hospital administration stating it has given its full support to the hospital's participation in the Elective PCI Program and include financial, staffing, and regulatory compliance support.

A31. In an attachment, provide a complete business plan that defines current resources for the cardiac catheterization lab and those resources needed to meet the program rules and regulations as defined in H&S Code section 1256.01 and the SCAI/ACCF/AHA guidelines. This must be signed by the hospital administration.

FACILITY SERVICE AREA

A32. Provide a topographic map of the region within a 100-mile radius of your facility. This map must be drawn to scale and include:

- a legend
- the scale to which the map is drawn
- city and county designations
- all hospitals with cardiac catheterization labs and/or cardiac surgery centers designated by location and name. Due to space restrictions, these hospital names may be referenced on a separate list that clearly designates each hospital and its location
- special designation for cardiac surgery centers with whom you have established transfer agreements
- transportation route between your facility and the cardiac surgery center(s)
- all major transportation channels in this region.
- clearly designated service area. If your facility service area is outside this region, provide a separate map of the full service area
- all major topographical features such as mountains, rivers, bridges, etc. Any geographical features that geographically isolate your facility or may impede patient access to or transport from your facility must be clearly designated.

A32a. Is an electronic map included in your application package? Yes No

If yes, clearly label the media with your facility name, file name, version of software used, any special opening instructions, and name and telephone number of the person to contact in the event of difficulty using the file.

A33. Is your facility in a defined health professional shortage area (HPSA), medically underserved area (MUA), or rural area as defined by the California Office of Statewide Health Planning and Development? California HPSA and MUA maps can be located through http://www.oshpd.ca.gov/HWDD/Data_GIS_faqs.html#q3.

If yes, please explain:

A34. What are the population statistics in terms of race, age, and income for your primary and extended services areas? Primary Service Area (PSA) is defined as the ZIP codes in which 60% of the hospital's inpatients reside. Extended Service Area (ESA) is defined as the ZIP codes in which 85% (minus the 60% of patients residing in the PSA ZIP codes) of hospital's inpatients reside.

Primary Service Area (PSA):

Extended Service Area (ESA):

A35. How would your patient population be better served if your facility were certified as an Elective PCI Program hospital? Submit your response as a separate attachment.

B. FACILITY SERVICES

***All attachments for Section B should be included as one electronic file (PDF or Word), named in the following format: facilityname-Section B**

B1. Provide a floor plan of the hospital, including ER, the ER to cath lab pathway, cath lab(s), ICU and/or CCU, and the pre- and post-catheterization units. Indicate the flow of cardiac patients through these units, and the number of beds included in each.

B2. Hospital days and hours of operation:

B3. Designate all special services provided at this facility and the date the service began. (Special services as defined in CCR Title 22, Division 5, Chapter 1, Article 5, Section 70351 include, but are not limited to, radiation therapy, burn center, psychiatric, neonatal intensive care unit, emergency center, hemodialysis, cardiac surgery, cardiac catheterization lab, and renal transplant.

1) 5)

2) 6)

3) 7)

4) 8)

Attach additional information if needed.

B4. Does the facility have an emergency room? ◯ Yes ◯ No

If yes, in a separate attachment, provide details of any ER drive-by or closure status in the past 12 months including date, number of hours diverted, reason for closure.

B5. Does the facility have a cardiac surgery service? ◯ Yes ◯ No

B6. If yes, does the facility intend to close the existing cardiac surgery service upon certification in the Elective PCI Program? ◯ Yes ◯ No

Facilities with cardiac surgery on site are not required to obtain certification to perform elective PCI.

B7. Does the facility have an active blood bank on site? ◯ Yes ◯ No

If no, advise when will this service be available?

Facilities without an active blood bank on site cannot participate in the program.

B8. Does the facility have a respiratory care service? ◯ Yes ◯ No

If yes, provide the following:

B8a. policy and procedure (P&P) that represents how respiratory care staff will support cardiac catheterization patients in the ICU, CCU, and cath lab, in both emergent and non-emergent situations.

B8b. regular shift and on-call schedules from the most recent six (6) months. This must provide evidence of 24 hours a day, 7 days a week, 365 days per year (24x7x365) staffing.

B8c. detail on how the respiratory care services and staffing will change to support the elective PCI program, if elective PCI is permitted.

B8d. respiratory care organization chart with staff names and titles, if not previously provided.

If no, please provide:
B8e. details whether this service will be available in the future and when.

B8f. provide responses to question B8a through B8d for this new service, labeled as questions numbered B8fa, B8fc and B8fd. B8fb does not apply.

Facilities without an active respiratory care service cannot participate in the program.

C. CARDIAC CATHETERIZATION SERVICES ADMINISTRATION

***All attachments for Section C should be included as one electronic file (PDF or Word), named in the following format: facility name-Section C**

GENERAL

C1. Is the applicant facility currently a designated STEMI-Receiving Center? ◯ Yes ◯ No

C2. Cardiac catheterization lab hours and days of operation: _____

C3. Provide a copy of the cardiac catheterization log from the most recent twelve (12) months. If it is unclear by log review which procedures were performed, why and by whom, please provide this information in a separate attachment.

C4. The SCAI/ACCF/AHA guidelines require the full service (STEMI receiving and elective PCI) cath lab operates 24x7x365. Provide documentation of:

C4a. current cath lab availability and scheduling

C4b. intended availability and scheduling after elective PCI is initiated

C5. The SCAI/ACCF/AHA guidelines and H&S Code section 1256.01 require that each facility does greater than thirty-six (36) primary PCI procedures annually. Provide statistics on type and number of procedures done in the catheterization lab(s) for the most recent twelve (12) months, as follows:

Treatment of Ischemic Heart Disease (IHD) Patients Presenting to Facility During the Most Recent Twelve (12) Months	**Number of Patients**
Patients presented to ER with possible IHD	
Diagnosed with STEMI	
Diagnosed with chest pain, acute coronary syndrome, Non-STEMI	
Diagnosed with STEMI and treated with fibrinolytic therapy only	
Total number of all cardiac cath lab procedures	
Total number of diagnostic catheterizations performed	
Total number of Primary PCIs performed	

Total number of PCIs performed on Non-STEMI, chest pain, ACS patients. If this number is greater than 0, in a separate attachment, provide reference case number (s), case descriptions and reason for	
Total number of PCIs performed	
Total "other" procedures. Describe in separate attachment.	
Total # primary PCI procedures/Total # STEMI patients (If less than 90%, in a separate attachment, advise why those patients were not treated with PCI)	

C6. The SCAI/ACCF/AHA guidelines and H&S Code section 1256.01 recommend that each facility perform greater than 200 elective and primary PCI procedures per year. Submit a detailed plan with supporting data that shows the minimum number of PCI procedures (primary and elective combined) the facility expects to perform annually and where the patients will come from.

All P&Ps submitted must include the effective date of the policy and evidence of governing board approval.

C7. Provide all P&P related to pre-, intra- and post-catheterization patient care including:

C7a. cardiac catheterization patient admission, transfer and discharge guidelines

C7b. PCI patient selection and exclusion guidelines

C7c. types of procedures permitted in the cath lab.

C7d. use of conscious sedation and/or anesthesia in the cath lab, including criteria for patient selection/exclusion and privileging for conscious sedation

C7e. staffing requirements during procedures using conscious sedation and/or anesthesia

C7f. required staffing of the cardiac catheterization team for both elective and non-elective procedures

C7g. roles and responsibilities for each cath lab team member

C7h. any allied health professionals permitted to work in the cath lab. Provide roles, responsibilities, restrictions, qualifications, credentialing, ongoing training requirements and performance standards

C7i. The SCAI/ACCF/AHA guidelines and H&S Code section 1256.01 require that staff capable of endotracheal intubation and ventilator management must transport with patient, if necessary. Provide P&P for:

- C7i1. which staff are privileged and permitted to perform endotracheal intubation
- C7i2. which staff are privileged and permitted to perform ventilator management
- C7i3. which staff will transport with patient. If this is cath lab or ICU/CCU personnel, include who will provide coverage at your facility during that staff member's absence
- C7i4. qualification, certification or training required to perform endotracheal intubation, ventilator management, hemodynamic monitoring, temporary pacemaker operation and IABP management
- C7i5. required training for maintenance of skills

C7j. use of heparin or other anticoagulants in the cath lab
C7k. handling potential patients for contrast allergy
C7l. emergency care or “code blue” in the cath lab
C7m. emergency transport protocols for failed PCI, if not included in general transport P&P provided elsewhere
C7n. door-to-balloon (d2b) time requirements, tracking, and reviewing of outlier cases for quality assurance
C7o. obtaining informed consent from patients for all cardiac catheterization procedures as well as potential transport and cardiac surgery services.

C8. Provide the following:

C8a. informed consent forms used for all cardiac catheterization procedures
C8b. the informed consent for patient transfer to a cardiac surgery site and, if necessary, to undergo cardiac surgery upon arrival
C8c. evidence that emergency care or “code blue” drills have occurred, per regulation, in the last 12 months

ST ELEVATION MYOCARDIAL INFARCTION (STEMI) CARE

C9. Full service hospitals selected to perform elective PCI must perform PCI as treatment of choice for STEMI. Is this your facility’s policy? ◯ Yes ◯ No

If yes, provide:

C9a. P&P for STEMI treatment hospital-wide and date of policy implementation. Policies must ensure STEMI patients receive priority care in the cath lab and how any conflicts in cath lab availability will be resolved. Provide examples of how this has been handled in the past, if it has occurred.
C9b. P&P for treatment of chest pain and non-STEMI
C9c. Evidence training on STEMI treatment protocols for all ER and cardiac service staff
C9d. If you answered “no” to question C9, attach your current facility policy for STEMI care.
C9e. When will your facility implement PCI as primary treatment of choice for STEMI?

Facilities that do not use PCI as treatment of choice for STEMI cannot participate in the program as a full service hospital.

C10. If not provided elsewhere, provide d2b times from the most recent twelve (12) months. For any cases outside of the required timeframes, provide an explanation.

D. CARDIAC CATHETERIZATION LAB PHYSICAL PLANT

***All attachments for Section D should be included as one electronic file (PDF or Word), named in the following format: facility name-Section D**

D1. Does your hospital currently have a functioning cardiac catheterization lab(s)?

◯ Yes ◯ No

Cath Lab #1 (Check One) Date placed in service:
Type of Procedures: Diagnostic only ☐ Therapeutic only ☐ Combination Diagnostic/Therapeutic ☐
Address 1 (if different than hospital address):
Address 2:
City, State Zip

Cath Lab #2 (Check One) Date placed in service:
Type of Procedures: Diagnostic only ☐ Therapeutic only ☐ Combination Diagnostic/Therapeutic ☐
Address 1 (if different than hospital address):
Address 2:
City, State Zip

Cath Lab #3 (Check One) Date placed in service:
Type of Procedures: Diagnostic only ☐ Therapeutic only ☐ Combination Diagnostic/Therapeutic ☐
Address 1 (if different than hospital address):
Address 2:
City, State Zip

D1a. If no, is construction required to establish the catheterization labs in this facility? ◯ Yes ◯ No
If yes, advise:
• the date construction is to begin:
• the date construction is to be completed:
• the date available for service (all licenses and certifications obtained):

D2. Does your facility have planned additions to the number of existing catheterization labs or major catheterization lab renovations? ◯ Yes ◯ No
If yes, provide details below:
• the date construction is to begin:
• the date construction is to be completed:
• the date available for service (all licenses and certifications obtained):

NOTE: Ensure that funding to build, modify, staff, support and maintain the additional unit(s) is included in the business plan requested in question A31.

D3. In a separate attachment(s), provide detailed diagrams of the cardiac catheterization lab(s) including cardiac catheterization equipment, emergency call buttons, and supplies.

EQUIPMENT

The SCAI/ACCF/AHA guidelines require each facility to have a well-equipped and maintained cardiac catheterization laboratory.

D4. Provide a list of all equipment in the cardiac catheterization laboratory(s) including date of purchase, equipment purpose, make, model, manufacturer, and manufacturer contact information (if multiple cath labs, list by each lab referenced in question D1 above).

D5. Provide P&P for:

D5a. equipment maintenance, including fluoroscopy

D5b. regulating and monitoring radiation exposure in the cath lab

Provide contact information as follows:

D6. Name of the person responsible for managing lab equipment: Title:
Address 1 (if different than hospital address):
Address 2:
City: State: Zip Code:
Telephone number: Fax number:
Email address:

D7. Name of person responsible for maintaining lab equipment (if different than above):
Title:
Address 1 (if different than hospital address):
Address 2:
City: State: Zip Code:
Telephone number: Fax number:
Email address:

D8. Name of the person responsible for managing the fluoroscopy equipment (if different than above):
Title:
Address 1 (if different than hospital address):
Address 2:
City: State: Zip Code:
Telephone number: Fax number:
Email address:

D9. Name of the person responsible for maintaining the fluoroscopy equipment (if different than above):
Title:
Address 1 (if different than hospital address):
Address 2:
City: State: Zip Code:

Telephone number: Fax number:
Email address:

D10. Provide contact information for the biomedical engineer for the cath lab.
Name: Title:
Address 1 (if different than hospital address):
Address 2:
City: State: Zip Code:
Telephone number: Fax number:
Email address:

D11. Provide the following documents:

D11a. a copy of all cardiac cath lab equipment maintenance logs for the past twelve (12) months
D11b. radiation monitoring logs for all staff and, if appropriate, patient radiation exposure for the past twelve (12) months
D11c. details on major investments, including equipment changes and upgrades, since the cath lab opened
D11d. details on major investments, including equipment changes and upgrades, planned in the cath lab during participation in the Elective PCI Program
D11e. evidence of emergency utility backup in the event of power failure (evidence of current compliance with all related OSHA, and Life Safety Codes is acceptable.)

D12. Has the cath lab ever been unavailable due to equipment failure? ☐ Yes ☐ No

If yes, provide in separate attachment details on when, why, how long, effects it had on patient population, and corrections made to the system to prevent future problems.

D13. Does the facility have access to other diagnostic modalities? ☐ Yes ☐ No
Check all that apply:

- ☐ Fractional Flow Reserve (FFR)
- ☐ Intravascular Ultrasound (IVUS)
- ☐ Optical Coherence Tomography (OCT)

If yes:

D13a. provide names of staff trained in FFR/IVUS/OCT procedures with proof of training and competency
D13b. provide FFR/IVUS/OCT maintenance logs

D14. Facility must have high resolution digital imaging capability and intra-aortic balloon pump support in the cath lab compatible with transport vehicles. Does your facility have these capabilities? ☐ Yes ☐ No

If yes, provide details on the systems and a confirmation statement from the emergency medical service (EMS) that their systems are compatible.

D15. Does the cardiac catheterization lab have the ability for real-time transfer of images and hemodynamic data to hospitals designated as “receiving” hospitals for cardiac surgery patients? ◯ Yes ◯ No

D15a. If yes, describe system

D15b. If no, is this type of communication planned? ◯ Yes ◯ No

D15c. When will it be available?

D16. Can your facility transmit audio and video images to review terminals for consultation at the receiving hospital? ◯ Yes ◯ No

D16a. If yes, describe system

D16b. If no, is this type of communication planned? ◯ Yes ◯ No

D16c. When will it be available?

SUPPLIES

SCAI/ACCF/AHA guidelines require that certified hospitals have an appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes, thrombectomy and distal protection devices, covered stents, temporary pacemakers, pericardiocentesis trays and FFR.

D17. Provide P&P on approval, procurement, inventory and maintenance of catheterization lab supplies.

D18. Provide current inventory lists for each cardiac cath lab. In addition to routine supplies, the facility must have emergency procedure supplies such as thrombectomy and distal protection devices, covered stents, temporary pacemakers, pericardiocentesis trays and FFR.

D19. Name of person responsible for managing supplies in cath lab:
Title:
Address 1 (if different than hospital address):
Address 2:
City: State: Zip Code:
Telephone number: Fax number:
Email address:

E. CARDIAC CATHETERIZATION LAB PERSONNEL

***All attachments for Section E should be included as one electronic file (PDF or Word), named in the following format: facilityname-Section E**

GENERAL

Participation as a full service hospital in the Elective PCI Program requires a cardiac catheterization lab that is available 24x7x365.

E1. Does the institution have systems for credentialing and governing the elective PCI program?

◯ Yes ◯ No

MEDICALSTAFF

E2. Provide a copy of the current governing body and medical staff by laws, rules and regulations.

E3. Provide P&P, position descriptions and other related documents that provide for:

E3a. interventionist qualifications, credentialing (including proctoring and privileging), ongoing training requirements and performance standards
E3b. interventionist duties, roles and responsibilities in respect to the cardiac cath lab and its patients pre-, intra- and post catheterization, elective and non-elective
E3c. interventionist shift and on-call scheduling

The SCAI/ACCF/AHA detail specific guidelines on the background of interventionists who should perform PCI in facilities without cardiac surgery on site. The facility shall only permit interventionists who meet those requirements to perform elective PCI:

- primary operators: perform ≥50 total PCI procedures/year (averaged over 2 years) with ≥11 of them primary PCI/year
- non-primary operators: perform≥50 total PCI procedures/year (averaged over 2 years)
- have complication rates and outcomes equivalent or superior to national benchmarks established by the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR).
- be “ABIM board certified in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams.”
- actively participates in the certified hospital quality assurance program

E4. Provide the total number of interventionists on the medical staff at your hospital: ☐

E5. Provide the total number of board certified interventionists on the medical staff: ☐

E6. Do all operators perform ≥50 total PCI procedures/year (including 11 primary PCIs for operators performing primary PCIs): ◯ Yes ◯ No

E7. Expected number of additional interventionists needed to support the Elective PCI Program: ☐

E8. Is individual PCI performance monitored for any operators with <50 total PCI procedures/year? ◯ Yes ◯ No

E9. Does the PCI program director have >500 lifetime PCI procedures? ◯ Yes ◯ No

E10. Documentation on how interventionist physicians would be available for the Elective PCI Program 24x7x365.

E11. If additional interventionists are required, how does your facility plan to obtain them and in what time frames?

SURGICALSTAFF

E12. Are any of the receiving hospital cardiac surgeons also on staff at your facility? ◯ Yes ◯ No

E12a. If yes, please provide the information below:

Cardiac surgeon name	On staff at which receiving hospital?	Date of privileging at your facility

E13. What are the roles and responsibilities of cardiac surgeons at your facility?

E14. Do the privileged cardiac surgeons participate in the quality assurance of cardiac catheterization at your facility? ◯ Yes ◯ No

If yes, please describe:

CATH LAB STAFF

E15. The SCAI/ACCF/AHA guidelines outline specific recommendations for cath lab personnel. Does your facility maintain cath lab nursing and technical staff with training in interventional laboratories and comfortable treating acutely ill patients with hemodynamic and electrical instability? ◯ Yes ◯ No

INTENSIVE CARE UNIT (ICU) AND/OR CARDIAC CARE UNIT (CCU) NURSING STAFF

E16. Where are intensive cardiac care and post-catheterization patients treated in your facility?

☐ ICU ☐ CCU ☐ both ☐ other:

E17. Plan for patient critical care if ICU and/or CCU are full

E18. The SCAI/ACCF/AHA guidelines outline specific recommendations for ICU/CCU personnel. Does your facility maintain ICU and/or CCU nursing staff who are experienced and comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, management of IABP, management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications? ◯ Yes ◯ No

F. CARDIAC CATHETERIZATION LABORATORY QUALITY ASSURANCE

***All attachments for Section F should be included as one electronic file (PDF or Word), named in the following format: facility name- Section F**

F1. Provide P&P and other documents for:

F1a. quality assurance in the hospital including the catheterization laboratory, pre- and post-catheterization patient areas, quality assurance committee membership, frequency of meetings, reporting hierarchy, etc.
F1b. required interventionist participation on the quality assurance committee, including required attendance and participation
F1c. benchmarking and quality improvement in the catheterization lab and related areas, include methodology for on-site data collection and assuring quality in this process. Must comply with SCAI/ACCF/AHA and NCDR guidelines.
F1d. current methodology for on-site outcomes analysis. Must comply with SCAI/ACCF/AHA and NCDR guidelines.
F1e. quality assurance for patient selection and exclusion
F1f. formalized periodic case review. In a separate attachment, describe the last 2 cases reviewed and outcome of the reviews.
F1g. review and follow up of all patients transferred for cardiac surgery, emergent or non-emergent, with or without the outcome of surgery and identification of any improvement opportunities. Provide details on the last 2 cases reviewed, including any improvement opportunities identified.
F1h. adverse event reporting and investigation

If requested, submit reports as follows:

F2. For the most recent twelve (12) months, individual interventionist and institutional risk-adjusted outcomes and quality of care for all procedures performed in the cardiac catheterization lab compared to state and national benchmarks as defined by the SCAI/ACCF/AHA and ACC-NCDR. If your facility subscribes to ACC-NCDR, you may submit the appropriate comprehensive quarterly and annual reports. If your facility does not subscribe to NCDR, then provide similar facility generated reports. Details on NCDR Cath PCI benchmark standards and reports can be obtained by contacting NCDR or the ACC.

F3. All adverse events from the most recent twelve (12) months associated with cardiac catheterization at your facility that occurred within 30 days of procedure, separated by type of adverse event, interventionist, outcome, and date of event. Provide at least one example of how your facility has applied its quality assurance principles and data to improve patient care after the occurrence of an adverse event.

F4. For each patient transferred for cardiac surgery after receiving either a diagnostic or interventional procedure at your facility, detail, at a minimum, type of procedure done at your facility, transfer times, reason for transfer, treatment at receiving hospital and patient outcome.

G. PATIENT TRANSFER TO CARDIAC SURGERY CENTERS

***All attachments for Section G should be included as one electronic file (PDF or Word), named in the following format: facility name-Section G**

The SCAI/ACCF/AHA, CCR and H&S Code section 1256.01 have well-defined criteria that hospitals without cardiac surgery on site must follow to ensure emergent patient transport to a cardiac surgery center.

GENERAL

G1. In the table below, provide details on the facility's transfer of ischemic heart disease (IHD) patients to cardiac surgery centers from the most recent twelve (12) months:

Patient Transfer History to Cardiac Surgery During the Most Recent Twelve (12) Months	Number of Patients
Total Number of IHD patients transferred to a cardiac surgery center	
Transferred before undergoing any cardiac catheterization procedure(s)	
Transferred after undergoing diagnostic cardiac catheterization procedure(s)	
Transferred due to adverse event from diagnostic cardiac catheterization	
Transferred for findings on diagnostic cardiac catheterization	
Transferred after undergoing interventional cardiac catheterization procedure(s)	
Transferred due to adverse event from interventional cardiac catheterization procedure	

G2. Transport protocols should be tested a minimum of twice per year. Provide evidence of transport protocol testing for the past 12 months.

G3. "Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in ≤30 min and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery. Tertiary facility must agree to accept emergent and non-emergent transfers for additional medical care, cardiac surgery or intervention. Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within <120 min of an urgent referral."

Provide documentation detailing distance, transport times, and transport methods for each cardiac surgery center with which your facility has an agreement.

LOCAL EMERGENCY MEDICAL SERVICE AGENCY (LEMSA) COORDINATION

G4. Does your LEMSA have a STEMI treatment protocol or plan? ◯ Yes ◯ No

Provide a copy of the county LEMSA plan, if available.

G5. Provide evidence that your facility has spoken with its county LEMSA and details of how your facility will integrate with existing local LEMSA services if your facility is approved as a certified hospital.

G6. Name of county LEMSA coordinator: Title:

Address 1:

Address 2:

City: State: Zip Code:

Telephone number: Fax number:

Email address:

TRANSPORT SERVICES

G7. Provide a copy of all current contracts with emergency medical service (EMS) capable of supporting advanced cardiac support emergency services to the cardiac surgery center(s) designated by your facility as a “receiving hospital(s)”. Transport contracts must:

- ensure provider is available to begin transport within ≤ 30minutes of the request and provide vehicle/helicopter with necessary life sustaining equipment, including intra-aortic balloon pump (IABP) and monitoring capability.
- ensure the immediate and efficient transfer of patients within 60minutes, 24x7x365 from certified hospital to the receiving hospital. Time for transfer of patients shall be calculated from the time it is determined that the transfer of a patient for emergency cardiac surgery is necessary at the eligible hospital to the time that the patient arrives at the receiving hospital.
- account for issues that may delay transport (i.e. weather, traffic patterns, and transport vehicles) and detail how these issues will be handled.

G8. Provide a letter from the management of each EMS noted below that their transport vehicles are capable of advanced life support and intra-aortic balloon pump support that is compatible with the applicant hospital’s systems.

G9. Name of EMS #1:
Contact Name:
Title:
Address 1:
Address 2:
City: State: Zip Code:
Telephone number: Fax number:
Email address:

G10. Name of EMS #2:
Contact Name:
Title:

Address 1:
Address 2:
City: State: Zip Code:
Telephone number: Fax number:
Email address:

RECEIVING CARDIAC SURGERY HOSPITAL(S):

In accordance with SCAI/ACCF/AHA guidelines, a formal and properly executed written agreement with a cardiac surgery center/receiving hospital that provides for the unconditional transfer of each non-primary PCI patient who requires additional care, including emergent or non-primary cardiac surgery or PCI, from the applicant hospital to the tertiary institution is required.

G11. Provide a copy of a current transfer agreement with at least one licensed GACH with cardiac surgery capabilities for emergency transfer of patients that, at a minimum, meets the transport time requirements in the SCAI/ACCF/AHA guidelines. The agreement must:

- state that cardiac surgeons and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours
- state that surgeon and receiving facility assure that the patient will be accepted based on medical condition, capacity of surgeons to provide services at the time of request and availability of resources.
- be signed by the administrations of both the transferring and receiving facilities

Provide one copy of Appendix B Cardiac Surgery Center Transfer Agreements to each receiving hospital with which your facility has an agreement. Submit the receiving hospitals response along with your facility's application.

G12. If a receiving hospital is not the closest cardiac surgery center geographically to your hospital, state why that hospital was chosen as the receiving facility. If this applies to more than one facility, document this for each receiving hospital involved.

H. ELECTIVE PCI PROGRAM INFORMATION

***All attachments for Section H should be included as one electronic file (PDF or Word), named in the following format: facility name-Section H**

This section expounds on the rules, regulations and guidelines related to the Elective PCI Program.

PATIENT SELECTION CRITERIA

Certified hospitals must follow stringent patient selection criteria, in accordance with the Current SCAI/ACCF/AHA guidelines. Patients managed under the elective PCI program must be selected and treated under these criteria. All patients receiving treatment in the cardiac catheterization lab

at an elective PCI program hospital must be included in the Cath PCI Registry, and in accordance with the ACC-NCDR guidelines.

DATA COLLECTION

Data collection at the certified hospitals must begin with the effective date of services and continue as long as the hospital participates in the program.

Each Elective PCI Program hospital is required to participate in the ACC-NCDR Cath PCI Registry throughout the term of the program.

H1. Are you already a member of the ACC-NCDR Cath PCI Registry? ◯Yes ◯No

H1a. If yes, provide the enrollment date: [ ]

H1b. If yes, does your facility input its cardiac catheterization lab data into the Cath PCI registry? ◯Yes ◯No

H1c. If no, advise your intention to enroll, expected date of enrollment and conditions thereof.

H1d. What third party interface software to the Cath PCI Registry does your facility currently use? [ ]

Facilities that do not participate in the ACC-NCDR Cath PCI Registry may not participate in the elective PCI program.

Each hospital will be required to follow guidelines regarding data entry, verification, and analysis, and quality and timeliness standards established by ACC-NCDR, SCAI/ACCF/AHA, CDPH and the Office of Statewide Health Planning and Development (OSHPD). Should CDPH elect to do so, all certified hospitals will be required to work with third-party representatives on data collection, verification, analysis and reporting. All hospitals will receive notification of any third-party representatives. Each hospital shall:

- ensure that data collection and reporting will only be performed by trained, competent staff and that such staff shall adhere to the ACC-NCDR standards. Provide staff names, dates, and locations for training on data entry upon completion.
- submit corrections to any data submitted to the ACC-NCDR Cath PCI Registry or CDPH as discovered by the hospital, by the ACC-NCDR, OSHPD, CDPH or its representative, in accordance with policies in place at that time. Data submitted must be at a level that the ACC-NCDR requires.
- designate an ACC-NCDR or data site manager that will serve as a primary contact between the hospital, the ACC-NCDR, OSHPD and CDPH and/or its representative, with regard to data reporting. The identity of each site manager shall be provided to CDPH upon certified hospital approval.

As specified in the SCAI/ACCF/AHA guidelines, “Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.” Programs failing to improve may have their certification suspended or revoked per H&S Code section 1256.01(h).

REPORTING

Each facility will be required to participate in, and provide timely submission of data to, the ACC-NCDR. Each facility must confer rights to transfer the data submitted to OSHPD. The performance for each individual certified hospital will be publicly reported on an annual basis.

Adverse events must be reported to CDPH as currently required by law.

Appendix C provides a sample of the state agency data release consent form that should be completed as part of your contract with ACC-NCDR. Provide a copy of the signed consent form along with your facility's application.

STATEMENT OF UNDERSTANDING AND AGREEMENT TO PARTICIPATE

We, _____ (hospital name), understand that:

1) This facility must comply with all existing federal, state, and local laws, rules and regulations, and conditions set forth in H&S Code section 1256.01.
2) If this certified hospital and/or its staff fail to achieve at or above national benchmark standards, this certified hospital status may be terminated.
3) If at any time a certified hospital fails to meet the criteria for being a certified hospital or fails to safeguard patient safety, as determined by the department, the department may suspend or revoke the certification issued to that hospital.
4) No interventionist who is not performing at or above national benchmark standards shall be permitted to perform procedures at this facility.
5) Failure to submit any required criteria or additional information shall disqualify the applicant from the application process and from consideration for participation in the program.
6) Any facility found to be performing or to have performed cardiac catheterizations outside of existing laws, rules, regulations, and guidelines established by the SCAI/ACCF/AHA and State of California will be considered non- compliant and will not be permitted to participate in the Elective PCI Program.
7) CDPH, its subcontractor and/or the oversight committee may make sites visits to any certified hospital at any time.
8) Beginning the 2nd year of implementation, certified hospitals must be performing greater than 200 total PCI's (primary and elective). Of those, greater than or equal to thirty-six (36) must be primary PCI'S. If at the beginning of Year Two of participation, a certified hospital cannot demonstrate that it will perform the minimum number of procedures, the facility hospital status may be terminated. Exceptions may be granted per SCAI/ACCF/AHA guidelines for facilities in underserved areas.

We agree to participate fully in the Elective PCI Program, under the direction of CDPH, its third-party representatives, OSHPD, and the Advisory Oversight Committee.

We agree to annual supplemental license fees that will be billed in addition to our current License and Certification fees. We understand that the amount of these fees will not exceed the total annual cost to CDPH or its subcontractor to oversee the program per year, divided among each participating hospital equally and considering percentage of resources used by each participating hospital.

We declare under penalty of perjury that the statements on this application and on the accompanying attachments are correct to our knowledge.

Signature

Title (Hospital Administrator) **Date:**

Signature

Title (Chief Financial Officer) _____ **Date** _____

Signature

Title (Chief of Cardiac Services) _____ **Date** _____

Signature

Title (Cardiac Catheterization Lab Director) _____ **Date** _____

*Signatures are required from each management position noted above.

APPENDIX A
POLICY AND PROCEDURE LIST

These P&Ps are listed by question number and in the order they appear in the application. Please refer to the application for the complete question.

Question Number	P&P
B8a	respiratory care staff support of cardiac catheterization patients in the ICU, CCU, and cath lab in both emergent and non-emergent situations.
C7a.	cardiac catheterization patient admission, transfer and discharge guidelines
C7b.	PCI patient selection and exclusion guidelines
C7c.	types of procedures permitted in the cath lab
C7d.	use of conscious sedation and/or anesthesia in the cath lab
C7e.	staffing requirements during procedures using conscious sedation and/or anesthesia
C7f.	required staffing of the cardiac catheterization team for both elective and non-elective
C7g.	procedures roles and responsibilities for each cath lab team member
C7h.	any allied health professionals permitted to work in the cath lab
C7i1.	which staff are privileged and permitted to perform endotracheal intubation
C7i2	which staff are privileged and permitted to perform ventilator management
C7i3.	which staff will transport with patient to cardiac surgery
C7i4.	qualification, certification or training required to perform endotracheal intubation, ventilator management, hemodynamic monitoring, temporary pacemaker operation and IABP
C7i5.	management required training for maintenance of skills
C7j.	use of heparin or other anticoagulants in the cath lab
C7k.	handling potential patients for contrast allergy
C7l.	emergency care or “code blue” in the cath lab
C7m.	emergency transport protocols for failed PCI, if not included in general transport P&P provided elsewhere
C7n.	door-to-balloon (d2b) time requirements, tracking, and reviewing of outlier cases for quality assurance
C7o.	obtaining informed consent from patients for all cardiac catheterization procedures as well as potential transport and cardiac surgery services.
C9a	STEMI treatment hospital-wide and date of policy implementation
C9b.	treatment of chest pain and non-STEMI
D5a.	equipment maintenance, including fluoroscopy
D5b.	regulating and monitoring radiation exposure in the cath lab
D17.	approval, procurement, inventory and maintenance of catheterization lab supplies
E3a.	interventionist qualifications, credentialing (including proctoring and privileging), ongoing training requirements and performance standards
E3b.	interventionist duties, roles and responsibilities
E3c.	interventionist shift and on-call scheduling, if appropriate
F1a.	quality assurance in the hospital
F1b.	required interventionist participation on the quality assurance
F1c.	committee benchmarking and quality improvement in the cath lab and related areas

F1d	current methodology for on-site outcomes analysis
F1e.	quality assurance for patient selection and exclusion
F1f.	formalized periodic case review
F1g.	review and follow up of all patients transferred for cardiac surgery
F1h.	adverse event reporting and investigation

P&P required from the receiving hospital

BB15c. accepting and prioritizing emergency transfer patients

APPENDIX B
CARDIAC SURGERY CENTER TRANSFER AGREEMENTS

***All attachments for Section BB should be included as one electronic file (PDF or Word), named in the following format: your facility name-Section BB**

Provide one copy of Appendix B Cardiac Surgery Center Transfer Agreement for each receiving hospital your facility has an agreement with. Submit the receiving hospital's response along with your facility's application in accordance with the guidelines specified.

Note to receiving hospital: When completing this document, "applicant hospital" refers to the facility with whom you have a transfer agreement and who is applying for participation as an elective PCI program hospital.

BB1. RECEIVING HOSPITAL NAME:
Address 1:

Address 2:
City: County: State: Zip Code:

BB2. Mailing address, if different from above:

Address 1 (if different than facility address):

Address 2:

City: County: State: Zip Code:

BB3. Telephone number: BB4. Fax number:

BB5. LOCATION OF CARDIAC SURGERY PROGRAM, IF DIFFERENT FROM ABOVE:
Address 1:

Address 2:

City: County: State: Zip Code:

BB6. Medicare Provider Number(s): BB7. National Provider Identifier:

BB8. California Facility License Number:
BB9. Name of receiving hospital administrator:
Title:
Professional license number: Expiration date: Date of hire:

Address 1 (if different than facility address):
City: State: Zip Code:

Address 2:
City: State: Zip Code:
Telephone number: Fax number:
Email address:

BB10. Name of person responsible for cardiac surgery: Title:

Professional license number: Expiration date: Date of hire:

Address 1 (if different than facility address):
City: State: Zip Code:

Address 2:
City: State: Zip Code:
Telephone number: Fax number:
Email address:

BB11. Is the receiving hospital affiliated with, or a subsidiary of, the applicant hospital?
Yes No
BB11a. If yes, provide details:

BB12. How will patients be transferred between the applicant hospital and your facility?

BB13. Detail the distance and the travel time required between your hospital and the applicant hospital:

BB14. Can a patient who experiences a complication at the referring hospital be reasonably transported to your facility and be in a surgical suite in less than 120 minutes from time EMS is initially notified of transfer? Yes No

BB14a. If yes, provide your facility's documented protocol:

BB15. Provide a letter from the administrator of the receiving hospital detailing the following:

BB15a. whether it is a member of the ACC-NCDR Cath PCI registry
BB15b. the number of transfer agreements it has with other cath labs, if any, and number of patients received for cardiac surgery from each facility on an annual basis
BB15c. its P&P for accepting and prioritizing emergency cardiac surgery transfer patients and how conflicts in operating room availability will be handled
BB15d. number of cardiac surgery operating rooms, operating teams and cardiac surgeons
BB15e. number of coronary arterial bypass grafting procedures it performs annually
BB15f. number of elective PCIs it performs annually

BB15g. confirmation that the receiving hospital has the ability to read real-time the audio, video images and hemodynamic data transferred from the applicant hospital cardiac catheterization lab
BB15h. names of interventionists who are on staff at both the applicant and receiving hospital
BB15i. a statement that the receiving hospital understands that if the applicant hospital is selected as a certified hospital, upon request, it must provide data to OSHPD, CDPH and/or its representatives on patients transferred from the participating certified hospital, and on its cardiac surgery and catheterization lab benchmark statistics

Appendix C
Sample State Agency Data Release
Consent Form

NOTE: The contents of this SAMPLE document are for example purposes only. Final content will be provided as part of the contracting process between ACCF and the appropriate State entity.

ADDENDUM TO THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION NATIONAL CARDIOVASCULAR DATA REGISTRY AGREEMENT BY AND BETWEEN THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION

AND

DATA RELEASE CONSENT FORM AUTHORIZING AND DIRECTING THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION TO TRANSMIT DATA FINDINGS TO OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT (OSHPD)

(“Participant”) and the American College of Cardiology Foundation (“ACCF”) acknowledge and agree as follows:

1. Participant has entered into an agreement with ACCF to provide certain data to ACCF’s National Cardiovascular Data Registry Cath PCI Registry and to receive certain comparative reports from ACCF (the “Agreement”).

2. The data provided by Participant to ACCF under the Agreement includes facility, physician, and patient-level data. Such data shall be referred to herein as the “ACC-NCDR Cath PCI Registry Data.” Participant acknowledges that in submitting ACC-NCDR Cath PCI Registry Data, it shall comply with the ACC-NCDR Cath PCI Registry Core Data Element Documentation, as described more fully in Paragraphs 2b and 2e of the Agreement.

3. Participant represents and warrants that it intends to apply for participation in the CDPH Elective PCI Program (“the Program”), including the execution of a Data Use Agreement as required by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

4. Participant acknowledges that it has been informed that ACCF and OSHPD have entered, or will enter, into an agreement for the purpose of providing Participant’s ACC-NCDR Cath PCI Registry Data in the form of an Aggregated Level Data Set as such term is defined at 45 C.F.R. Part 164.514 (e) (1).

“ACC-NCDR Cath PCI Registry Aggregate Level Data Set” to OSHPD for the sole purpose of providing such data for use in the Program for the duration of this Agreement.

5. Participant authorizes and directs ACCF to transmit ACC-NCDR Cath PCI Registry Data, based on ACC-NCDR Cath PCI Registry data submitted by Participant, to OSHPD for the purposes described in Paragraph 4 above.

6.This Addendum shall be effective for the duration of this Participant's participation in the Program. This Addendum may be terminated by Participant or ACCF upon written notice at any time. Termination of this Addendum shall not constitute a termination of the Agreement, unless otherwise provided by Participant or ACCF.

7. As amended by this Addendum, the Agreement is in all respects ratified and confirmed, and the Agreement and this Addendum shall be read, taken, and construed as one and the same instrument. To the extent any inconsistency exists between the HIPAA Appendix that is attached to the Agreement and this Addendum, the terms of such HIPAA Appendix shall control. In all respects not inconsistent with the terms of this Addendum, the Agreement is hereby ratified, approved, and confirmed.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Addendum to be executed on the day of , 20

PARTICIPANT	**ACCF**
Participant #: Signature: Title: Date:	Signature: Title: Date:

Please remit this completed form to the following address:
The American College of Cardiology Foundation