MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR CARDIAC CATHETERIZATION SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval of the initiation, replacement, expansion, or acquisition of cardiac catheterization services, and the delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code, cardiac catheterization services are a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) “Adult cardiac catheterization service” means providing cardiac catheterization services on an organized, regular basis to patients age 18 and above, and for electrophysiology procedures to patients age 15 and older.

(b) “Applicant” means one of the following types of facilities:

(i) Ambulatory surgical center (ASC) which is defined as any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416 that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

(ii) Freestanding surgical outpatient facility (FSOF) which is defined as a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned and operated as a part of a licensed hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the Code.

(iii) Hospital which is defined as a health facility licensed under Part 215 of the Code.

(c) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.

(d) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory. This term also does not include CIED procedures that are performed in an interventional radiology laboratory or operating room in a licensed hospital that has CON approval for diagnostic cardiac catheterization or in an FSOF that has CON approval for diagnostic cardiac catheterization and CIED procedures.

(e) "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric/congenital cardiac catheterizations.

(f) “Cardiac catheterization session” means a continuous time period during which a patient may undergo one or more diagnostic or therapeutic cardiac or peripheral procedures in a cardiac

catheterization laboratory. The term session applies to both adult and pediatric/congenital catheterizations.

(g) “Cardiac implantable electronic device (CIED) procedure” means any procedure involving the implantation, revision, relocation, or extraction of a pacemaker or ICD device, except leadless pacemakers. The term also includes all generator changes. The term also includes the insertion, revision, relocation, or extraction of all leads, except for procedures involving leads greater than 12 months old. A facility that provides CIED procedures may also perform right-sided cardiac ablation procedures except ventricular tachycardia ablations.

(h) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(i) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(j) “Complex therapeutic session” means a continuous time period during which a patient undergoes one or more of the following procedures:

(i) PCI for chronic total occlusion

(ii) TAVR, mitral/pulmonary/tricuspid valve repair or replacement, paravalvular leak closure

(iii) ablation for atrial fibrillation (AF) or ventricular tachycardia (VT), pacemaker or ICD lead extraction.

(k) “Coronary atherectomy” means orbital or rotational atherectomy for calcium modification.

(l) "Department" means the Michigan Department of Health and Human Services (MDHHS).

(m) “Diagnostic cardiac catheterization procedure” includes right heart catheterization, left heart catheterization, coronary angiography, coronary artery bypass graft angiography, intracoronary administration of drugs, fractional flow reserve (FFR), intra-coronary imaging such as intravascular ultrasound (IVUS), optical coherence tomography (OCT), or near-infrared spectroscopy (NIRS) when performed without a therapeutic procedure, intra-cardiac echocardiography, and diagnostic electrophysiology study.

(n) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart.

(i) A hospital that has CON approval for diagnostic cardiac catheterization services may also perform CIED procedures.

(ii) A FSOF that has CON approval for diagnostic cardiac catheterization and CIED procedures may also perform CIED procedures.

(iii) A facility that has CON approval for diagnostic cardiac catheterization services may also perform mechanical circulatory support, (e.g., IABP, Impella, etc.) pericardiocentesis, transvenous pacemaker, on an urgent or emergent basis to stabilize a patient.

(o) “Diagnostic cardiac catheterization session” means a continuous time period during which a patient may undergo one or more diagnostic cardiac catheterization procedures.

(p) “Diagnostic peripheral procedure” includes angiography or hemodynamic measurements in the arterial or venous circulation (excluding the heart).

(q) “Diagnostic peripheral session” means a continuous time period during which a patient may undergo one or more diagnostic peripheral procedures in a cardiac catheterization laboratory.

(r) “Elective percutaneous coronary intervention (PCI)” means a PCI procedure performed on a non-emergent basis.

(s) “Elective PCI services without on-site open heart surgery (OHS)” means performing PCI on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI expert consensus statement on percutaneous coronary intervention without on-site surgical backup (Grines cl et al, JSCAI Grines, Journal of the Society for Cardiovascular Angiography & Interventions, volume 2, issue 2, 2023) and its update or further guideline changes. A hospital that provides elective PCI without on-site OHS may also perform leadless pacemaker procedures, coronary atherectomy, and cardiac ablation procedures except ventricular tachycardia ablations. A facility that provides elective PCI without on-site OHS may also perform myocardial biopsy only on patients who have undergone a previous heart transplant.

(t) "Electrophysiology study" means a study of the electrical conduction activity of the heart and characterization of atrial and ventricular arrhythmias obtained by means of a cardiac catheterization procedure. The term also includes the implantation of permanent pacemakers and ICD devices.

(u) “Excess procedure equivalents” means the number of procedure equivalents performed by an existing cardiac catheterization service in excess of 1200 per cardiac catheterization laboratory and 300 PCI sessions (810 procedure equivalents) per service. The number of cardiac catheterization laboratories used to compute excess procedure equivalents shall include both existing and approved but not yet operational cardiac catheterization laboratories. In the case of a cardiac catheterization service that operates or has a valid CON to operate more than one laboratory at the same site, the term means number of procedure equivalents in excess of 1200 multiplied by the number of cardiac catheterization laboratories at the same site. For example, if a cardiac catheterization service operates, or has a valid CON to operate, 2 cardiac catheterization laboratories at the same site, the excess procedure equivalents is the number that is in excess of 2400 procedure equivalents and in excess of 300 PCI sessions (810 procedure equivalents).

(v) “ICD” means an implantable cardioverter defibrillator or a subcutaneous implantable cardioverter-defibrillator.

(w) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396g and1396i to 1396u.

(x) “Metropolitan counties” means counties designated by the Federal Office of Rural Health Policy (FORHP) as non-fully eligible counties.

(y) "Pediatric/congenital cardiac catheterization service" means providing cardiac and electrophysiology catheterization services on an organized, regular basis to infants and children ages 18 and below and patients born with congenital heart disease.

(z) “Percutaneous coronary intervention” (PCI) means a therapeutic cardiac catheterization procedure to resolve anatomic and/or physiologic problems in the coronary arteries of the heart. A PCI session may include several procedures including balloon angioplasty, atherectomy, laser, stent implantation and thrombectomy. The term does not include the intracoronary administration of drugs, FFR or IVUS where these are the only procedures performed.

(aa) “Peripheral catheterization session” means a continuous time period during which a patient may undergo one or more diagnostic or therapeutic procedures in the arterial or venous circulation (excluding the heart) when performed in a cardiac catheterization laboratory.

(bb) “Primary percutaneous coronary intervention (PCI)” means a PCI performed on an emergent basis on a patient with ST-Segment elevation, new left bundle branch block, ECG evidence of true posterior MI, or cardiogenic shock.

(cc) “Primary PCI service without on-site OHS” means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. A hospital that provides primary PCI without on-site OHS may also perform leadless pacemaker procedures and cardiac ablation procedures except ventricular tachycardia ablations.

(dd) “Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a cardiac catheterization laboratory based on the type of procedures being performed. If a diagnostic and therapeutic procedure is performed in the same session, the higher procedure equivalent weighting will be used to evaluate utilization.

(ee) “Rural area” means the counties designated by the Federal Office of Rural Health Policy (FORHP) as being fully eligible for rural health grant programs or the census tracts within metropolitan counties that have been determined by the FORHP to meet the criteria to be eligible for rural health grant programs. The department shall utilize the most recent list of areas eligible for rural health grant programs published by FORHP in making the determination.[1]

(ff) “Structural heart procedure” means a therapeutic cardiac catheterization procedure to resolve anatomic and/or physiologic problems of the heart valves or chambers. Procedures include: balloon valvuloplasty, balloon atrial septostomy, transcatheter valve repair, transcatheter valve implantation,

[1] Health Resources & Services Administration (HRSA)- Rural Service Areas and Target Populations - List of rural counties and designated eligible census tracts in metropolitan counties.

paravalvular leak closure, left atrial appendage occlusion, PFO/ASD/VSD/PDA closure, alcohol ablation of cardiac tissue, embolization of coronary fistulae and abnormal vascular connections in the heart.

(gg) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart.

(hh) “Therapeutic cardiac catheterization session” may include: cardioMEMS, PCI (elective, emergent), pericardiocentesis, cardiac ablation, structural heart procedures, pacemaker, ICD, lead, generator procedures, or myocardial biopsy. This also includes implantation of a circulatory support device such as IABP, Impella, ECMO or TandemHeart where this is the only therapeutic procedure. when PCI is performed in more than one coronary artery during the same setting, this is counted as one session.

(ii) “Therapeutic peripheral procedure” means a therapeutic catheterization procedure to resolve anatomic and/or physiologic problems in the arterial or venous circulation (excluding the heart). Procedures may include percutaneous transluminal angioplasty (PTA), atherectomy, drug eluting balloon, laser, stent implantation, IVC filter implantation or retrieval, catheter-directed ultrasound/thrombolysis, and thrombectomy.

(jj) “Therapeutic peripheral session” means a continuous time period during which a patient may undergo one or more therapeutic peripheral procedures in a cardiac catheterization laboratory.

(kk) “Therapeutic pediatric/congenital cardiac catheterization session” may include: structural heart procedure (as listed above), pulmonary artery angioplasty/stent implantation, pulmonary valve perforation, angioplasty/stent implantation for aortic coarctation, cardiac ablation, pacemaker/ICD implantation, and PCI.

(2) Terms defined in the Code have the same meanings when used in these standards.

Section 3. Requirements to initiate cardiac catheterization services

Sec. 3. An applicant hospital proposing to initiate cardiac catheterization services shall demonstrate the following, as applicable to the proposed project.

(1) An applicant hospital proposing to initiate an adult diagnostic cardiac catheterization service shall demonstrate the following as applicable to the proposed project:

(a) An applicant hospital proposing to initiate a diagnostic cardiac catheterization service with a single laboratory in a rural area shall project a minimum of 500 procedure equivalents including 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(b) An applicant hospital proposing to initiate a diagnostic cardiac catheterization service with a single laboratory in a metropolitan county shall project a minimum of 750 procedure equivalents that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(c) An applicant hospital proposing to initiate a diagnostic cardiac catheterization service with two or more laboratories shall project a minimum of 1,000 procedure equivalents per laboratory that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(2) An applicant hospital proposing to initiate an adult therapeutic cardiac catheterization service shall demonstrate the following:

(a) The applicant hospital provides, is approved to provide, or has applied to provide adult diagnostic cardiac catheterization services at the hospital. The applicant hospital must be approved for adult diagnostic cardiac catheterization services in order to be approved for adult therapeutic cardiac catheterization services.

(b) An applicant hospital operating an adult diagnostic cardiac catheterization service has performed a minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterizations during the most recent 12-month period preceding the date the application was submitted to the Department if the service has been in operation more than 24 months.

(c) The applicant hospital has applied to provide adult OHS services at the hospital. The applicant hospital must be approved for an adult OHS service in order to be approved for an adult therapeutic cardiac catheterization service.

(d) The applicant hospital shall project a minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(3) An applicant hospital proposing to initiate a pediatric/congenital cardiac catheterization service shall demonstrate the following:

(a) The applicant hospital has a board certified pediatric cardiologist with training in pediatric/congenital catheterization procedures to direct the pediatric catheterization laboratory.

(b) The applicant hospital has standardized biplane equipment as defined in the most current American Academy of Pediatrics (AAP) and American College of Cardiology Foundation (ACCF)/Society for Cardiovascular Angiography and Interventions (SCAI) guidelines for pediatric cardiovascular centers.

(c) The applicant hospital has on-site pediatric and neonatal ICU as outlined in the most current AAP and ACCF/SCAI guidelines above.

(d) The applicant hospital has applied to provide pediatric OHS services at the hospital. The applicant hospital must be approved for a pediatric OHS service in order to be approved for pediatric/congenital cardiac catheterization services.

(e) The applicant hospital has on-site pediatric extracorporeal membrane oxygenation (ECMO) capability as outlined in the most current ACCF/SCAI guidelines.

(f) A pediatric/congenital cardiac catheterization service shall have a quality assurance plan as outlined in the most current ACCF/SCAI guidelines.

(g) The applicant hospital shall project a minimum of 600 procedure equivalents in the category of pediatric/congenital cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services

Sec. 4. An applicant proposing to initiate primary or elective PCI services without on-site OHS services shall demonstrate the following, as applicable:

(1) An applicant hospital proposing to initiate primary or elective PCI without on-site OHS services shall demonstrate the following:

(a) The applicant hospital operates an adult diagnostic cardiac catheterization service that is in full compliance with Section 10(4)(a) of these standards during the most recent 12 months preceding the date the application was submitted to the Department.

(b) The applicant hospital has at least two interventional cardiologists to perform the PCI procedures and each cardiologist has performed at least 50 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date the application was submitted to the Department.

(c) The nursing and technical catheterization laboratory staff are experienced in handling acutely ill patients and comfortable with interventional equipment; have acquired experience in dedicated interventional laboratories at an OHS hospital; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency shall be documented annually.

(d) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional equipment.

(e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management. Competency shall be documented annually.

(f) A written agreement with an OHS hospital that includes all of the following:

(i) Involvement in credentialing criteria and recommendations for physicians approved to perform PCI procedures.

(ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.

(iii) Provision for ongoing cross training for emergency department, catheterization laboratory, and critical care unit staff to ensure experience in handling the high acuity status of PCI patient candidates. Competency shall be documented annually.

(iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all PCI cases.

(v) Development and ongoing review of patient selection criteria for PCI patients and implementation of those criteria.

(vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt care.

(vii) Written protocols, signed by the applicant hospital and the OHS hospital, for the immediate transfer within 60 minutes travel time from the cardiac catheterization laboratory to evaluation on site in the OHS hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. If the applicant hospital can demonstrate that there is no OHS service within 60 radius miles or 60 minutes travel time from the proposed site, then the OHS hospital can be more than 60 minutes travel time from the proposed site. The protocols shall be reviewed and tested on a quarterly basis.

(viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.

(g) A written protocol must be established and maintained for case selection for the performance of PCI.

(h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer from the emergency department to the cardiac catheterization laboratory must be developed and maintained so that door-to-balloon targets are met.

(i) At least two physicians credentialed to perform PCI must commit to functioning as a coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate with administrative and clinical staff in establishing and implementing protocols, call schedules, and quality assurance procedures pertaining to PCI designed to meet the requirements for this certification and in keeping with the current guidelines for the provision of PCI without on-site OHS services promulgated by the American College of Cardiology and American Heart Association.

(j) The applicant hospital shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within PCI services without on-site OHS services, and the applicant hospital shall identify a physician point of contact for the data registry.

(k) Cath lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI Services Without On-Site OHS including the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of demonstrating compliance with these criteria in their application.

(l) The applicant hospital shall project the following based on data from the most recent 12-month period preceding the date the application was submitted to the Department, as applicable.

(i) If the applicant hospital is applying for a primary PCI service without open heart surgery, the applicant hospital shall project a minimum of 36 primary PCI procedures per year.

(ii) If the applicant hospital is applying for an elective PCI service without on-site OHS, the applicant hospital shall project a minimum of 200 PCI procedures per year if located in a metropolitan county, or 100 PCI procedures per year if located within a rural area .

(m) An applicant hospital shall agree that, if approved, it will not begin performing left-sided ablations until it has performed at least 10 right-sided ablations in a 12 month period.

(n) If the applicant hospital is applying for an elective PCI service without on-site OHS, the applicant hospital also shall demonstrate the following:

(i) The applicant hospital operated a primary PCI service for at least one year prior to the date of application.

(ii) The applicant hospital submitted data to a data registry administered by the Department or its designee and been found to have acceptable performance as compared to the registry benchmarks for the most recent 12 months prior to the date of application.

(o) If the applicant hospital is currently providing OHS services and therapeutic cardiac catheterization services and is proposing to discontinue OHS services and therapeutic cardiac catheterization services, then the applicant hospital shall apply to initiate primary and elective PCI services without on-site OHS using this section. The applicant hospital shall demonstrate all of the requirements in this section and is subject to all requirements in Section 10.

(2) An applicant FSOF proposing to initiate diagnostic cardiac catheterization and elective PCI shall demonstrate the following:

(a) The applicant has identified at least one interventional cardiologist to perform the diagnostic cardiac catheterizations and PCI procedures who has performed at least 50 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date this application was submitted to the Department. The interventional cardiologist shall have completed an interventional cardiology fellowship training program, be board certified in interventional cardiology, have performed a total of at least 250 PCI sessions as the primary operator, and have a minimum of 2 years experience at an attending level.

(b) The applicant has identified nursing and technical catheterization laboratory staff that are experienced in handling acutely ill patients and comfortable with interventional equipment and have acquired experience in dedicated interventional laboratories at an OHS hospital. Competency shall be documented annually.

(c) The applicant has identified cardiac care unit nurses who are adept in hemodynamic monitoring and IABP management. Competency shall be documented annually.

(d) The laboratory or laboratories will be equipped with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional equipment. The laboratories will be equipped with systems for assessing hemodynamic significance of coronary lesions (i.e., FFR, IFR, or other) and intracoronary imaging technology (i.e., IVUS or OCT) for ensuring PCI optimization.

(e) A written agreement with an OHS hospital that is within 30 minutes travel time that includes all of the following:

(i) Involvement in credentialing criteria and recommendations for physicians approved to perform PCI procedures.

(ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.

(iii) Regularly held joint cardiology/catheterization laboratory conferences to include review of PCI cases.

(iv) Development and ongoing review of patient selection criteria for PCI patients and implementation of those criteria.

(v) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt care.

(vi) Written protocols, signed by the applicant and the OHS hospital, for the immediate transfer from the cardiac catheterization laboratory to evaluation on site in the OHS hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. The protocols shall be reviewed and tested on a quarterly basis.

(vii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.

(f) A written protocol shall be established and maintained for case selection for the performance of PCI consistent with the case selection criteria documented in the SCAI Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers (Box et al. Catheter Cardiovasc Interv. 2020;1-9).

(g) The applicant shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within PCI services without on-site OHS services, and the applicant shall identify a physician point of contact for the data registry.

(h) Cath lab facility requirements shall conform to the Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers (Box et al. Catheter Cardiovasc

Interv. 2020;1-9). The applicant shall be liable for the cost of demonstrating compliance with the principles documented in this Position Statement in their application.

(i) The applicant shall project the following based on verifiable data from the most recent 12-month period preceding the date the application was submitted to the Department, as applicable:

(i) If the applicant is proposing a single lab, at least 750 procedure equivalents total, including at least 540 procedures equivalents from elective PCIs (200 PCI sessions).

(ii) If the applicant is proposing multiple labs, at least 1,000 procedure equivalents per lab, including at least 540 procedure equivalents total from elective PCIs (200 PCI sessions).

(j) The applicant shall have or obtain within 12 months of beginning operations Ambulatory Surgery Center (ASC) Certification or Hospital Outpatient Department (HOPD) status from the Centers for Medicare and Medicaid Services (CMS). An applicant that does not currently hold the certification shall attest that the certification will be obtained within 12 months of beginning operations.

(3) An applicant FSOF proposing to perform CIED procedures shall demonstrate all of the following:

(a) The FSOF is approved to perform diagnostic cardiac catheterization and elective PCI or is applying to provide both of those services as a part of this application.

(b) The applicant is located less than 30 minutes travel time from a hospital with OHS service.

(c) The applicant has or will have cardiac catheterization lab capabilities including pericardiocentesis equipment on site.

(d) The applicant has identified at least one physician who meets all of the following:

(i) is cardiology board certified for permanent pacemaker implants;

(ii) is EP board certified for ICD implants;

(iii) has active privileges for implanting devices, moderate sedation, and admitting at the hospital identified in (3)(b);

(iv) has at least 2 years of post-fellowship experience as an implanter; and

(v) has implanted at least 75 devices as the primary operator in the previous 2 years post fellowship training.

(e) The applicant shall project at least 100 CIED procedures.

(f) The applicant shall have or obtain within 12 months of beginning operations Ambulatory Surgery Center (ASC) Certification or Hospital Outpatient Department (HOPD) status from the Centers for Medicare and Medicaid Services (CMS). An applicant that does not currently hold the certification shall attest that the certification will be obtained within 12 months of beginning operations.

Section 5. Requirements to replace an existing cardiac catheterization service or laboratory

Sec. 5. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray equipment or a relocation of the service to a new site. The term does not include a change in any of the other equipment or software used in the laboratory. An applicant proposing to replace a cardiac catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:

(1) An applicant proposing to replace cardiac catheterization laboratory equipment shall demonstrate the following:

(a) The existing laboratory or laboratories to be replaced are fully depreciated according to generally accepted accounting principles or demonstrates either of the following:

(i) The existing angiography x-ray equipment to be replaced poses a threat to the safety of the patients.

(ii) The replacement angiography x-ray equipment offers technological improvements that enhance quality of care, increases efficiency, and reduces operating costs.

(b) The existing angiography x-ray equipment to be replaced will be removed from service on or before beginning operation of the replacement equipment.

(2) An applicant hospital proposing to replace a cardiac catheterization service to a new site shall demonstrate the following:

(a) The proposed project is part of an application to replace the entire hospital.

(b) The applicant hospital has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:

(i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

(ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.

(iii) A minimum of 600 procedure equivalents in the category of pediatric/congenital cardiac catheterization procedures.

(iv) A minimum of 500 procedure equivalents for a hospital in a rural area with one laboratory.

(v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.

(vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for a hospital with two or more laboratories.

(c) The existing cardiac catheterization service has been in operation for at least 36 months as of the date the application has been submitted to the Department.

(3) An applicant hospital proposing to replace a cardiac catheterization service to a new site simultaneously with an open heart surgery service shall demonstrate the following:

(a) The existing cardiac catheterization service to be replaced has been in operation for at least 36 months as of the date an application is submitted to the Department.

(b) The proposed new site is a hospital that is owned by, is under common control of, or has a common parent as the applicant hospital.

(c) The proposed new site is the same site where the existing OHS service is to be located which is within the same planning area as the OHS service and within 5 miles of the existing OHS and cardiac catheterization service if located in a metropolitan county or within 10 miles of the existing OHS and cardiac catheterization service if located in a rural area .

(d) The existing cardiac catheterization service to be relocated performed at least the applicable minimum number of cardiac catheterization cases set forth in Section 10 as of the date an application is deemed submitted by the Department.

Section 6. Requirements to expand a cardiac catheterization service

Sec. 6. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall demonstrate the following:

(1) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:

(a) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

(b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.

(c) A minimum of 600 procedure equivalents in the category of pediatric/congenital cardiac catheterization procedures.

(d) A minimum of 540 procedure equivalents in the category of PCI procedures.

(2) The applicant has performed a minimum of 1,400 procedure equivalents per existing and approved laboratories during the most recent 12-month period preceding the date the application was submitted to the Department.

Section 7. Requirements to acquire a cardiac catheterization service

Sec. 7. Acquiring a cardiac catheterization service and its laboratories means obtaining possession and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for

existing angiography x-ray equipment. An applicant proposing to acquire a cardiac catheterization service or renew a lease for equipment shall demonstrate the following as applicable to the proposed project:

(1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the following:

(a) The proposed project is part of an application to acquire the entire facility.

(b) An application for the first acquisition of an existing cardiac catheterization service after February 27, 2012 shall not be required to be in compliance with the applicable volume requirements in Section 10. The cardiac catheterization service shall be operating at the applicable volumes set forth in the project delivery requirements in the second 12 months of operation of the service by the applicant and annually thereafter.

(c) For any application proposing to acquire an existing cardiac catheterization service, except the first application approved pursuant to subsection (b), an applicant shall be required to document that the cardiac catheterization service to be acquired is operating in compliance with the volume requirements set forth in section 10 of these standards applicable to an existing cardiac catheterization service on the date the application is submitted to the Department.

(2) An applicant proposing to renew a lease for existing angiography x-ray equipment shall demonstrate the renewal of the lease is more cost effective than replacing the equipment.

Section 8. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)

Sec. 8. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an angiography system performing minimally invasive procedures of the heart and blood vessels with full anesthesia capabilities. An applicant hospital or FSOF proposing to add one or more hybrid OR/CCLs at an existing or proposed cardiac catheterization service shall demonstrate each of the following:

(1) The applicant hospital operates or proposes to operate a diagnostic cardiac catheterization service and a primary or elective PCI service without on-site OHS; or a therapeutic service; and is in compliance with sections 3, 4, and 10 of these standards as applicable.

(2) The applicant FSOF operates, or proposes to operate, a diagnostic cardiac catheterization service and elective PCI service and is in compliance with section 4 and 10 of these standards, as applicable.

(3) The applicant agrees to perform only those cardiac catheterization procedures in the hybrid OR/CCL that are authorized under the applicable definitions of service levels approved at the facility.

(4) The applicant shall submit a document explaining the justification of adding the hybrid OR/CCL and outlining the operational narrative for utilizing the hybrid or/ccl and what types of procedures will be performed.

(5) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories at the facility, the applicant facility is in compliance with section 4 or Section 6 of these standards.

(6) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s), the applicant facility is in compliance with the provisions of Section 5, if applicable.

(7) The applicant facility meets the applicable requirements of the CON Review Standards for Surgical Services.

(8) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

(9) For each hybrid OR/CCL approved and operational, a facility shall have 0.5 excluded from its inventory of cardiac catheterization laboratories for the purposes of computing the procedure equivalents per room, for replacement under section 5, for expansion under section 6, for acquisition under section 7, and for project delivery requirements as applicable under section 10. A facility for which all of its operating room(s) are hybrid OR/CCL(s) shall not have 0.5 excluded from its inventory of cardiac catheterization laboratories for the purposes of computing the procedure equivalents per room for expansion under section 6. A facility will not be limited to the number of hybrid OR/CCL(s) within a single licensed facility.

Section 9. **Requirement for Medicaid participation**

Sec. 9. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is initiating a new service or is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 10. Project delivery requirements and terms of approval for all applicants

Sec. 10. An applicant shall agree that, if approved, the cardiac catheterization service and all existing and approved laboratories shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.
(2) Compliance with the following quality assurance standards:
(a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory that has within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.
(b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability.
(c) The medical staff and governing body shall receive and review at least annual reports describing the activities of the cardiac catheterization service including complication rates, morbidity and mortality, success rates and the number of procedures performed.
(d) Each physician credentialed by a facility to perform diagnostic left-heart catheterization and/or coronary angiography must perform, as the primary operator, an average of at least 50 diagnostic cardiac catheterization sessions involving a left-heart catheterization or coronary angiography per year averaged over the most recent 2 years starting in the second 12 months after being credentialed. This two-year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means a cardiac catheterization session in which that physician performed, as the primary operator, at least one left-heart catheterization or coronary angiography, in any combination of facilities. Physicians falling below this volume requirement must be placed on a focused professional practice evaluation (FPPE) plan***,*** which must include an independent review of all diagnostic cardiac catheterization sessions by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician diagnostic procedure volume will be annualized on the 24-month period preceding the absence. When a diagnostic cardiac catheterization session and ad hoc therapeutic cardiac catheterization session are performed together, diagnostic and therapeutic sessions are counted separately for the purposes of this subsection. If a physician is doing right heart only procedures, then they are not required to meet this volume requirement. Physicians who are credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures are not required to meet the volume requirement for diagnostic cardiac catheterization sessions.
(e) Each physician credentialed by a facility to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, an average of at least 50 adult therapeutic cardiac catheterization sessions per year averaged over the most recent two years starting in the second 12 months after being credentialed. This two-year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization sessions performed by that physician in any combination of facilities. Physicians falling below this volume

requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must include an independent review of all therapeutic cardiac catheterization sessions by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician therapeutic procedure volume will be annualized on the 24-month period preceding the absence. When a diagnostic cardiac catheterization session and ad hoc therapeutic cardiac catheterization session are performed together, diagnostic and therapeutic sessions are counted separately for the purposes of this subsection (this includes interventional cardiologists and electrophysiologists). For interventional cardiologists, the therapeutic session volume excludes pacemaker and ICD implantation. For electrophysiologists, pacemaker and ICD implants performed in an operating room may also be counted toward the physician therapeutic volume.

(f) Each physician credentialed by a hospital to perform pediatric/congenital cardiac catheterizations shall perform, as the primary operator, an average of at least 50 pediatric/congenital cardiac catheterization sessions per year averaged over the most recent 2 years starting in the second 12 months after being credentialed. This two-year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means pediatric/congenital cardiac catheterization sessions performed by that physician in any combination of hospitals. Physicians falling below this volume requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must include an independent review of all cardiac catheterization sessions by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician therapeutic procedure volume will be annualized on the 24-month period preceding the absence.

(g) Each physician credentialed by a primary PCI or an elective PCI hospital to perform left-sided ablations shall perform, as the primary operator, an average of at least 50 adult left-sided ablation sessions per year averaged over the most recent two years starting in the second 12 months after being credentialed. This two-year average will be evaluated on a rolling basis annually thereafter. the annual case load for a physician means adult left-sided ablation sessions performed by that physician in any combination of facilities. Physicians falling below this volume requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must include an independent review of left-sided ablation sessions by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician left sided ablation volume will be annualized on the 24-month period preceding the absence.

(h) Each physician credentialed by an elective PCI hospital to perform coronary atherectomy procedures shall perform, as the primary operator, an average of at least 10 coronary atherectomy procedures per year averaged over the most recent two years starting in the second 12 months after being credentialed. This two-year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means coronary atherectomy procedures performed by that physician in any combination of facilities. Physicians falling below this volume requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must include an independent review of all coronary atherectomy procedures by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician coronary atherectomy procedure volume will be annualized on the 24-month period preceding the absence.

(i) Each physician credentialed by an FSOF to perform PCI shall meet the following criteria:

(i) has performed at least 50 PCI sessions annually as the primary operator during the most recent preceding 24 months;

(ii) has completed an interventional cardiology fellowship training program;

(iii) is board certified in interventional cardiology;

(iv) has performed a total of at least 250 PCI sessions as the primary operator; and

(v) has a minimum of 2 years experience at an attending level.

(j) Each physician credentialed by a FSOF to perform CIED procedures shall meet the following criteria:

(i) performed at least 75 device implants as the primary operator in the previous 24 months;
(ii) has at least 2 years of post-fellowship experience as an implanter;
(iii) is cardiology board certified for permanent pacemaker implants;
(iv) is cardiology or EP board certified for ICD implants; and
(v) has active privileges for implanting devices, moderate sedation, and admitting at the hospital identified in Section 4(3)(b).

(k) Each physician credentialed by an elective PCI hospital to perform left-sided ablations shall meet the following criteria:
(i) has performed at least 150 ablation procedures as the primary operator in the previous 24 months;
(ii) has at least 2 years of post-fellowship experience;
(iii) is EP board certified; and
(iv) has active privileges for performing ablations and admitting at the hospital identified in section 4(1).

(l) Each physician credentialed by an elective PCI hospital without on-site OHS to perform coronary atherectomy shall meet the following criteria:
(i) has performed a total of at least 50 coronary atherectomy procedures as the primary operator post- fellowship;
(ii) has at least three years of experience as the primary operator for coronary atherectomy procedures post-fellowship; and
(iii) is board certified in interventional cardiology

(m) Each physician credentialed to perform right-sided ablations shall meet the following criteria:
(i) has performed at least 150 ablation procedures as the primary operator in the previous 24 months;
(ii) has at least 2 years of post-fellowship experience.
(iii) is EP board certified for ablation; and
(iv) has active privileges for performing ablations and admitting at the hospital identified in section 4(3)(b).

(n) An adult diagnostic cardiac catheterization service shall have a minimum of two physicians on its active staff meeting the following criteria:
(i) are trained consistent with the recommendations of the American College of Cardiology;
(ii) are credentialed by the facility to perform adult diagnostic cardiac catheterizations; and
(iii) have performed a minimum of 100 adult diagnostic cardiac catheterization sessions in the preceding 12 months. The annual case load for a physician means a cardiac catheterization session in which that physician performed, as the primary operator, at least one diagnostic cardiac catheterization, in any combination of facilities.

(o) An adult therapeutic cardiac catheterization service shall have a minimum of two physicians on its active hospital staff meeting the following criteria:
(i) are trained consistent with the recommendations of the American College of Cardiology;
(ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
(iii) have performed a minimum of 50 adult therapeutic cardiac catheterization sessions in the preceding 12 months. The annual case load for a physician means a cardiac catheterization session in which that physician performed, as the primary operator, at least one therapeutic cardiac catheterization, in any combination of hospitals.

(p) A pediatric/congenital cardiac catheterization service shall have at least one physician on its active hospital staff meeting the following criteria:
(i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
(ii) is credentialed by the hospital to perform pediatric/congenital cardiac catheterizations; and
(iii) has trained consistently with the recommendations of the American College of Cardiology.

(q) A pediatric/congenital cardiac catheterization service shall maintain a quality assurance plan as outlined in the most current ACCF/SCAI Guidelines.

(r) A diagnostic cardiac catheterization and elective PCI program located at an FSOF shall obtain Ambulatory Surgery Center (ASC) Certification or Hospital Outpatient Department (HOPD) status from

the Centers for Medicare and Medicaid Services (CMS) within 12 months of beginning operations and shall have at least one interventional cardiologist on its active staff meeting the following criteria:

(i) has performed at least 50 PCI sessions annually as the primary operator during the most recent 24-month period;

(ii) has completed an interventional cardiology fellowship training program;

(iii) is board certified in interventional cardiology;

(iv) has performed a total of at least 250 PCI sessions as the primary operator; and

(v) has a minimum of 2 years experience at an attending level.

(s) An FSOF performing CIED procedures shall have at least one electrophysiologist on its active staff meeting the following criteria:

(i) is cardiology board certified for PPM implants;

(ii) is EP board certified for ICD implants;

(iii) has active privileges for implanting devices, moderate sedation, and admitting at the hospital identified in Section 4(3)(b);

(iv) has at least 2 years of post-fellowship experience as an implanter; and

(v) has implanted at least 75 devices as the primary operator in the previous 2 years post fellowship training.

(t) A cardiac catheterization service shall be directed by an appropriately trained physician. The Department shall consider appropriate training of the director if the physician is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an adult cardiac catheterization service shall have performed at least 100 catheterizations per year during each of the five preceding years. The Department may accept other evidence that the director is appropriately trained.

(u) A cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

(v) The applicant facility providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service shall participate with a data registry administered by the Department or its designee that monitors quality and risk adjusted outcomes.

(3) Compliance with the following access to care requirements:

(a) The service shall accept referrals for cardiac catheterization from all appropriately licensed practitioners.

(b) The service shall participate in Medicaid at least 12 consecutive months within the first two years of operation and annually thereafter.

(c) The service shall not deny cardiac catheterization services to any individual based on ability to pay or source of payment.

(d) The operation of and referral of patients to the cardiac catheterization service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

(4) Compliance with the following monitoring and reporting requirements:

(a) The service shall be operating at or above the applicable volumes in the second 12 months of operation of the service, or an additional laboratory, and annually thereafter:

(i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures for a hospital in a metropolitan county.

(ii) 150 procedure equivalents in the category of adult cardiac catheterization procedures, excluding peripheral, for a hospital in a rural area.

(iii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.

(iv) 600 procedure equivalents in the category of pediatric/congenital cardiac catheterization procedures.

(v) 250 procedure equivalents for a hospital in a rural area with one laboratory.

(vi) 750 procedure equivalents for a hospital in a metropolitan county or an FSOF with one laboratory.

(vii) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.
(viii) 36 adult primary PCI cases for a primary PCI service without on-site OHS service.
(ix) 200 adult PCI procedures for an elective PCI service without on-site OHS service located in a hospital within a metropolitan county or FSOF.
(x) 100 adult PCI procedures for an elective PCI service without on-site OHS service located in a hospital located within a rural area.
(xi) 100 CIED procedures for an FSOF providing CIED services.

(b) The applicant shall participate in a data collection network established and administered by the Department or its designee. Data may include, but is not limited to, annual budget and cost information, operating schedules, patient demographics, morbidity and mortality information, and payor. The Department may verify the data through on-site review of appropriate records.

(c) The applicant hospital providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within cardiac catheterization services. The Department or its designee shall require that the applicant hospital submit summary reports as specified by the Department. The applicant hospital shall provide the required data in a format established by the Department or its designee. The applicant hospital shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant hospital shall become a member of the data registry specified by the Department upon initiation of the service and continue to participate annually thereafter for the life of that service.

(d) The applicant facility shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(5) Compliance with the following primary and elective PCI requirements for facilities providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service, if applicable:

(a) The requirements set forth in Section 4.

(b) The hospital shall immediately report to the Department any changes in the interventional cardiologists who perform the primary PCI procedures.

(c) The hospital shall maintain a 90-minute door-to-balloon time or less in at least 75% of the primary PCI sessions (excluding patients with cardiogenic shock).

(d) The applicant facility shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within PCI services by service level. The Department or its designee shall require that the applicant facility submit all consecutive PCI cases performed within the facility and meet data submission timeliness requirements and threshold requirements for PCI data submission, accuracy and completeness established by a data registry administered by the Department or its designee. The applicant facility shall provide the required data in a format established by the Department or its designee. The applicant facility shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant facility shall become a member of the data registry specified by the Department upon initiation of the service and continue to participate annually thereafter for the life of that service. At a minimum, the applicant facility shall report the following as applicable:

(i) the number of patients treated with and without STEMI,
(ii) the proportion of PCI patients with emergency CABG or required emergent transfer,
(iii) risk and reliability adjusted patient mortality for all PCI patients and a subset of patients with STEMI,
(iv) PCI appropriate use in elective non-acute MI cases, and
(v) rates of ad-hoc multi-vessel PCI procedures in the same session.

(e) The applicant facility shall maintain a physician point of contact for the data registry.

(f) For primary PCI services without on-site OHS service and elective PCI services in a hospital without on-site OHS service, catheterization lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the

SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of demonstrating compliance with these criteria.

(g) For diagnostic cardiac catheterization and elective PCI services at an FSOF, catheterization lab facility requirements shall conform to the Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers (Box et al. Catheter Cardiovasc Interv. 2020;1-9). The applicant facility shall be liable for the cost of demonstrating compliance with the principles documented in this position statement.

(h) The Department shall use these thresholds and metrics in evaluating compliance: performance at a level above the 50th percentile of the statewide performance on each metric listed under subsection

(i) The Department shall notify those facilities that fail to meet any of the minimally acceptable objective quality metric thresholds including those under subsection (d)(ii) – (v). The Department shall require these facilities to:

(i) submit a corrective action plan within one month of notification and

(ii) demonstrate that performance has improved to meet or exceed all applicable objective quality metric thresholds, including those under subsection (d)(ii) – (v), within 12 months of notification.

(j) The applicant initiating elective PCI without on-site OHS services, whether in a hospital or FSOF, shall have Accreditation for Cardiovascular Excellence (ACE) accreditation or an equivalent body perform an on-site review within 3, 6, and 12 months after implementation. The applicant shall submit the summary reports of the on-site review to the Department and maintain on-going accreditation.

(6) Compliance with all of the following requirements for FSOFs and hospitals without on-site OHS service, providing CIED procedures:

(a) Maintain a written transfer agreement and protocols with the hospital identified in Section 4(3)(b).

(b) Maintain cardiac catheterization lab capabilities including pericardiocentesis equipment on site.

(c) Report acute outcomes of procedures to a registry identified by the Department.

(d) Maintain device follow up protocols.

(7) The applicant shall provide notice to the Department of any planned decrease or discontinuation of service(s) no later than 30 days after the planned decrease or discontinuation of the service(s).

(8) Nothing in this section prohibits the Department from taking compliance action under MCL 333.22247.

(9) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 11. Methodology for computing cardiac catheterization equivalents

Sec. 11. The following shall be used in calculating procedure equivalents and evaluating utilization of a cardiac catheterization service and its laboratories:

Procedure	Description	Procedure equivalent	
		Adult	**Pediatric**
Diagnostic cardiac catheterization/ peripheral session	Right heart catheterization, left heart catheterization, coronary angiography, coronary artery bypass graft angiography, intracoronary administration of drugs, fractional flow reserve (FFR), intra-coronary imaging [intravascular ultrasound (IVUS), optical coherence	1.5	2.7

Procedure	Description	Procedure equivalent	
		Adult	Pediatric
	tomography (OCT)] when performed without a therapeutic procedure, intra-cardiac echocardiography (ICE), diagnostic electrophysiology study, angiography in the peripheral arterial or venous circulation		
Therapeutic cardiac catheterization session	PCI, pericardiocentesis, cardiac ablation, cardiac biopsy, coronary atherectomy, structural heart procedures, and/or pacemaker, ICD, lead, or generators procedures as well as IABP, Impella, ECMO, or TandemHeart when this is the only therapeutic procedure	2.7	4.0
Therapeutic peripheral session	Percutaneous transluminal angioplasty (PTA), atherectomy, laser, stent implantation, IVC filter implantation or retrieval, catheter-directed ultrasound/thrombolysis, thrombectomy	2.7	4.0
Complex therapeutic session	PCI for chronic total occlusion (CTO), TAVR, mitral/pulmonary/tricuspid valve repair or replacement, paravalvular leak closure, ablation for atrial fibrillation (AF) or ventricular tachycardia (VT), pacemaker or ICD lead extraction	4.0	7.0
Prolonged therapeutic session	Cardiac therapeutic session >6 hours	6.0	7.0
Procedure equivalents from peripheral diagnostic and therapeutic procedures count toward the volume requirement for initiation of cardiac catheterization services (Section 3) and expansion of a cardiac catheterization service (Section 6).			

Section 12. Documentation of projections

Sec. 12. An applicant required to project volumes shall demonstrate the following as applicable to the proposed project:

(1) The applicant shall specify how the volume projections were developed and shall include only those sessions performed in a cardiac catheterization laboratory.

(a) The applicant shall include a description of the data source(s) used as well as an assessment of the accuracy of the data used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

(b) The Department shall subtract any previous commitment, pursuant to subsection 4(d).

(2) An applicant hospital proposing to initiate a primary PCI service shall demonstrate and certify that the hospital treated or transferred 36 ST segment elevation AMI cases during the most recent 12-month period preceding the date the application was submitted to the Department. Cases may include thrombolytic eligible patients documented through pharmacy records showing the number of doses of thrombolytic therapy ordered and medical records of emergency transfers of AMI patients to an appropriate hospital for a primary PCI procedure.

(3) An applicant proposing to initiate an elective PCI service without on-site OHS services, whether in a hospital or FSOF, shall demonstrate and certify that the proposed service shall treat 200 or more patients, or 100 or more patients if a hospital is located in a rural area , with PCI annually using data from the most recent 12-month period preceding the date the application was submitted to the Department as follows and applicable:

(a) All primary PCIs performed at the applicant hospital.

(b) All registered patients transferred from the applicant hospital to another hospital for PCI.

(c) 90% of patients who received diagnostic cardiac catheterizations at the applicant facility and received an elective PCI at another cardiac catheterization service within 30 days, for an applicant in a metropolitan county or 60 days for an applicant in a rural area , of the diagnostic catheterization (based on physician commitments).

(d) 50% of the elective PCI procedures performed by the committing physician at another cardiac catheterization service within 20 miles from the proposed service for patients who did not receive diagnostic cardiac catheterization at the applicant facility (based on physician commitments).

(e) An applicant hospital with current OHS services and therapeutic cardiac catheterization services that is proposing to discontinue OHS services and therapeutic cardiac catheterization services and is applying to initiate primary or elective PCI services without on-site OHS services may count all primary and elective PCI at the applicant hospital within the most recent 12-month period preceding the date the application was submitted to the Department.

(4) If a projected number of sessions under subsection (1) or (3) includes procedures performed at another existing cardiac catheterization service(s), an applicant shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing cardiac catheterization service(s) is in compliance with the volume requirements applicable to that facility, and will continue to be in compliance with the volume requirements applicable to that facility subsequent to the initiation, expansion, or replacement of the cardiac catheterization services proposed by an applicant. Only excess procedure equivalents equal to or greater than what is being committed pursuant to this subsection may be used to document projections under this subsection. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) The name of each physician that performed cardiac catheterization session to be transferred to the applicant cardiac catheterization facility.

(b) The number of cardiac catheterization sessions each physician identified in subdivision (a) performed during the most recent 12-month period for which verifiable data is available.

(c) The location(s) at which the cardiac catheterization sessions to be transferred were performed, including evidence that the existing location and the proposed location are within 20 miles of each other.

(d) A written commitment from each physician identified in subdivision (a) that he or she will perform at least the volume of cardiac catheterization sessions to be transferred to the applicant cardiac catheterization service for no less than 3 years subsequent to the initiation, expansion, or replacement of the cardiac catheterization service proposed by an applicant.

(e) The number of cardiac catheterization sessions performed at the existing cardiac catheterization service from which cardiac catheterization sessions will be transferred during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable data is available.

(f) Subsection 4(d) shall not apply if the proposed project involves the initiation of a cardiac catheterization service at a new FSOF at a new geographical site utilizing the historical cardiac catheterization procedure equivalents of the applicant and the new service is owned by the same applicant. The applicant facility committing cardiac catheterization sessions data has completed the departmental form that certifies the cardiac catheterization sessions were performed at the committing facility and the cardiac catheterization procedure equivalents will be transferred to the proposed cardiac catheterization service for no less than three years subsequent to the initiation of the cardiac catheterization service proposed by the applicant.

Section 13. Comparative reviews; Effect on prior CON Review Standards

Sec. 13. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON Review Standards supersede and replace the CON Review Standards for Cardiac Catheterization Services approved by the CON Commission on June 12, 2025, and effective on August 27, 2025.