

Section 405.29 - Cardiac Services

Effective Date

09/25/2019

405.29 Cardiac Services

(a) Definitions. For the purposes of this section, the following terms shall have the following meanings:

(1) Adult patient means a patient 18 years of age or older at the time of admission;

(2) Pediatric patient means a patient who has not reached their eighteenth birthday at the time of admission to the hospital;

(3) Cardiac Surgery Center means a general hospital that is approved through the certificate of need process to perform surgery on the heart and great vessels, and is approved for and provides cardiac diagnostic and interventional services including, but not limited to percutaneous coronary interventions (PCI) and diagnostic cardiac angiography procedures. Heart transplant procedures may only be performed at Cardiac Surgery Centers that are also approved as heart transplant centers in accordance with standards at Section 709.9 of this Title and approved for organ sharing by the United Network for Organ Sharing (UNOS). Cardiac Surgery Centers must operate in compliance with this Section, and must meet the construction provisions of Part 711 and Part 712 of this title. Cardiac Surgery Centers may be approved to serve adult patients (Adult Cardiac Surgery Centers) and or pediatric cardiac patients (Pediatric Cardiac Surgery Centers). However, separate certificate of need approvals are required for Adult and Pediatric Cardiac Surgery Centers in accordance with standards at Section 709.14 of this Title.

(4) Cardiac Catheterization Laboratory Center means a general hospital approved through the certificate of need process to perform catheter based procedures in specially equipped laboratories. Such laboratories are rooms with specialized radiological equipment and supplies used primarily to perform cardiac based angiographic or electrophysiological (EP) procedures on the heart or great vessels. Cardiac Catheterization Laboratory Centers may be approved to serve adult and or pediatric cardiac patients, but separate certificate of need approvals are required in accordance with standards at Section 709.14 of this Chapter for each service. Cardiac Catheterization Laboratory Centers must operate in compliance with standards set forth in this section. Cardiac Catheterization Laboratory Centers are further categorized by the procedures performed as defined below:

(i) A PCI capable cardiac catheterization laboratory center performs percutaneous coronary and other percutaneous procedures to diagnose and treat abnormalities of the heart or great vessels in adult patients. Such PCI capable cardiac catheterization laboratory centers may be approved with or without cardiac surgery at the same hospital site, however, those with no cardiac surgery on site must meet additional criteria at subparagraph (c)(8)(i) of this section;

(ii) A Diagnostic Cardiac Catheterization Service performs catheter based angiographic procedures on the heart or great vessels and is strictly limited to the diagnosis of abnormalities in adult patients. Such hospitals must maintain an affiliation with a Cardiac Surgery Center as specified in subparagraph 405.29(c)(8)(i) of this section, and are subject to annual review by DOH to determine the continuing operation of the center. Catheter based interventional procedures, such as percutaneous coronary intervention, are prohibited at Diagnostic Cardiac Catheterization Service hospitals;

(iii) A Cardiac EP Laboratory Program shall be located in a Cardiac Catheterization Laboratory Center and is approved through the certificate of need process to perform catheter based cardiac electrophysiology (EP) procedures. Such programs may be approved with or without cardiac surgery at the same hospital site, however, those with no cardiac surgery on site must meet additional criteria at paragraph 405.29(e)(5) of this section.

(iv) A Pediatric Cardiac Catheterization Laboratory Center shall be located at a Cardiac Surgery Center approved through the certificate of need process to provide cardiac surgery to pediatric patients and is approved to perform catheter based diagnostic and interventional procedures on pediatric patients; and

(5) Cardiac Reporting System is a New York State reporting system that gathers demographic, clinical, procedural and outcomes information from Cardiac Surgery Centers and Cardiac Catheterization Laboratory Centers on every patient who has undergone a surgical procedure or a percutaneous interventional procedure on the heart or great vessels. The Cardiac Reporting System includes separate reporting modules to capture procedure specific data elements for the procedure (cardiac surgery or percutaneous interventions) and age group (adult or pediatric) involved.

(b) State Cardiac Advisory Committee. There shall be a State Cardiac Advisory Committee consisting of physicians and other professionals with expertise in cardiac care appointed by the Commissioner of Health. The State Cardiac Advisory Committee shall, at the request of the Commissioner, consider any matter relating to Cardiac Services including, but not limited to review of existing and prospective services, and shall advise the Commissioner thereon.

(c) General Provisions.

(1) Cardiac Catheterization Laboratory Center services shall be limited to general hospitals.

(2) Hospitals shall not admit patients for cardiac surgery or cardiac catheterization laboratory procedures unless the hospital is approved to provide such services.

(3) Hospitals that provide cardiac surgery, Diagnostic Cardiac Catheterization Service, interventional cardiac laboratory services including percutaneous coronary intervention (PCI) and other percutaneous cardiac interventions, or cardiac electrophysiology (EP) must comply with subdivision 405.22 (a) of this Part.

(4) Review and Approval. Site visits to and or data and record reviews from existing and prospective new centers by the Department, members of the Cardiac Advisory Committee or other designees of the Commissioner shall be made as indicated, as an adjunct to initial approval and or for

consideration of continued approval. Such site visits and reviews shall include, but not be limited to, evaluation of data, review of service specific quality of care, and compliance with minimum workload standards as set forth in this section.

(5) Closure.

(i) Failure to meet one or more statutory or regulatory requirements or inactivity in a program for a period of 6 months may result in actions to include: probationary status, withdrawal of approval as a Cardiac Surgery Center and or Cardiac Catheterization Laboratory Center.

(ii) Voluntary Closure. The hospital must give written notification, including a closure plan to the Department at least 60 days prior to planned discontinuance of Cardiac Surgery or Cardiac Catheterization Laboratory Center Services. No Cardiac Surgery Center and no Cardiac Catheterization Laboratory Center shall discontinue operation without first obtaining written approval from the Department.

(6) Notification of significant changes. A hospital must notify the Department of Health in writing within 7 days of any significant changes in its Cardiac Surgery Center or Cardiac Catheterization Laboratory Center services including, but not limited to, any temporary or permanent suspension of services; departure of or change in the physician program director; if the program is without a physician credentialed to perform one or more of the procedures or services of the Cardiac Surgery Center or Cardiac Catheterization Laboratory Center; or inability to meet workload requirements.

(7) Data collection and reporting. Data as deemed necessary by the Commissioner shall be maintained for cardiac patients treated by the hospital and submitted upon request to the Department of Health in a format specified by the Department. Such data shall include, but not be limited to data documenting appropriate case selection and or appropriate access to care and, Cardiac Reporting System data for Cardiac Surgery Centers and Cardiac Catheterization Laboratory Centers.

(8) Quality Assurance. There shall be an organized quality assurance program for cardiac surgery and cardiology that requires participation by all clinical members of the cardiac surgery team and or cardiac laboratory team and includes: monitoring of volume and outcomes; morbidity and all case mortality review; regular multidisciplinary conferences including all health professionals involved in the care of cardiac patients; medical/nursing audit; utilization review, pre hospital and post hospital care review, and a system that assesses pre-operative risk and evaluates outcome trends. Quality improvement efforts must recognize that patients move through multiple systems of care (EMS, Emergency Department, catheterization laboratory etc.) and optimum quality improvement efforts must include participation from as many systems as possible to address those issues at the juncture of systems of care.

(i) In addition, cardiac catheterization laboratory centers located in hospitals with no cardiac surgery on-site must enter into and comply with a fully executed written clinical sponsorship agreement with a New York State cardiac surgery center. The agreement will include provisions that address, at a minimum:

(a) cardiac surgery center representatives shall participate in the affiliated cardiac catheterization laboratory center hospital's quality assurance committee and other reviews of the quality of

cardiac care provided by the affiliated cardiac catheterization laboratory center and in the provision of recommendations for quality improvement of cardiac services. Each cardiac surgery center and each affiliated cardiac catheterization laboratory center hospital shall take actions necessary, including but not limited to entering into a written agreement to authorize such participation by the cardiac surgery center representatives in the affiliated cardiac catheterization laboratory center hospital's quality assurance committee and for purposes of such participation, the cardiac surgery center representative or representatives shall be deemed members of the affiliated cardiac catheterization laboratory center hospital's quality assurance committee. Cardiac surgery center representatives may only access confidential patient information for quality assurance committees as set forth in the affiliation agreements and these regulations. Members of hospitals' quality assurance committees must maintain the confidentiality of patient information and are subject to the confidentiality restrictions of Public Health Law Section 2805-m and other applicable confidentiality restrictions as provided by law. The cardiac surgery center representative(s) shall participate in the review of information and data for quality improvement purposes as described in the agreement which may include:

- (1) statistical data and reports used in quality improvement activities;
 - (2) the affiliated cardiac catheterization laboratory center hospital's quality improvement program, policies, and procedures;
 - (3) care provided by medical, nursing, and other health care practitioners associated with the cardiac services;
 - (4) appropriateness and timeliness of patient referrals and of patients retained at the affiliated cardiac catheterization laboratory center hospital who met criteria for transfer to the cardiac surgery center hospital; and
 - (5) adverse events or occurrences including death and major complications for patients receiving cardiac care at the affiliated cardiac catheterization laboratory center hospital.
- (b) joint cardiology/cardiac surgery conferences to be held at least quarterly, with a focus on continuous quality improvement to include review of: all cardiac laboratory related morbidity and mortality, review of a random selection of uncomplicated routine cases, patient selection, rates of normal outcomes for diagnostic studies performed, rates of studies needed to be repeated prior to intervention, quality of the studies conducted, rates of patients referred for and receiving interventional procedures subsequent to the diagnostic cardiac catheterization procedure, and the number and duration of cardiac catheterization laboratory system failures;
- (c) a mechanism for a telemedicine link between the cardiac catheterization laboratory center and the cardiac surgery center that provides the capability for off-site review of digital studies, and a commitment on the part of each hospital to provide timely treatment consultation by appropriate physicians on an as needed basis;
- (d) the cardiac surgery center's involvement in developing privileging criteria for physicians performing cardiac catheterization procedures at the hospital with no cardiac surgery on-site;

(e) development and ongoing review of patient selection criteria and review of implementation of those criteria. The process shall include a comprehensive review of the appropriateness of treatment for a random selection of cases;

(f) consultation on equipment, staffing, ancillary services, and policies and procedures for the provision of cardiac catheterization laboratory procedures;

(g) a pre-procedure risk stratification tool which ensures that high risk and or complex cases are treated at a cardiac surgery center;

(h) procedures to provide for appropriate patient transfers between facilities;

(i) an agreement to notify the department of any proposed changes to the initial agreement and to obtain department approval prior to the change;

(j) an agreement to jointly sponsor and conduct annual studies of the impact that the cardiac catheterization laboratory center service has on costs and access to cardiac services in the hospital's service area;

(k) a plan for how the proficiency of physicians, nurses and other staff at the affiliated cardiac catheterization laboratory center will be maintained through rotational or other training opportunities; and

(l) a plan for how the cardiac catheterization laboratory center will maintain the capacity to provide PCI services on a 24 hour a day, 365 days a year basis and be capable of assembling a dedicated team within 30 minutes of the activation call to provide coronary interventions 24 hours a day and 365 days each year.

(ii) The Department's Cardiac Surgery Center reviews, as specified at paragraph 405.29(c)(4), shall include review of the quality of the services the Cardiac Surgery Center has provided to each of the Cardiac Catheterization Laboratory Centers with which it has a written agreement as specified at subparagraph 405.29(c)(8)(i); and

(iii) Cardiac Surgery Centers with one or more affiliated Cardiac Catheterization Laboratory Centers shall provide professional education and training for physicians, nurses and other staff of the affiliated centers for which it provides quality of care review. Education and training shall be designed to update and enhance staff knowledge and familiarity with relevant procedures and technological advances.

(9) The hospital must have written policies and procedures clearly delineating medical equipment vendor activities in the hospital including restrictions on vendor participation in clinical services.

(10) Cardiac Surgery Centers shall be approved to operate as PCI Capable Cardiac Catheterization Laboratory Centers without a separate certificate of need (CON) approval, but must operate in compliance with standards at 405.29 (e) (1) and 405.29 (e) (2) of this Title.

(11) Hospitals with approved cardiac catheterization laboratories approved prior to July 1, 2009 to perform PCI with no cardiac surgery on site shall be approved to operate as PCI Capable Cardiac Catheterization Laboratory Centers without a Certificate of Need approval but must operate in compliance with standards at 405.29(e)(1) and 405.29(e)(2) of this Title.

(12) Hospitals with approved cardiac catheterization laboratories approved prior to July 1, 2009 to perform cardiac electrophysiology procedures shall be approved to operate as Cardiac EP Laboratory Programs without a Certificate of Need approval but must operate in compliance with standards at 405.29(e)(1) and 405.29(e) (5) of this Title.

(d) Cardiac Surgery Center Criteria. The following criteria apply to Cardiac Surgery Centers approved to perform adult and or pediatric cardiac surgery. The cardiac surgery services must be provided in a manner which protects the health and safety of the patients in accordance with generally accepted standards of medical practice:

(1) Direction. The physician director is responsible for the overall quality of the cardiac surgical program and carries out this responsibility through the administrative structure of the institution, including but not limited to the governing body. The hospital must notify the Department of Health within 7 days of any change in the cardiac surgery program director, together with the name and curriculum vitae of the new director. The director shall be a qualified physician board certified in Thoracic Surgery or meet accepted equivalent training and experience.

(i) The Director shall:

(a) Continuously monitor the performance of all surgeons working in the cardiac surgical program, including each individual surgeon's annual case load and level of competence. The director shall advise the Chief of Service, Hospital Medical Director and Credentials Committee on requirements for credentialing and privileging within the cardiac surgery department and will provide assessments of compliance with standards of care, policies and guidelines as part of the credentialing and privileging process;

(b) In conjunction with the medical staff, monitor the quality and appropriateness of cardiac related patient care and ensure that identified problems are reported to the quality assurance committee and are resolved; and

(c) Assure the timely and accurate reporting of the cardiac surgery component of Cardiac Reporting System data to the Department.

(2) Structure and Service Requirements. Hospitals providing cardiac surgery services shall be adequately staffed and equipped for cardiac diagnostic and therapeutic services including, but not limited to cardiac surgery, percutaneous coronary interventions (PCI) and diagnostic cardiac catheterization and, in addition, provide the following:

(i) For Adult Cardiac Surgery Centers:

(a) Cardiac Surgical intensive care, organized, staffed and available on a 24 hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required by adult cardiac surgery patients, and

(b) coronary care organized, staffed and available on a 24-hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required of complex cardiac conditions, and

(c) PCI Capable Cardiac Catheterization Laboratory Center services meeting standards at 405.29(e)(1) and 405.29(e)(2).

(ii) For Pediatric Cardiac Surgery Centers: age appropriate intensive care, organized, staffed and available on a 24-hour basis by clinical personnel trained and equipped to meet the needs of pediatric patients undergoing cardiac surgery, and Pediatric Cardiac Catheterization Laboratory Center services meeting standards at 405.29(e)(1) and 405.29(e)(4).

(iii) For all Cardiac Surgery Centers:

(a) Operating Rooms adequately staffed and equipped for the needs of the Cardiac surgery patient;

(b) Preoperative and post operative care areas to serve the needs of the surgery patient;

(c) A qualified cardiac surgeon must be immediately available for consultation. The surgeon must remain available (arrive on-site within 20 minutes of being called) after each cardiac surgery procedure. The surgeon must remain available until at least such time that the patient is evaluated on post operative day one and for a clinically appropriate period of time thereafter to handle cardiac surgery emergencies;

(d) The hospital must assure that a cardiac surgery team is immediately mobilized for handling cardiac surgery emergencies. In the event that a patient must return on an emergency basis to the operating room, appropriate resources shall be immediately available in order to have the patient in the operating room and the team ready within 20 minutes of an identified surgical emergency. There shall be written documentation of a triage protocol including identification of specific responsibilities;

(e) Non-invasive cardiac diagnostic equipment and capabilities;

(f) In addition, the hospital shall provide clinical support services in keeping with generally accepted standards. Such services shall be integrated and available on an inpatient basis, but there shall also be adequately and appropriately organized outpatient services to preclude unnecessary hospitalization and ensure continuity of care;

(g) Cardiac surgery conferences shall be held no less than 10 times per year at which the staff reviews the studies of a statistically significant number of cases. Records of these conferences indicating attendance, cases reviewed and decisions on patient management shall be maintained; and

(h) The hospital shall attempt to determine and document the status of the patient at 30 days post surgery for those who are no longer inpatient and throughout the hospital stay for those who are discharged from the cardiac surgery service to another service within the hospital. Status shall include living or deceased and other pertinent criteria as determined by the Commissioner.

(3) Staffing. All personnel shall be qualified for their responsibilities through appropriate training and educational programs.

(i) Physicians shall all be residency trained and board certified, or meet accepted equivalent training and experience for physicians in their respective specialty and shall be appropriately credentialed and privileged as part of the medical staff, and shall be available in sufficient numbers

and on a 24 hour basis to meet the needs of the cardiac surgery patients. Such specialists shall, at a minimum include:

(a) Cardiothoracic surgeons in sufficient numbers to meet the ongoing needs of the patients, and each of whom performs a minimum of 50 cardiac surgeries per year. Review by the physician director shall be conducted and provided to the Chief of Service, Hospital Medical Director and Medical Staff

Credentials Committee for all physicians whose annual volume is below 50 cardiac surgeries to determine what actions are deemed necessary. In addition, for programs approved to perform pediatric cardiac surgery, cardiac surgeons with advanced training and or with significant experience in pediatric cardiac surgery to meet the needs of the pediatric patients;

(b) Anesthesiologist(s), who have acceptable minimum experience with cardiac surgical procedures;

(c) Specialists with expertise in critical care and the care of post cardiac surgery patients;

(d) Cardiologists to care for adults and, for programs approved to care for pediatric patients, pediatric cardiologists, with expertise in children's cardiovascular diseases, each of whom meet qualifications in accordance with generally accepted standards from recognized specialty organizations; and

(e) Complement of additional physicians shall be in keeping with generally accepted standards to meet the needs of cardiac surgery patients and shall include, but not be limited to practitioners, readily available for consultation in additional specialties, including hematology, pulmonology, neurology, nephrology and clinical pharmacology.

(ii) Nurses. Nursing personnel shall be certified in advanced cardiac life support (ACLS) or meet acceptable equivalent training and experience and shall include:

(a) A registered professional nurse, with 24-hour accountability, in charge of coordinating the care of post cardiac surgery patients and in charge of staffing levels for the unit;

(b) Registered professional nurses, licensed practical nurses and nursing assistants in such ratios that are commensurate with the type and amount of nursing needs of the patients.

(iii) Nurse Practitioners, Advanced Practice Nurses and or Registered Physician Assistants may be utilized when these specialists are appropriately credentialed and privileged on the medical staff.

(iv) The Cardiac Surgery Center shall have perfusionists who have special training and experience in an active program of open heart surgery, including a thorough background in sterile techniques, perfusion physiology, and the use of monitoring equipment and must demonstrate, through a formal review process, competencies in these areas. The operator may be a specially trained physician, nurse, or technician, at the discretion of the director of the center.

(v) The Cardiac Surgery Center shall have a data manager who has special training in the clinical criteria used in the cardiac surgery module of the Cardiac Reporting System as provided by the Department or its designee, is designated and authorized by the hospital and shall work in collaboration with the physician director to ensure accurate and timely reporting of Cardiac

Reporting System data to the Department. In addition to the data manager, relevant medical and administrative staff must be trained in the use of the Cardiac Reporting System and the specific data element definitions involved.

(4) Patient Selection Criteria and Limitations. Criteria shall be adopted by the Cardiac Surgery Center to be used as indications of appropriate case selection. Such criteria shall be in keeping with generally accepted standards and, at a minimum, shall provide the following limitations:

(i) The hospital shall not perform heart transplantation unless the hospital is a Cardiac Surgery Center approved for heart transplantation and approved for organ sharing by UNOS;

(ii) The hospital shall not electively admit patients for implantable ventricular assist devices unless the hospital is a Cardiac Surgery Center approved for heart transplantation or has an agreement with at least one New York State heart transplantation center that provides for appropriate consultation and expertise for such cases;

(iii) The hospital shall not admit patients under the age of 18 for cardiac surgery unless the hospital is a Cardiac Surgery Center approved for pediatric cardiac surgery or unless the patient's diagnosis indicates a condition, such as acquired heart disease, that can be most appropriately treated in an adult program with pediatric trained personnel and pediatric consultative services. Such exceptions must be supported by written documentation of consultation with a pediatric cardiologist; and

(iv) Cardiac Surgery Centers approved to perform pediatric cardiac surgery that are not also approved as Adult Cardiac Surgery Centers shall not admit patients over the age of 18 for cardiac surgery unless the procedure will be performed to treat a congenital anomaly and the hospital can meet the additional clinical needs of the patient.

(5) Minimum workload standards. There shall be sufficient utilization of a Cardiac Surgery Center to insure both quality and economy of services, as determined by the Commissioner. An institution seeking to maintain approval shall present evidence that the annual minimum workload standards have been achieved and maintained. The following annual minimum workload standards must be achieved within two years following initiation of the service to ensure both quality and economy of services:

(i) Adult Cardiac Surgery Centers shall maintain an annual minimum of 100 procedures on adult patients; and

(ii) Pediatric Cardiac Surgery Centers shall maintain an annual minimum of 75 pediatric cardiac surgery procedures excluding the number of isolated Patent Ductus Arteriosus (PDA) repairs. The annual minimum volume shall be deemed to be met when two or more Pediatric Cardiac Surgery Centers, at least one of which must perform a minimum of 75 pediatric cardiac surgery procedures a year (excluding isolated PDA repairs), join in a coordinated program based on a fully executed written agreement, approved by the Commissioner, and the combined volume of the collaborating Pediatric Cardiac Surgery Centers (excluding the number of PDA repairs) is greater than 100 procedures a year. The agreement between the collaborating hospitals must include, at a minimum, information on: quality improvement, peer review and coordination of care of patients between the coordinated Pediatric Cardiac Surgery Centers. The agreement must specify that the

Department will be provided 60 day prior written notice of any proposed change, termination or expiration of the agreement. Changes must be found acceptable to the Department prior to implementation and any proposed termination or expiration of the agreement will result in termination of the coordinated Pediatric Cardiac Surgery Center program.

(6) Waiver of minimum workload standards. The Commissioner may waive the workload requirements upon a satisfactory showing by a Cardiac Surgery Center as determined by the Commissioner upon seeking advice from Cardiac Advisory Committee representatives that the quality of care provided is adequate as supported, at a minimum, by a review of cases and outcome trends conducted by the Department, and:

(i) There are extenuating circumstances precluding compliance with the workload requirements; and or

(ii) There is documented evidence that need for cardiac surgery in the hospital's geographical service area would be substantially unmet if the program were closed.

(e) Cardiac Catheterization Laboratory Center Criteria

(1) The following criteria apply to all Cardiac Catheterization Laboratory Centers. Cardiac Catheterization Laboratory Center services must be provided in a manner which protects the health and safety of the patients in accordance with generally accepted standards of medical practice.

(i) Direction. The physician director is responsible for the overall quality of the Cardiac Catheterization Laboratory Center and must have the appropriate authority to carry out those responsibilities through the support of the Chief of Cardiology, the Medical Director of the hospital and the hospital administration. The hospital must notify the Department within 7 days of a change in the directorship of the Cardiac Catheterization Laboratory Center, together with the name and curriculum vitae of the new director;

(ii) Qualifications of the Director. The director must be Board certified in Internal Medicine and the subspecialty of Cardiac Disease or meet equivalent standards, be experienced in the performance of procedures specific to type of Cardiac Catheterization Laboratory Center services provided, have good management skills and must be appropriately credentialed and privileged as a member of the medical staff;

(iii) The Director shall:

(a) Continuously monitor the performance of all cardiologists working in the Cardiac Catheterization Laboratory Center, including but not limited to, each cardiologist's annual case load requirement and level of competence. The director shall advise the Chief of Service, the Hospital Medical Director and the Credentials Committee on requirements for credentialing and privileging in the Cardiac Catheterization Laboratory Center and shall provide assessments of compliance with standards of care, policies and guidelines as part of the credentialing and privileging process;

(b) In conjunction with the medical staff, monitor the quality and appropriateness of cardiac related patient care and ensure that identified problems are reported to the quality assurance committee and are resolved; and

(c) For centers approved as PCI Capable Cardiac Catheterization Laboratory Centers, assurance of the timely and accurate reporting the Cardiac Catheterization Laboratory Center module of the Cardiac Reporting System data to the Department.

(iv) Structure and Service Requirements:

(a) All Cardiac Catheterization Laboratory Centers must provide diagnostic services, including but not limited to diagnostic radiology, clinical laboratory, and invasive and noninvasive cardiac diagnostic procedures. Such services shall be available on an inpatient and outpatient basis;

(b) All Cardiac Catheterization Laboratory Centers must have a process in place that allows for appropriate transfer of cases to a higher level of care to handle cardiac emergencies;

(c) Cardiac Catheterization Laboratory Centers approved to provide care to adult patients must provide Coronary Care organized, staffed and available on a 24-hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required of complex cardiac conditions;

(d) Cardiac Catheterization Laboratory Centers approved to perform pediatric procedures must provide age appropriate intensive care, organized, staffed and available on a 24-hour basis by clinical personnel trained and equipped to meet the needs of pediatric patients undergoing cardiac laboratory procedures;

(e) Cardiology conferences shall be held no less than 10 times per year at which the staff reviews the studies of a statistically significant number of cases. Records of these conferences indicating attendance, cases reviewed and decisions on patient management shall be maintained;

(f) Records of the disposition of the cases shall be maintained in compliance with standards set forth in section 405.10 of this Title;

(g) The number of patients referred annually for surgery and the center(s) to which they are referred shall be maintained and readily available upon request from the Department of Health;

(h) Statistics shall be kept on the number of normal invasive cardiac diagnostic studies performed, and written criteria shall be adopted and used for determining when a study is to be considered abnormal. Such criteria shall be in keeping with generally accepted standards of medical practice; and

(i) The hospital shall ensure high quality imaging and radiation protection for patients and personnel in accordance with Section 405.15 of this Title.

(j) In addition to standards at subparagraph (c)(8)(i) of this section, for cardiac catheterization laboratory centers approved under a clinical sponsorship agreement as set forth in section 709.14(d)(5) of this Title, the written and signed clinical sponsorship agreement between a cardiac surgery center and the cardiac catheterization laboratory center without cardiac surgery on site must be maintained and must specify that the department shall be provided 60 day prior written

notification of any proposed change, termination or expiration of the agreement, any changes must be found acceptable to the department prior to implementation and any proposed termination or expiration shall require prior submission of a plan of closure to the department. The agreement shall provide for an integration of expertise and resources from the cardiac surgery center that would support a high quality program at the hospital without cardiac surgery on site, and shall delineate responsibilities of each institution. The agreement shall further provide that the parties agree that termination or expiration of the agreement shall result in closure of the co-operated cardiac catheterization laboratory center.

(v) Staffing. All personnel shall be qualified for their responsibilities through appropriate training and educational programs.

(a) Physicians shall all be board certified, or meet accepted equivalent training and experience for physicians in their respective specialty, and shall be appropriately credentialed and privileged as part of the medical staff. Such specialists shall, at a minimum, include a cardiologist and or pediatric cardiologist depending upon the age group(s) served; a cardiac angiographer whose basic medical training is in keeping with generally accepted standards;

(b) Nurses with appropriate education and training shall be regularly assigned to the center; and

(c) Additional healthcare personnel as needed, each of whom is qualified through appropriate training and education to serve the needs of Cardiac Catheterization Laboratory Center patients.

(vi) Patient Selection Criteria.

(a) The hospital shall not admit patients under the age of 18 for a cardiac laboratory procedure unless the hospital is an approved Pediatric Cardiac Catheterization Laboratory Center or unless the patient's diagnosis indicates a condition, such as acquired heart disease, that can be most appropriately treated in an adult program with pediatric trained personnel and pediatric consultative services, or except as provided in 405.29(e)(5)(iii)(c). Such exceptions must be supported by written documentation of consultation with a pediatric cardiologist;

(b) Pediatric Cardiac Catheterization Laboratory Centers that are not also approved as adult cardiac services programs shall not admit patients over the age of 18 for a cardiac laboratory procedure unless the procedure will be performed to diagnose or treat a congenital anomaly and the hospital can meet the additional needs of the patient;

(c) The hospital shall not admit adult patients for percutaneous coronary intervention or other percutaneous cardiac interventions unless it is an approved PCI Capable Cardiac Catheterization Laboratory Center; and

(d) The hospital shall not provide Cardiac EP Laboratory Program services unless it is an approved Cardiac Catheterization Laboratory Center with an approved Cardiac EP Laboratory Program.

(2) PCI Capable Cardiac Catheterization Laboratory Centers.

PCI Capable Cardiac Catheterization Laboratory Centers must meet the following standards:

(i) Structure and Service Requirements

a) PCI Capable Cardiac Catheterization Laboratory Centers must be appropriately staffed and equipped for diagnostic and therapeutic services including but not limited to diagnostic cardiac catheterization and percutaneous coronary and other percutaneous interventions;

b) PCI Capable Cardiac Catheterization Laboratory Centers must maintain capabilities to perform emergency percutaneous coronary interventions including, but not limited to percutaneous coronary intervention for the treatment of ST elevation Myocardial Infarction (STEMI) on a 24 hour a day, 365 days a year basis and must be capable of assembling a dedicated team within 30 minutes of the activation call to provide coronary interventions 24 hours a day and 365 days each year.

Exception to this standard shall be made only for temporary and extenuating circumstances and when:

(1) Local Emergency Medical Services have been notified and documentation is in place for triaging patients in need of emergency PCI , and

(2) The Department of Health has been provided with a specific description of the circumstances, documentation of the revised triage arrangements and a timeline for return to the 24 hour provision of services, and has approved the arrangement.

c) The hospital must insure that once an ambulance calls to indicate transport of an emergency cardiac patient, the PCI team is immediately mobilized;

d) The hospital must effectively and efficiently identify patients in need of an emergency percutaneous coronary intervention and must transfer those patients rapidly (within 30 minutes) from the Emergency Department to the cardiac laboratory; and

e) The hospital must have a system documented and in place to ensure effective and efficient identification and transfer of a patient from the cardiac laboratory to a cardiac surgical program either in the hospital or at another hospital.

(ii) Staffing.

(a) Physicians shall all be board certified, or meet accepted equivalent training and experience for physicians in their respective specialty and shall be appropriately credentialed and privileged as members of the medical staff and in sufficient numbers to meet the care needs of the patients;

(b) A minimum of three interventional cardiologists, at least one of whom dedicates the majority of his or her professional time at the facility, must be credentialed and privileged on the medical staff to perform percutaneous coronary interventions. Each interventional cardiologist shall maintain sufficient volume on-site to maintain familiarity with the laboratory and shall perform a minimum of 75 total percutaneous coronary intervention cases per year of which 11 are emergency percutaneous coronary intervention cases, and not all 75 minimum cases or 11 minimum emergency cases must be performed at one site. Review by the physician director shall be conducted and provided to the Chief of Service, Hospital Medical Director and Medical Staff Credentials Committee for all physicians whose volume falls below these minimum volumes to determine actions deemed necessary; and

(c) the PCI capable cardiac catheterization laboratory center shall have a data manager who has special training in the clinical criteria used in the PCI module of the cardiac reporting system as provided by the department or its designee, is designated and authorized by the hospital and shall work in collaboration with the physician director to ensure accurate and timely reporting of cardiac reporting system data to the department. In addition to the data manager, relevant medical and administrative staff must be trained in the use of the cardiac reporting system and the specific data element definitions involved. For PCI capable cardiac catheterization laboratory centers that have a co-operated parent cardiac surgery center, responsibilities related to the cardiac reporting system may be performed by the cardiac surgery center on behalf of the data manager of the PCI capable cardiac catheterization laboratory center as long as all data is delineated at the facility level.

(iii) patient selection criteria. PCI capable cardiac catheterization laboratory centers shall adopt criteria for appropriate coronary artery diagnostic and interventional procedures in accordance with generally accepted standards for cardiac patients. For centers with no cardiac surgery on site and not co-operated with a New York State cardiac surgery center, patient selection criteria shall be reviewed and approved annually by the affiliated sponsored cardiac surgery center in accordance with subparagraph (c)(8)(i) of this section.

(iv) minimum workload standards. Each PCI capable cardiac catheterization laboratory center must maintain a minimum volume of at least 36 emergency percutaneous coronary intervention cases per year. For hospitals that are part of a co-operated article 28 network and multi-site facilities with more than one approved PCI capable cardiac catheterization laboratory center, and for PCI capable cardiac catheterization laboratory centers operating under a clinical sponsorship agreement pursuant to section 709.14(d)(5) of this Title, minimum volume standards for emergency PCI procedures are site specific and may not be combined for purposes of achieving minimum workload standards.

(a) PCI capable cardiac catheterization laboratory centers with an annual volume below 150 percutaneous coronary intervention cases a year for two consecutive calendar years, or a volume below 36 emergency percutaneous coronary intervention cases a year for two consecutive calendar years, must procure the services of an independent physician consultant, acceptable to the department, who shall conduct an annual review of the appropriateness and quality of the percutaneous coronary intervention cases performed at the facility and shall provide a copy of the findings directly to the department. Findings will be used by the department to determine whether continued approval or withdrawal of approval best meets the needs of the patients in the planning area.

(v) PCI Capable Cardiac Catheterization Laboratory Centers with no cardiac surgery on-site must enter into a formal relationship documented by a fully executed written agreement with a Cardiac Surgery Center meeting standards at 405.29 (c)(8)(i).

(3) Diagnostic cardiac catheterization services. No additional diagnostic cardiac catheterization services shall be approved. Diagnostic cardiac catheterization services hospitals are not approved to perform percutaneous coronary intervention or cardiac surgery, are subject to annual reviews of volume, appropriateness of cases and other quality indicators for diagnostic cardiac catheterization, and must meet the following standards:

(i) Affiliation agreement. The hospital must enter into and maintain a fully executed written agreement with a Cardiac Surgery Center with demonstrated high volume and high quality interventional cardiac services (cardiac surgery and percutaneous coronary interventions). The agreement, must be approved by the Commissioner, and must provide, at a minimum, for the standards at 405.29(c)(8)(i).

(ii) Patient Selection Criteria. Written criteria shall be adopted by the Diagnostic Cardiac Catheterization Service hospital to be used as indications for coronary angiography and or other cardiac invasive diagnostic procedures and shall be available for review during site visits.

(iii) Minimum Workload Standards. There shall be sufficient utilization of a Diagnostic Cardiac Catheterization Service to ensure both quality and economy of services, as determined by the Commissioner. For hospitals that are part of an Article 28 network and for multi-site facilities with more than one approved Cardiac Catheterization Laboratory Center, minimum volume standards are site specific and may not be combined for purposes of achieving minimum workload standards. Any institution seeking to maintain approval shall present evidence that the annual minimum workload standards have been achieved and maintained. Diagnostic Cardiac Catheterization Services shall achieve and maintain an annual minimum volume of 200 angiographic diagnostic cardiac catheterization procedures within two years of initial approval. Such procedures include left and or right heart catheterization with or without the use of contrast visualization and with or without coronary arteriograms, and such procedures exclude:

(a) Placement of permanent or temporary pacemaker or Automatic Implantable Cardioverter Defibrillator (AICD);

(b) Any floating type catheter;

(c) Bundle of His study;

(d) Balloon septostomy;

(e) Radionuclide study;

(f) Right heart catheterization without contrast visualization in adults;

(g) Placement of intra-aortic balloon pump, and

(h) Non-Coronary studies.

(iv) Waiver of Minimum Workload Standards. The Commissioner may temporarily waive the workload requirements upon a satisfactory showing by the hospital that the quality of care provided is adequate as supported, at a minimum, by a review conducted by the Department of cases, outcome trends and appropriateness of care, and that:

(a) there are extenuating circumstances temporarily precluding compliance with the workload requirements, and

(b) there is a documented unmet need in the center's geographical service area that cannot be met by existing PCI Capable Cardiac Catheterization Laboratory Center Laboratory Centers.

(4) Pediatric Cardiac Catheterization Laboratory Centers. In addition to the standards at paragraph 405.29(e)(1) of this subdivision, Pediatric Cardiac Catheterization Laboratory Centers must meet the following standards:

- (i) Pediatric Cardiac Catheterization Laboratory Centers are limited to hospitals approved to perform pediatric cardiac surgery and that meet standards at 405.29(d) of this section; and
- (ii) During any interventional pediatric cardiac catheterization procedure and for a clinically appropriate period of time following such a procedure, a qualified pediatric cardiac surgeon must be immediately available for consultation and available on-site within 30 minutes, when requested, to perform procedures as needed to meet the patient's needs.

(5) Cardiac EP Laboratory Programs. In addition to the standards at paragraph 405.29(e)(1) of this section, Cardiac EP Laboratory Programs must meet the following standards:

(i) Structure and Service Requirements.

(a) Cardiac electrophysiology laboratories must be adequately staffed and equipped for providing intracardiac electrophysiology procedures;

(b) An ultrasound (echocardiographic) machine must be readily available to the laboratory during all electrophysiology procedures;

(c) The Cardiac EP Laboratory Program must have written protocols utilized for addressing complications including tamponade; and

(d) Cardiac EP Laboratory Programs serving patients between the ages of 12 and 18 with adult cardiac surgery on site, but no pediatric cardiac surgery on site, must maintain pediatric trained personnel.

(ii) Staffing. Staffing for Cardiac EP Laboratory Programs shall include:

(a) Electrophysiologists, board certified or with separate equivalent training and experience each of whom shall maintain an average annual volume of 50 adult cardiac electrophysiology procedures based on review of two years of cases, or 20 pediatric cardiac electrophysiology procedures per year depending on the population served. Review by the physician director shall be conducted and provided to the Chief of Service, Hospital Medical Director and Medical Staff Credentials Committee for all physicians whose volume falls below these minimum workload standards to determine what actions are deemed necessary;

(b) Physicians, on staff and immediately available to the laboratory with the expertise to perform local exploration and diagnose and treat tamponade; and

(c) Registered Nurses specifically trained in electrophysiology.

(iii) Patient selection criteria.

(a) Written criteria shall be adopted to be used as indications and contraindications for cardiac electrophysiology procedures in accordance with generally accepted standards of medical care for cardiac patients.

(b) Notwithstanding 405.29(e)(1)(vi)(a) of this section, a hospital with a Cardiac EP Laboratory Program and no cardiac surgery on-site shall not admit patients under the age of 18, patients in need of chronic lead extractions, patients being treated for ventricular tachycardia ablations, and patients being treated for atrial fibrillation ablations for Cardiac EP Laboratory Program services. Additional patient selection criteria for Cardiac EP Laboratory Programs with no cardiac surgery on-site shall be developed in collaboration with a Cardiac Surgery Center with an active Cardiac EP Laboratory Program and the agreed upon criteria shall be documented in writing.

(c) Notwithstanding 405.29(e)(1)(vi)(a) of this section, a hospital with a Cardiac EP Laboratory Program and with adult cardiac surgery on-site, but no Pediatric Cardiac Surgery on-site may perform cardiac electrophysiology procedures on patients between the age of 12 and 18 when the patient's diagnosis and condition can be most appropriately treated in an adult program and when pediatric trained personnel are available to meet the additional needs of the patient and when consultation with a pediatric cardiologist is documented in writing for each pediatric patient.

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