

Section 709.14 - Cardiac services

Effective Date

09/30/2020

709.14 Cardiac services. (a) These standards will be used to evaluate certificate of need applications for cardiac catheterization laboratory center services and cardiac surgery center services. It is the intent of the Public Health and Health Planning Council that these standards, when used in conjunction with the planning standards and criteria set forth in section 709.1 of this Part, become a statement of planning principles and decision-making tools for directing the distribution of cardiac catheterization laboratory center services and cardiac surgery center services. These planning principles and decision-making tools build on the existing regional resources that have been developed through the regulatory planning process. The goals and objectives of the standards expressed herein are expected to promote access to cardiac catheterization laboratory center services and cardiac surgery center services, and maintain provider and operator volumes associated with high quality care, and avoid the unnecessary duplication of resources while addressing the geographic distribution of services necessary to meet the needs of patients in need of emergency percutaneous coronary interventional (PCI) procedures. Additionally, it is intended that the methodology provide sufficient flexibility to consider additional circumstances that reflect on the need for cardiac services, including providing flexibility for regional health systems to provide cardiac services at sites that are convenient to patients in the communities they serve.

(b) Cardiac Surgery Centers. The factors for determining the public need for Cardiac Surgery Center services shall include, but not be limited to the following:

(1) The planning area for determining the public need for Cardiac Surgery Center services shall include the applicant's designated Health Systems Agency (HSA) region and the use area of the applicant facility. For purposes of determining Cardiac Surgery Center services need, the use area of a facility is defined as the area within a 100 mile radius of the applicant facility.

(2) Planning for cardiac surgery center services shall ensure that, to the extent possible, eighty percent of the total population of each HSA region resides within 100 miles of one or more facilities providing cardiac surgical services.

(3) A facility proposing to initiate an adult cardiac surgery center must document a cardiac patient base and current cardiac interventional referrals sufficient to support a projected annual volume of at least 300 cardiac surgery cases and a projected annual volume of at least 36 emergency PCI cases within two years of approval. The criteria for evaluating the need for additional adult cardiac surgery centers within the planning area shall include consideration of appropriate access and utilization, and the ability of existing services within the planning area to provide such services. Waiver of this requirement may be considered if:

(i) the HSA region's age adjusted, population based use rate is less than the statewide average use rate; and

(ii) existing adult cardiac surgery centers in the applicant facility's planning area do not have the capacity or cannot adequately address the need for additional cardiac surgical procedures, such determinations to be based on factors including but not necessarily limited to analyses of recent volume trends, analyses of Cardiac Reporting System data, and review by the area Health Systems Agency(s); and

(iii) existing cardiac surgical referral patterns within the planning area indicate that approval of an additional service at the applicant facility will not jeopardize the minimum volume required at other existing cardiac surgical programs.

(4) No finding of need for the addition of Pediatric Cardiac Surgery Center services will be made unless each existing Pediatric Cardiac Surgery Center service in the planning area is operating and expected to continue to operate at a level of at least 200 pediatric cardiac surgical procedures per year, and unless such existing Pediatric Cardiac Surgery Center services do not have the further capacity to meet projected need for additional pediatric cardiac surgical procedures. Where public need is established herein, a facility proposing to provide pediatric cardiac surgical services must demonstrate the ability to perform a minimum of 200 pediatric cardiac surgical procedures per year by the end of the second full calendar year of operation or demonstrate the ability to perform a minimum of 50 cases a year on-site and operate as part of a coordinated program based on a fully executed written agreement, approved by the Commissioner, with another pediatric cardiac surgery program in accordance with standards at 405.29(d)(5)(ii). For hospitals seeking approval as part of a coordinated program, the agreement must be submitted with the certificate of need application and must be approved by the Department prior to initiation of the service.

(5) A facility proposing to provide Adult and or Pediatric Cardiac Surgery Center services shall:

(i) submit a written plan to the Department of Health which, when implemented, will ensure access to cardiac surgical services for all segments of the HSA region's population. Such plan shall provide a detailed plan to reach patients not currently served within the planning area, ensure continuity of care for patients transferred between facilities, and shall otherwise promote planning for cardiac services within the region; and

(ii) propose a hospital based heart disease prevention program that, when implemented, shall include:

(a) Treatment plans for cardiac inpatients with a principal diagnosis of ischemic heart disease. These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

(1) protocols shall be developed and implemented for the assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle. Such protocols shall be in keeping with generally accepted standards;

(2) The hospital shall provide patient education that shall include, but not be limited to, information on the importance of assessing risk factors for heart disease in first-degree relatives, and the importance of cardiopulmonary (CPR) training for family members and care givers;

(3) Discharge plans must include:

(i) a request for consent to allow patient medical information to be shared with the patient's primary care providers;

(ii) patient referral to their primary care provider with documentation of treatments provided by the hospital and follow-up care recommended by the hospital; and

(iii) patient referral to cardiac rehabilitation programs appropriate to their needs.

(b) professional education:

(1) The hospital shall sponsor or co-sponsor at least three professional education programs per year related to heart disease risk assessment and control and that are open to local community based health professionals.

(c) hospital-based heart health promotion:

(1) The program shall implement policies and health programs in the hospital and establish environments that promote heart-healthy behaviors among hospital staff, employees and visitors, including:

(i) prohibiting the sale and use of tobacco products on hospital premises;

(ii) offering and promoting, on a regular basis, healthful choices in hospital cafeterias and patient menus; and

(iii) offering employee wellness and fitness programs that provide opportunities for employees to make healthy choices.

(d) community based heart health promotion:

(1) The hospital shall organize or participate in a consortium of existing community-based organizations and key community leaders to engage in activities to improve cardiac health in the community; and

(2) organize or participate in at least one major community based campaign (not including health fairs) each year related to major heart disease risk factors.

(e) program administration:

(1) Hospitals shall identify a team within their organization to coordinate heart disease prevention activities. Members of the team shall include a broad range of expertise, including but not limited to: community organization, planning, and social marketing, public health skills and health education.

(6) When considering an application to meet public need for Adult and or Pediatric Cardiac Surgery Center services, priority consideration shall be given to the expansion of an existing service as opposed to the initiation of a new Cardiac Surgery Center.

(7) Where public need is established herein, priority consideration will be given to applicants that agree to serve the medically indigent and patients regardless of the source of payment.

(8) Applicants proposing to initiate an Adult and or Pediatric Cardiac Surgery Center service must:

(i) demonstrate the ability to comply with standards set forth in 405.29 (c), 405.29(d), and 711.4(h) of this Title; and

(ii) in addition, a facility providing Pediatric Cardiac Surgery Center services also must comply with the requirements specified in section 711.4(f) of this Title.

(9) All hospitals approved as Adult Cardiac Surgery Centers shall be approved as PCI Capable Cardiac Catheterization Laboratory Centers and must meet standards in Sections 405.29(c), 405.29(e)(1), and 405.29(e)(2) of this Title. All hospitals approved as Pediatric Cardiac Surgery Centers shall be approved as Pediatric Cardiac Catheterization Laboratory centers and must meet the standards at 405.29(c), 405.29(e)(1) and 405.29(e)(4) of this Title.

(c) For the purposes of this section the terms Cardiac Catheterization Laboratory Center, Percutaneous Coronary Intervention (PCI) Capable Cardiac Catheterization Laboratory Center, Cardiac Electrophysiology (EP) Laboratory Program and Pediatric Cardiac Catheterization Laboratory Center shall have the same meanings as in section 405.29 (a)(4) of this Title.

(d) Public need for cardiac catheterization laboratory centers:

(1) PCI capable cardiac catheterization laboratory centers. The factors and methodology for determining the public need for PCI capable cardiac laboratory centers shall include, but not be limited to the following:

(i) PCI capable cardiac catheterization laboratory centers at hospitals with a cardiac surgery center on site. Applicants approved as cardiac surgery centers are approved PCI capable cardiac catheterization laboratory centers as provided under section 709.14 (b)(9) of this Part and must meet standards at Sections 405.29(c), (e)(1) and (2) of this Title.

(ii) PCI capable cardiac catheterization laboratory centers at hospitals with no cardiac surgery on site. Determinations of public need for PCI capable cardiac catheterization laboratory centers at hospitals with no cardiac surgery on-site will be differentiated between: (A) hospitals that are established by the Public Health and Health Planning Council as co-operators with a hospital that is a cardiac surgery center as defined in section 405.29(a)(3) of this Title; and (B) hospitals that have a clinical sponsorship with a cardiac surgery center as defined in section 405.3(f)(3) of this Title and that are applying to be a PCI capable cardiac catheterization laboratory center. For the purposes of this section, clinical sponsorship shall mean that the hospital applying to be a PCI capable cardiac catheterization laboratory center has entered into a clinical sponsorship agreement with a cardiac surgery center acceptable to the department and in accordance with the standards established in section 405.29(c)(8)(i) of this Title.

(iii) For both co-operated hospitals and hospitals that are proposing to enter into a clinical sponsorship agreement, factors for determining public need shall include, but are not limited to:

(a) the planning area for determining the public need for PCI capable cardiac catheterization laboratory centers at hospitals with no cardiac surgery on-site shall be the area within a one hour average surface travel time, as determined by the department of transportation and adjusted for typical weather conditions, of the applicant facility, unless otherwise determined by the Commissioner in accordance with section 709.1(c) of this title;

(b) documentation by the applicant must demonstrate the hospital's ability to provide high quality appropriate care that would yield a minimum of 36 emergency PCI procedures per year within the first year of operation.

(1) Documentation of the number of cardiologists on staff at the proposed site, credentialed by the co-operated hospital, and/or employed by the clinical sponsorship hospital who currently perform percutaneous coronary interventions at other hospital sites and a summary of experience (including the most recent three years of volume and outcomes) for each.

(2) Documentation in support of volume projections for emergency PCI procedures must include, at a minimum: discharge data indicating the number of patients with a diagnosis of acute myocardial infarction (AMI) and/or other diagnoses associated with PCI, the number of doses of thrombolytic therapy ordered for acute MI patients in the applicant hospital's emergency department (as documented through hospital pharmacy records), and documentation of transfers to existing PCI capable cardiac catheterization laboratory centers for PCI.

(3) Additional documentation that may be submitted in support of the need for a proposed PCI capable cardiac catheterization laboratory center include:

(i) the number of acute care beds at the applicant hospital and the range of acute care services provided;

(ii) documentation by the applicant of barriers that impact care experienced by specific population groups within the planning area and demonstration of cultural competency at the applicant site specific to the proposed populations to be served by the applicant;

(iii) documentation by the applicant demonstrating outreach to underserved populations that identifies potential new PCI cases within the service area;

(iv) emergency department discharge data;

(v) documentation by the applicant of regional demographics and transport patterns within the applicant's emergency medical service (EMS) region that impact the provision of cardiac care;

(vi) the geographic distribution of PCI capable cardiac catheterization laboratory center services and the ability of such existing centers to serve the patients in the applicant's service area;

(vii) letters from local physicians quantifying the number of PCI referrals from their practice and the portion of those that would have been treated at the applicant facility if PCI had been available;

(c) a written plan submitted by the applicant that demonstrates the hospital's ability to comply with standards for PCI capable cardiac catheterization laboratory centers at sections 405.29(c), (e)(1) and (2) of this Title;

(d) a written plan submitted by the applicant that outlines staff training and demonstrates the hospital's readiness to accommodate the needs of the PCI patients;

(e) a written plan has been submitted by the applicant which would promote access to cardiac catheterization laboratory center services for all segments of the hospital service area's population. The document shall include:

(1) a description of current and proposed initiatives for improving outcomes for patients with heart disease,

(2) a plan documenting the hospital's ability to maintain a comprehensive program in which high quality interventional procedures are provided as a component of a broad range of cardiovascular care within the hospital and within the community, to include an emphasis on processes of care and a description of how a patient will traverse through the system of care to be offered,

(3) a plan for ensuring continuity of care for patients transferred between facilities,

(4) documentation of outreach to regional EMS councils served by the applicant,

(5) documentation that EMS system capabilities have been taken into consideration in the delivery of cardiac services;

(6) a description of activities that promote planning for cardiac services within the region; and

(7) a description of current and proposed initiatives and strategies for reaching patients not currently served within the area.

(f) Comments and recommendations received from community organizations;

(g) The hospital shall propose and implement a hospital heart disease prevention program as set forth at subparagraph (b)(5)(ii) of this section;

(h) a description of existing and planned activities to serve the medically indigent and populations that experience health disparities.

(2) Cardiac EP Laboratory Programs. Factors for determining public need for Cardiac EP Laboratory Programs shall include but not be limited to the following:

(i) Each applicant for a Cardiac EP Laboratory Program shall be an approved PCI Capable Cardiac Catheterization Laboratory Center or an approved Diagnostic Cardiac Catheterization Service operating in compliance with standards at sections 405.29(c) and 405.29(e). Applicants for EP laboratory programs will also be considered in conjunction with requests for approval of PCI Capable Cardiac Catheterization Laboratory Center services.

(ii) Each applicant shall submit documentation, describing how the hospital will comply with standards at 405.29(e)(5) of this Title.

(iii) Each applicant shall submit documentation of existing referrals for cardiac electrophysiology patients treated by cardiologists on staff at the hospital.

(iv) Applicants for cardiac EP Laboratory Programs at hospitals with no Cardiac Surgery Center on-site must submit a copy of the patient selection criteria for the proposed program in accordance with the standards at section 405.29(e)(5)(iii) of this Title.

(v) Hospitals approved as cardiac surgery centers shall be deemed to have demonstrated public need to perform cardiac electrophysiology.

(3) Pediatric Cardiac Catheterization Laboratory Centers. Public need for a Pediatric Cardiac Catheterization Laboratory Center shall be determined only in conjunction with an application for a Pediatric Cardiac Surgery Center and when need has been demonstrated for Pediatric Cardiac Surgery Centers in accordance with standards at Section 709.14(b) of this Part.

(4) For co-operated hospitals under subdivision (d)(1)(ii) of this section:

(i) The application for PCI services must be submitted jointly by the applicant facility and the co-operated parent.

(ii) Documentation acceptable to the department must be submitted demonstrating that all cardiac catheterization laboratory centers within the co-operated parent's system have staff sharing agreements that include, at a minimum, provisions for rotation and training of staff with the parent hospital and integration into the parent hospital's quality and patient safety programs, quality assurance and peer review.

(iii) Documentation acceptable to the department must be submitted demonstrating that the co-operated parent hospital will be responsible for maintaining the competency of the cardiac interventionalist physicians, nursing, and technical staff performing services at the applicant facility.

(iv) Documentation acceptable to the department must be submitted demonstrating that the co-operated parent hospital will be responsible for ensuring that the applicant facility can provide PCI services on a 24 hour a day, 365 days a year basis and is 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.

(v) If the co-operated parent is not in the planning area of the applicant facility, then the applicant facility must document that it has an emergency transfer agreement with a New York State Cardiac Surgery Center in the planning area that has an on-site cardiac surgery program.

(5) For applicant hospitals in a clinical sponsorship relationship with a New York State Cardiac Surgery Center:

(i) the application for PCI services must be submitted by the applicant hospital.

(ii) the sponsoring New York State Cardiac Surgery Center must be located in the same planning area as the applicant hospital.

(iii) the sponsoring New York State Cardiac Surgery Center must perform at a level of at least 600 PCI procedures per year.

(iv) a written and signed PCI clinical sponsorship agreement with the sponsoring New York State Cardiac Surgery Center, acceptable to the department and in accordance with standards at section 405.29(c)(8)(i) of this Title, must be submitted. The PCI clinical sponsorship agreement must specify that the department shall be provided 60 days prior written notification of any proposed change, termination or expiration of the agreement, and any changes must be found acceptable to the department prior to implementation. The agreement shall further provide that the parties agree

that termination or expiration of the agreement shall result in closure of the applicant hospital's cardiac catheterization laboratory center.

(v) both the applicant hospital and the sponsoring hospital must submit written documentation demonstrating that the respective governing bodies have approved the clinical sponsorship agreement.

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