

441—124.1(135) Cardiac catheterization and cardiovascular surgery standards.**124.1(1) Purpose and scope.**

a. These standards are measures of some of those criteria found in Iowa Code section 135.63(1) “a” through “q” and 135.63(3). Criteria that are measured by a standard are cited in parentheses following each standard.

b. Certificate of need applications that are to be evaluated against these cardiac catheterization and cardiovascular surgery standards include:

- (1) Proposals to commence or expand capacity to perform cardiac catheterization.
- (2) Proposals to add new or replace cardiovascular surgery services.
- (3) Any other applications that relate to cardiac catheterization or cardiovascular surgery.

124.1(2) Definitions. The following definitions apply to the terms used in this rule:

“*Adult cardiac catheterization laboratory*” means a diagnostic facility exclusively for intracardiac or coronary artery catheterization on adults.

“*Adult cardiovascular surgery*” means cardiovascular surgery exclusively for adults.

“*Angiocardiology*” means the recording of moving X-ray images (fluoroscopic images) of the heart and great vessels. After injection of radiopaque chemicals, moving X-rays of the chemical’s flow are projected on a screen called a fluoroscope. Moving pictures (cineangiocardiology) or still pictures in sequence (serialography) may be recorded of the X-ray image.

“*Angiography*” means the photographic recording of X-ray or radiologic images of blood vessels in any part of the body—the heart, the head, the great vessels, the kidney, etc. In the procedure, blood vessels are injected with a radiopaque chemical. Immediately following injection, X-rays are employed to image the path of the injected chemical. These X-ray images are then photographically recorded.

“*Cardiovascular surgery*” means the services associated with and surgery performed for congenital or acquired diseases of the heart, great vessels, or pericardium, including the placement of transvenous and epicardial pacemakers.

“*Closed heart surgery*” means cardiovascular surgery in which a small incision and repairs are made without direct vision of the area.

“*Coronary artery catheterization*” means a diagnostic study of the coronary arteries in which a small catheter passes through an artery in the leg, neck or arm into a coronary artery orifice. Intravascular pressure measurements are taken, and angiography of the coronary arteries is performed. Catheterization and cineangiocardiology of the left ventricle are an integral part of this procedure.

“*Coronary artery surgery*” means surgery to correct inadequate blood flow to the heart using revascularization techniques to bypass significantly obstructed coronary artery lesions.

“*Intracardiac*” means a diagnostic study of the heart, pulmonary arteries, or both in which a small catheter passes through a vein or artery in the neck, leg or arm and advances into the great vessels, the heart or the pulmonary arteries. Through this procedure, one can measure pressure within the heart and in adjacent veins and arteries, collect blood samples for blood gas analysis and inject radiopaque material, and visualize cardiac and vessel anatomy. The procedure permits detection of congenital and acquired heart abnormalities, the study of ventricular function, the estimation of the orifice size, the placement of pacemakers, etc. Cardiac catheterization is incomplete without cineangiography, intracardiac pressure measurements, blood gas analysis and the ability to diagnose intracardiac shunts.

“*Open heart surgery*” means cardiovascular surgery in which an incision of sufficient size is made to allow direct vision of the area. Open heart surgery requires temporary use of a heart-lung (cardiopulmonary bypass) machine since blood flow through the heart is greatly reduced or stopped altogether.

“*Pediatric cardiac catheterization laboratory*” means the same as adult cardiac catheterization laboratory, except exclusively for children and infants.

“*Pediatric cardiovascular surgery*” means cardiovascular surgery exclusively for infants and children.

124.1(3) Availability of services.

a. Minimum utilization—cardiovascular surgery (Iowa Code section 135.63(1) “c,” “g,” and “h”).

(1) Adult cardiovascular surgical programs should project an annual minimum rate of over 200, or no approval will be granted. Higher case loads over 200 per annum are encouraged.

(2) Pediatric cardiovascular surgical units should project a minimum of 100 pediatric heart operations after the first year, at least 75 of which must be open heart procedures.

(3) Combined adult and pediatric cardiovascular surgery units should project the minimum projected annual rates for both adult and pediatric surgery.

(4) An applicant should project utilization of cardiovascular surgery, catheterization and cardiac care units based upon service area population demographics, current regional or national utilization rates of the service, disease incidence and prevalence rates, current cardiac care treatment modes, and in consideration of those adult cardiovascular surgery units currently operating in Iowa and bordering states within the project's service area.

b. Expansions—cardiovascular surgery (Iowa Code section 135.63(1) “c,” “d,” “e,” “g,” and “h”).

(1) There should be no additional adult cardiovascular surgery units initiated unless each existing unit within the project's service area is operating at a minimum of 200 open heart surgery cases per year.

(2) There should be no additional pediatric cardiovascular surgery units initiated unless each existing unit within the project's service area is operating at 100 surgeries per year. If one team serves more than one institution, the numbers for those institutions should be combined.

(3) If the annual utilization of the other cardiovascular surgery units within the area is below the levels noted above, future utilization above that current level must be reasonably projected or reasons for permanently utilizing the equipment below the level must be demonstrated.

(4) An applicant will demonstrate that an attempt was made to determine with the cooperation of existing providers whether such a reduction would occur. Existing providers of consequence are generally within two hours' surface travel time for adult services and within three hours' surface travel time for pediatric services.

c. Minimum utilization—cardiac catheterization (Iowa Code section 135.63(1) “c,” “d,” “g,” and “h”).

(1) Adult cardiac catheterization laboratories should be projected to operate at a minimum of 300 catheterizations per annum.

(2) Pediatric catheterization laboratory units should project a minimum of 150 catheterizations per annum.

(3) Combined units should meet each of the adult and pediatric standards.

(4) An applicant should project utilization of cardiac catheterization units based upon service area population demographics, current regional or national utilization rates of the service, disease incidence and prevalence rates, current cardiac care treatment modes, and in consideration of those adult cardiovascular surgery units currently operating in Iowa and bordering states within the project's service area.

d. Expansions—cardiac catheterizations (Iowa Code section 135.63(1) “c,” “d,” “e,” “g,” and “h”).

(1) There should be no additional adult cardiac catheterization unit opened unless the number of studies per year in each existing unit within the project's service area is greater than 300. No additional pediatric unit should be opened unless the number of studies per year in each existing unit within the project's services area is greater than 150.

(2) If the annual utilization of the other cardiovascular surgery units within the area is below the levels noted above, future utilization above that current level must be reasonably projected or reasons for permanently utilizing the equipment below the level must be demonstrated.

(3) An applicant must demonstrate that an attempt was made to determine with the cooperation of existing providers whether such a reduction would occur. Existing providers of consequence are those within two hours' surface travel time for adults or three hours' surface travel time for pediatrics.

124.1(4) Costs.

a. Financial feasibility. (Iowa Code section 135.63(1) “f,” “i,” and “p”) Cardiovascular surgery and catheterization equipment and associated remodeling or construction should be depreciated over a period consistent with generally accepted accounting standards.

b. Cost-effectiveness. Proposed new or replacement cardiac catheterization laboratories cost per catheterization and cardiovascular surgery services estimated costs per surgery should, when compared to their peers, demonstrate cost-effectiveness.

124.1(5) Accessibility. (Iowa Code section 135.63(1) “c” and “d”)

a. Cardiovascular surgery units and cardiac catheterization labs should meet the needs of the communities that the units and labs are meant to serve.

b. Cardiac catheterization and cardiovascular surgery service should be provided regardless of ability to pay in consideration of those programs available in the state that serve the medically indigent.

124.1(6) Quality. (Iowa Code section 135.63(1) “i” and “k”)

a. Each surgery unit and cardiac catheterization lab shall demonstrate a reasonable set of criteria that are used in selecting appropriate candidates for surgery and catheterization.

b. Staffing minimums.

(1) The open heart surgery team should minimally consist of:

1. At least two certified or board-eligible cardiovascular surgeons for the first 75 to 130 pediatric open heart surgeries. If pediatric surgery is performed, one surgeon must have special training and experience in surgery for congenital cardiac defects.

2. Board-certified or board-eligible adult or pediatric cardiologist(s). The latter only if pediatric surgery is performed, the former only if adult surgery is performed.

3. Board-certified or board-eligible anesthesiologist with special training in the management of cardiovascular cases’ respiratory care.

4. Radiologist trained in the cardiovascular field.

5. Pathologist familiar with cardiac problems.

6. Surgical nursing staff specially trained in heart disease.

7. Cardiopulmonary bypass pump technicians.

8. Other ancillary staff as needed.

(2) Each applicant will document that the proposed surgery unit can be so staffed when completed and operational.

c. Equipment and facilities. An applicant seeking to provide cardiovascular surgery should demonstrate that the following support services will be available:

(1) General X-ray diagnostic facilities and facilities for emergency X-rays on a 24-hour basis.

(2) A cardiac catheterization laboratory or angiography lab available on a 24-hour basis.

(3) A cardiographics laboratory with facilities for recording the following tests: EKG, vector cardiogram, phonocardiogram, echocardiogram, and exercise stress testing.

(4) A supporting blood bank and hematology laboratory.

(5) A microbiology laboratory.

d. Cardiac catheterization labs serving infants and children should have biplane angiographic equipment, either cineangiographic or cut film. Pediatric cardiac catheterization labs should be supervised by board-certified or board-eligible pediatric cardiologists; adult cardiac catheterization labs should be supervised by a board-certified or board-eligible adult cardiologist.

124.1(7) Continuity. (Iowa Code section 135.63(1) “g,” “h,” “i,” and “k”)

a. An applicant should demonstrate that an attempt was made to solicit letters of support from area hospitals and physicians to indicate a community need.

b. An applicant should provide documentation that emergency medical transport services will be available.

c. Institutions providing cardiovascular surgery services should include mechanisms for comprehensive medical followup, including adequate medical records exchange.

124.1(8) Acceptability. (Iowa Code section 135.63(1)) Facilities with cardiovascular surgery and cardiac catheterization indicate a willingness to observe and respect the rights of patients.

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