

641—203.2(135) Cardiac catheterization and cardiovascular surgery standards.**203.2(1) Purpose and scope.**

a. These standards are measures of some of those criteria found in Iowa Code sections 135.64(1)“a” to “g,” and 135.64(3). Criteria which are measured by a standard are cited in parentheses following each standard.

b. Certificate of need applications which 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 which relate to cardiac catheterization or cardiovascular surgery.

203.2(2) Definitions.

a. Adult cardiac catheterization laboratory—a diagnostic facility exclusively for intracardiac or coronary artery catheterization on adults.

b. Pediatric cardiac catheterization laboratory—the same as adult cardiac catheterization laboratory, except exclusively for children and infants.

c. Cardiac catheterization—

(1) Intracardiac—a diagnostic study of the heart, and 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, 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.

(2) Coronary artery catheterization—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 cineangiography of the left ventricle are an integral part of this procedure.

d. Angiography.

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.

Angiocardiography.

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 (cineangiography) or still pictures in sequence (serialography) may be recorded of the X-ray image.

e. Adult cardiovascular surgery—cardiovascular surgery exclusively for adults.

f. Pediatric cardiovascular surgery—cardiovascular surgery exclusively for infants and children.

g. Cardiovascular surgery—the services associated with and surgery performed for congenital or acquired diseases of the heart, great vessels, or pericardium, including the placement of travenous and epicardial pacemakers.

(1) Open heart surgery—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, as blood flow through the heart is greatly reduced or stopped altogether.

(2) Coronary artery surgery—surgery to correct inadequate blood flow to the heart through using revascularization techniques to bypass significantly obstructed coronary artery lesions.

h. Closed heart surgery—cardiovascular surgery in which a small incision and repairs are made without direct vision of the area.

203.2(3) Availability of services.

a. Minimum utilization—cardiovascular surgery (Iowa Code sections 135.64(1) “c,” “g,” “h”).

(1) Adult cardiovascular surgical programs should project an annual minimum rate of over 200, or no approval shall 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/pediatric cardiovascular surgery units should project the minimum projected annual rates for both adult and pediatric surgery, or no approval shall be granted.

(4) Applicants 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 those adult cardiovascular surgery units currently operating in Iowa, and bordering states within two hours surface travel time, if the applicant proposes an adult unit; and in consideration of pediatric cardiovascular surgery units currently operating in Iowa and bordering states within three hours surface travel time, if the applicant’s proposed unit is pediatric. If a combined unit is proposed both the two- and three-hour considerations for existing adult and pediatric units apply. The assumptions, data and methodology used to arrive at projections shall be provided in each application.

b. Expansions—cardiovascular surgery (sections 135.64(1) “c,” “d,” “e,” “g,” “h”).

(1) There should be no additional adult cardiovascular surgery units initiated unless each existing unit within two hours surface travel time is operating at a minimum of 350 open heart surgery cases per year.

(2) There should be no additional pediatric cardiovascular surgery units initiated, unless each existing unit within three hours surface travel time is operating at 130 surgeries per year. (If one team serves more than one institution the numbers for those institutions should be combined.)

(3) No additional cardiovascular surgery units should be approved which will reduce the volume of existing services below 350 procedures annually for adults and 130 annually, 75 of which are open heart, for pediatric units. The 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 within two hours surface travel time for adult services and within three for pediatric services.

(4) Adult cardiovascular surgical service units should be granted only to institutions which can demonstrate an unserved population base of 500,000 persons. An unserved area is one which lies outside of an existing unit’s service area.

(5) Pediatric cardiovascular surgical services should be granted unto institutions which can demonstrate an unserved population base of 2.5 million with 30,000 live births per year.

c. Minimum utilization—cardiac catheterization (sections 135.64(1) “c,” “d,” “g,” “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 annually.

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

(4) 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 those adult cardiovascular surgery units currently operating in Iowa, and bordering states within two hours surface travel time if the proposed unit is for adults; and in consideration of pediatric cardiovascular surgery units currently operating in Iowa, and bordering states within three hours surface travel time if the proposed unit is for children. If a combined unit is proposed both time considerations shall apply. The assumptions, data and methodology used to arrive at projections shall be provided in the application.

d. Expansions—cardiac catheterizations (sections 135.64(1) “c,” “d,” “e,” “g,” “h”).

(1) There should be no additional adult cardiac catheterization unit opened unless the number of studies per year in each existing unit within two hours surface travel time is greater than 500. No

additional pediatric unit should be opened unless the number of studies per year in each existing unit within three hours surface travel time is greater than 250.

(2) There should be no additional cardiac catheterization units initiated which would reduce the volume of existing units below 500 adult catheterizations, 200 of which are intracardiac or coronary artery catheterizations, or 150 pediatric catheterizations, or both for combined units. The applicant must attempt and 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 for pediatrics.

e. There should be no new cardiac catheterization unit open in any facility not performing open heart surgery (sections 135.64(1) “e,” “g,” “h,” “k”).

203.2(4) Costs.

a. Financial feasibility. (Sections 135.64(1) “f,” “i,” “p”) Cardiovascular surgery and catheterization equipment, and associated remodeling or construction should be depreciated over a period consistent with American Hospital Association schedules as limited by existing reimbursement payors.

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.

203.2(5) Accessibility. (Sections 135.64(1) “c,” “d”)

a. Cardiovascular surgery units and cardiac catheterization labs should be available 24 hours a day, seven days a week for emergency coverage.

b. Facilities with cardiovascular surgery/cardiac catheterization should have available 24-hour, seven days a week ambulance and emergency room service.

c. Travel distance should be within two hours surface travel time or less for 80 percent of the projected service area for pediatric services.

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

203.2(6) Quality. (Sections 135.64(1) “i,” “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. A 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. Specially trained in heart disease surgical nursing staff.

7. Cardiopulmonary bypass pump technicians.

8. Other ancillary staff as needed.

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

c. Equipment and facilities. The 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.

203.2(7) Continuity. (Sections 135.64(1) “g,” “h,” “i,” “k”)

a. The applicant should demonstrate that an attempt was made to solicit letters and to establish referral agreements from area hospitals and physicians to indicate a willingness to participate in a cooperative endeavor to refer to the proposed service.

b. The 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.

203.2(8) Acceptability. (Section 135.64(1) “c”) Facilities with cardiovascular surgery and cardiac catheterization indicate a willingness to observe and respect the rights of patients as stated in the Patients Bill of Rights adopted by the American Hospital Association February 6, 1973, and reprinted in 1975.