IOWA ADMINISTRATIVE CODE [641]
CHAPTER 203
STANDARDS FOR CERTIFICATE OF NEED REVIEW
[Prior to 7/29/87, Health Department[470] Ch 203]

641—203.1(135) Acute care bed need.

203.1(1) *Purpose and scope.*

a. The methodology described in this section provides the basis for estimating the anticipated number of patient-days of acute care hospital service that Iowa citizens will need in the future. The methodology embodies predictive indicators of acute care usage, population and demographic adjustments, and "target" usage rates. The "target" rates express the intent to reduce the levels of acute care usage in areas of the state where that usage is excessive, and not otherwise attributable to the presence of high-usage population groups.

b. The number of acute care beds which will be needed by each of the state's hospitals in the future is a function of the number of patient-days of acute care that will be needed by Iowa citizens, with allowance for the needs of specific population groups and for the travel distance to and location of the state's hospitals.

c. Certificate of need project applications are to be evaluated against the projected bed need determination for those hospitals seeking permission to:

1. Construct new acute care beds;
2. Modernize or renovate acute care beds/patient nursing units;
3. Convert acute care beds from one service use to another;
4. Add to the square footage space of the hospital, where it might be architecturally feasible and cost-effective to convert excess bed space.

d. The methodology responds to the following criteria for evaluation of certificate of need applications:

1. The need of the population for the health services;
2. Availability of alternative, less costly or more effective methods of providing the proposed services;
3. Relationships of the proposed service to the existing health care system of the area;
4. Consideration of the capacity to provide services and consideration of alternatives such as sharing or cooperating arrangements;
5. Other existing facilities providing similar services to those proposed are being used in an appropriate and efficient manner.

203.1(2) *Definitions.*

a. "Estimated patient-day use rate" means the number of days of hospital care provided per year, per thousand residents of a county (or the state). The rate is calculated by adding together all of the patient-days per year for residents of a county (or state), obtained from the records of hospitals where those residents received services. The total patient-days is then divided by the number of residents in the county (or the state), and the answer is expressed as "X patient-days per 1,000 persons." A patient day use rate can be calculated for any specific age group by identifying the number of patient-days of use by residents in that age group and dividing by the number of residents in that age group.

b. "Target use rate" for a county means the patient-day use rate that establishes a projected need level for the county at a future point in time. A target use rate can be determined for a specific age group, using the method described above. In this methodology, target use rates will be determined for four age groups: 0-14, 15-44, 45-64, and 65 and older.

Therefore, each county will have four target use rates. For each county, the target use rate for each age group shall be the lowest of (1) the estimated patient-day use rate for the county during the survey period or (2) the state average estimated patient day use rate during the survey period. The rates in effect at the time that an application is declared complete by the state are the rates employed in reviewing that application.

c. "Patient destination patterns" means the distribution, by hospital, of the total patient-days of each county. The patterns show where patients were referred for hospital service.

d. "Patient destination proportion" means the percentage of a given county's patient-days that occurred in any given hospital.

e. "Target occupancy rate" means the desired average annual percent of a given hospital's usable beds that will be occupied. An occupancy rate is determined by dividing a hospital's average daily census (ADC) of patients by the facility's number of usable beds. A "target" occupancy establishes desired levels of efficiency.

f. "Acute care beds" means short-stay hospital beds including general medical/surgical, pediatric, obstetric, psychiatric and other short-stay specialized beds.

203.1(3) *Data requirements.*

a. Patient destination patterns, patient destination proportions, and the patient-use of acute care services shall be determined from the most recent statewide patient origin and destination study. Such a study shall be conducted at intervals not to exceed three years and shall be the responsibility of the department of public health. The initial study conducted in 1977 produced target utilization rates. Those target rates produced by subsequent studies shall be reviewed as to their continued appropriateness at the time each three-year study is analyzed. If better data is submitted in the interim between studies such shall be considered in readjusting the target use rates. As revised target use rates are determined by study, the Statewide Health Coordinating Council (SHCC) shall review the new target use rates to determine their appropriateness. All Iowa hospitals shall participate in the survey and shall cooperate with the department in providing the most accurate information available. Out-of-state hospitals will also be surveyed in order to obtain information on Iowa residents receiving hospital care out of the state.

b. Population estimates and projections shall be obtained from the most recent Official Iowa Population Projections, published by the department of economic development. The projecting horizon used in this methodology shall be ten years in the future. Using the year of the most recent patient origin and destination study as "year one," projected patient-day use rates will be applied to the projected populations in "year ten" (example: from the information in the 1977 patient origin and destination study, projections will be made for 1987).

c. Data pertaining to bed capacity and annual patient-days shall be obtained from the most recent Annual Report for Hospital and Related Health Facilities submitted by hospitals to the department of public health.

203.1(4) *Methodology.*

a. Annual "estimated patient-day use rate" by county:

(1) Annually adjust the patient-day information obtained from the one month patient origin and destination study by multiplying the patient-days of each hospital by the ratio of annual patient-days (obtained from the Annual Report) to sample month patient-days (obtained from the patient origin and destination study).

(2) To determine estimated annual county patient-days for each of the age groups (0-14, 15-44, 45-64 and 65 and older) for any given county do the following: first, annually adjust all patient-days identified in the one month survey as described in (1) above; second, for each hospital identify the residence of origin of their annually adjusted patient-days by each specific county; third, for each county identify the annually adjusted patient-days for that county's residents from all of those hospitals which served the residents of the county during the patient origin study period. Follow the same procedure for each age group.

(3) To determine the county patient-day use rate for each age group divide the number of patientdays for that age group (identified in (2) above) by the population of the county in that age group. Express the results as "X number of patient-days per 1,000 residents in Y age group."

b. Annual "estimated patient-day use rate" by state. For each age group add together the estimated annual county patient-day for that age group in all counties and divide by the state population in that age group.

c. To determine target use rates—each county will have four target use rates; one for each of the age groups 0-14, 15-44, 45-64, and 65 and older. The target use rate for any age group for a county will be the lowest of:

(1) Estimated annual patient-day use rate for the age group in that county;

(2) Estimated annual patient-day use rate for the age group in the state.

d. To determine projected patient-days for a county—multiply the target rate for each age group by the projected county population in that age group for the year ten years after the most recent patient origin survey (counting the survey year as "year one").

e. To determine facility projected patient-days—for each of the four age groups divide up the projected patient-days for each county among the hospitals that served the county during the patient origin study period. The distribution of any county's projected patient-days (in each age group) will be made in accordance with the percentage distribution of patient-days (in each age group) among the various hospitals in the study period. The percentage distribution number for any given hospital of the patient-days of any given county is called the "patient destination proportion." Add together all of the projected patient-days in each of the four age groups going to each hospital from all of the counties served by that hospital.

f. To determine a facility's projected patient-days for out-of-state residents—first, determine the in-state and out-of-state percentage of patient-days identified for each facility during the patient origin survey period; next divide a given facility's in-state percentage into its number of projected patient days in the patient origin survey. The projected patient-days for facility A from Iowa counties is 2,000. To expand the patient-days to allow for the anticipated out-of-state patients divide 2,000 by .90 to get 2,222. (Ninety percent of 2,222 would be 2,000 and 222 would allow for the 10 percent out-of-state patients expected to use the hospital in the future projection.)

g. To determine facility projected bed need—divide the projected patient-days for the facility by 365 days to estimate the projected average daily census of patients. The average daily census for the facility will determine the facility's projected bed need when allowance is made for a margin of unoccupied beds. The margin of unoccupied beds provides for the fluctuations in average-to-peak service periods. The smaller hospitals have a greater margin allowed in order to accommodate the necessary emergency and primary care functions that account for the majority of their patients. The following scale incorporates the margin and

provides the link between the projected average daily census for a facility and the projected bed need.

If Average Daily Census (ADC) is:		Presumed Occupancy Rate:
1-30	BN = 1.670 X ADC	60%
31-70	BN = 50 + 1.250 X (ADC – 30)	61-70%
71-160	BN = 100 + 1.111 X (ADC – 70)	71-80%
161-249	BN = 200 + 1.124 X (ADC – 60)	81-83%
250 or more	BN = 1.205 X ADC	83%

Specific exception—University of Iowa Hospitals and Clinics serve a unique role as a nearly exclusively tertiary facility with many specialized units. Its occupancy rate should allow for greater peak load fluctuation and therefore will have an occupancy rate of 80%.

203.1(5) *Contingencies.*

a. Patient-days for hospitals that close in the interim between revisions of the patient origin and destination study will be divided among other hospitals serving the same counties as the hospital that closed. The projected patient-days will be divided according to the percentage of the county's patientdays going to each of the other hospitals serving that county. (Example: County A has a projected 1,000 patient-days divided among three hospitals—

Facility X = 60% of the patient-days = 600 patient-days
Facility Y = 20% of the patient-days = 200 patient-days
Facility Z = 20% of the patient-days = 200 patient-days

If Facility Z closes, the 200 patient-days would be distributed to Facilities X and Y according to the following ratios:

Facility X = 600/800	600/800 X 200 = 150 patient-days
Facility Y = 200/800	200/800 X 200 = 50 patient-days

Facilities X and Y will then have projected patient-days of 750 and 250 respectively.)

b. Joint planning in multiple-hospital communities is encouraged and any alternative distribution plan for the aggregate community bed need in those communities may be presented by the hospitals affected. So long as the total community bed need does not exceed the sum of the individual facility needs for the community and so long as all of the hospitals in the community agree to the alternative distribution plan, the plan will replace the distribution pattern determined by this methodology.

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 *"q,"* 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 cineangiocardiography 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 (cineangiocardiography) 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 cineangiocardiographic 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.

641—203.3(135) Radiation therapy or radiotherapy standards.

203.3(1) *Purpose and scope.*

a. These standards are measures of some of those criteria 1 (a to q) and 3 found in Iowa Code section 135.64. 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 radiation therapy standards include:

(1) Proposals to commence or expand the kind or capacity of megavoltage radiation therapy services.

(2) Proposals to replace a radiation therapy unit.

(3) Any other applications which relate to radiation therapy.

203.3(2) *Definitions.*

a. Radiation modality. The method of applying ionizing radiation in the treatment of patients with malignant disease. Externally applied modes.

Superficial X-ray therapy. The use of a conventional X-ray machine, which generates X-rays of up to 150 kilovolts (150 kv), to treat superficial lesions, such as skin cancer.

Orthovoltage X-ray therapy. The use of a conventional X-ray machine which generates X-rays between 150 kv up to and including 800 kvs. (These X-rays are of insufficient energy to avoid preferential bone absorption or to be "skin sparing".)

Megavoltage therapy. The use of ionizing radiation in excess of one million electron volts. Energies above one million electron volts cause considerably less skin damage, increase depth dose markedly, and result in much less scatter from the therapeutic beam. Megavoltage machines are classified as follows:

1. Particle accelerators. These machines use a supply of electrons, which are accelerated into high energy beams. These beams are either caused to strike a target resulting in high energy X-ray production, or are used themselves as the treatment beam. Particle accelerators generate from 4 million up to as many as 45 million electron volts. Most common particle accelerators are the linear accelerator and the betatron.

2. Isotope sources (gamma ray teletherapy units).

Cobalt 60 units—emit gamma rays of approximately 1.2 million electron volts.

Cesium teletherapy units—utilize gamma rays of approximately 650 kv.

b. Megavoltage therapy unit. A piece of megavoltage therapeutic radiologic equipment.

c. Radiation therapy facility. A piece of megavoltage therapeutic radiologic equipment, the accompanying support equipment, and the physical space which houses the equipment.

d. Treatment (procedure). All those radiation fields applied in a single patient visit. Interstitial/intracavitary treatment counts as one visit.

e. Dosimetrist. A technologist who calculates, verifies, and develops maps for the dose distribution of radiation within the patient. The technologist is an essential member of the treatment planning team.

f. Radiation therapist (radiation oncologist). A physician who is board certified or board eligible in therapeutic radiology or in general radiology and who devotes full time to the practice of radiation therapy.

g. Radiation therapy technologist. An individual registered or eligible for registration by the American Board of Radiologic Technologists, or its equivalent, in radiation therapy.

h. Transverse tomograms. A special diagnostic X-ray procedure to determine the depth of thetumors inside the body.

i. Conjoint radiation oncology center (cancer center). A multi-institution, multidisciplinarynetwork to provide radiation therapy for cancer patients. Each institution has an equal voice in decision making and direction of the work of the center. Integration of patient care management, common utilization of personnel and equipment, and a single system of records between center institutions assures optimal care regardless of entry portal. A common cancer registry of all patients treated by center hospitals is maintained.

j. Simulator. Used to reproduce the geometry of the external beam treatment technique, and consists of an isocentrically mounted X-ray source with X-rays passing per a collimation system to reproduce the therapy beam.

k. New patient. A patient receiving treatment for the first time at a given radiation therapy facility.

203.3(3) *Availability.*

a. Minimum utilization. (Sections 135.64(1)*"c," "g," "h"*)

(1) A megavoltage radiation therapy unit which is of relatively low energy, including small linear accelerators (4-10 MEVs), cobalt units and cesium teletherapy units, should serve a population of at least 200,000 persons, and treat at least 300 new patients annually within three years after initiation of the service.

(2) A megavoltage radiation therapy unit which is of medium energy, including linear accelerators of 12-20 MEVs should only be placed in facilities which are currently treating with megavoltage radiation therapy a minimum of 500 new patients annually.

(3) A megavoltage radiation therapy unit which is of high energy, including those linear accelerators of greater than 20 MEVs, should only be placed in facilities which are currently treating at least 750 new patients annually with megavoltage radiation therapy.

(4) To determine the number of new patients needing megavoltage radiation therapy annually in a service area, the following formula shall be applied:
Multiply the service area population times .00304 (3.04/1,000 population was the mean cancer incidence rate in 1976 in Iowa as filed by the Surveillance, Epidemiology, and End Results Program— SEER). A service area population is determined by each facility's catchment area as reported in the most recent patient origin study of the Iowa department of public health. Multiply this product times .5 (50 percent of all new cancer patients require radiation therapy).

(5) Institutions which form a conjoint oncology center should have at least 500 new patients annually who are amenable to megavoltage therapy.

b. Expansions. (Sections 135.64(1)*"c," "d," "e," "g," "h"*)

(1) There should be no additional megavoltage units of comparable size approved unless each existing megavoltage unit of that size within 90 minutes travel time of the proposed unit is performing at least 6,000 treatments per annum.

(2) Proposed new small megavoltage units within 90 minutes travel time of other small units must identify an unserved population base of 200,000 apart from that 200,000 currently served by institutions in the service area.

(3) Megavoltage treatments per annum should be projected by multiplying the number of projected new patients needing megavoltage therapy times 20.

(4) There should be no additional megavoltage radiation therapy units of comparable size within 90 minutes surface travel time of existing units which would reduce the projected volume of treatments per annum in existing units of comparable size to less than 6,000 treatments per annum and which would result in less than 300 projected new patients per annum for that existing unit. The applicant will attempt and demonstrate that an attempt was made to determine with the cooperation of existing providers whether such a reduction would occur.

(5) New conjoint centers should be justified if more than 3,000 new patients are currently being treated by radiation therapy in an existing center.

c. A simulator which can accurately reproduce the geometry of each external beam technique
should be available for every two megavoltage units in a radiation oncology department.

203.3(4) *Costs.*

a. Financial feasibility. (Sections 135.64(1)*"f," "i," "p"*)

(1) Megavoltage radiation therapy units should be depreciated over a period no shorter than that indicated by "Estimated Useful Lives of Depreciable Hospital Assets" published by the American Hospital Association. Associated remodeling should be depreciated according to generally accepted accounting principles and over a period no shorter than indicated in the above-named publication.

(2) Recognizing anticipated volume rate structure, and third party reimbursement, the applicant should present a breakeven analysis for the service. If the analysis shows breakeven will fail to occur after three years of the service's initiation, the applicant should demonstrate why operating a service with the revenues below costs appears desirable.

(3) Charges will be based on actual or projected yearly treatments, but not less than 6,000 treatments.

b. Cost-effectiveness. (Section 135.64(1)*"e"*) Costs per unit of service should not exceed 10 percent of the state average unit cost for the service. If costs exceed 10 percent of that average the applicant shall demonstrate how the proposal represents the most cost-effective way to deliver the service and explain why the project was chosen instead of alternative ways of meeting the need for the service.

203.3(5) *Accessibility*. (Sections 135.64(1)*"c," "d"*)

a. Travel distance shall be within 90 minutes auto travel time for the projected service area population. *b.* Radiation therapy services should be provided regardless of ability to pay, in consideration of those programs available in the state which serve the medically indigent.

203.3(6) *Quality*. (Sections 135.64(1)*"i," "k"*)

a. Minimum staffing requirements for radiation therapy facilities:

(1) Each facility shall have the services of radiation therapists which should be staffed at a level of one therapist per 400 new cancer patients needing treatment.

(2) Each facility shall have the services of radiation physicists which should be staffed at a level of one physicist per 800 new patients.

(3) Each facility shall have the services of radiation therapy technologists which should be staffed at a level of two technologists per megavoltage unit.

(4) Each facility should have the services of nurses.

(5) Each facility should have the services of dosimetrists which should be staffed at a level of one dosimetrist per 500 new patients.

b. Reserved.

c. Each conjoint center shall have at least two cancer biologists available.

d. Each conjoint center shall have one radiation technologist available for each simulator.

e. Replacement or development of orthovoltage treatment should not occur.

f. The long-range plans for radiation therapy services shall be submitted to the Iowa department of public health.

g. Multidisciplinary tumor boards should be established in all institutions housing megavoltage or orthovoltage machines.

h. A source of continuing education should exist within each conjoint center to reach participating community referral hospitals and physicians.

i. Each conjoint center should have a unified training program in radiation therapy for radiation therapists.

j. Each radiation therapy facility should offer psychosocial counseling services and nutritional counseling.

203.3(7) *Continuity.* (Sections 135.64(1)*"g," "h," "i," "k"*)

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

b. A minimum of 75 percent of all radiation therapy procedures should be projected to be done on an outpatient basis. If the applicant believes that 75 percent is inappropriate for its facility, then documentation which shows how its facility is different and why it sufficiently justifies not meeting this 75 percent outpatient rate, shall be provided.

203.3(8) *Acceptability.* (Section 135.64(1)*"c"*) Facilities with radiation therapy services shall document 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. Provisions for counseling services shall be available.

641—203.4(135) Computerized tomography standards.

203.4(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code sections 135.64(1)*"a"* to *"l."* 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 computerized tomography standards include:

(1) Proposals to commence or expand the capacity of computerized tomography services.

(2) Any other applications which relate to computerized tomography services.

203.4(2) *Definitions.*

a. Computerized tomographic (CT) scanner—a diagnostic tool which rotates about and which sends X-ray beams through cross-sectional layers of the body or brain. The X-ray beams which emerge from the body or brain are absorbed by a detector. Differences in the amount of X-rays absorbed by the detector indicate differences in tissue density. As the scanner rotates it takes many images of a cross-section. The images on the detector are transmitted to a computer which displays on a TV a reconstructed cross-sectional picture or slice. Contrast media is then usually injected to alter absorption of the detector, and the scan repeated; this is called enhancement.

(1) Whole body scanner—one capable of imaging the entire body.

(2) Head scanner—one capable of imaging only the brain and structures adjacent to the head.

b. Enhanced scan—a scan performed on a patient who has been treated with a contrast medium so that specific organs or areas of the body will be displayed more distinctly on the scan image.

c. Arteriography—imaging of blood vessels supplying the area of interest following injection of contrast media.

d. Pneumoencephalogram—the X-ray imaging of the skull and its content after introducing air or gas into the fluid-filled spaces within and around the brain and spinal cord.

e. Radioisotope brain scan—nuclear imaging of the concentration of radioactive isotopes which have been injected by biochemical or physiological actions into the brain, referred to later as nuclear brain scan.

f. H.E.C.T. (head equivalent C.T. unit)—a unit by which to measure the capacity of a CT scanner, and being defined as the average number of minutes necessary to perform a single unenhanced CT head study on a body scanner (including the room and equipment preparation time). By comparing the average times for performing various types of scan

procedures to the time necessary to perform an unenhanced head scan, the following table of equivalencies was determined:

On a head scanner—

One unenhanced head scan = 1.05 HECTs

One enhanced head scan = 1.26 HECTs

A procedure involving both types of scans = 1.85 HECTs

On a body scanner—

One unenhanced head scan = 1.00 HECTs

One enhanced head scan = 1.16 HECTs

A procedure involving both types of scans = 1.74 HECTs

One unenhanced body scan = 1.48 HECTs

One enhanced body scan = 2.00 HECTs

A procedure involving both types of scans = 2.75 HECTs

g. Operational capacity for a CT scanner—the operational capacity of a scanner is 3000 HECTs per year, plus or minus 10 percent.

h. Minimum shared-market area for a scanner (hereafter referred to as "area")—the smallest geographic area within which any scanner installation is judged to affect the utilization rate of any other scanner is the community (as defined by the U.S. Bureau of the Census) or a Standard Metropolitan Statistical Area (where an area is so designated).

i. Emergency medical service (EMS) level II trauma service—the level of various services and staffing that qualify a facility to be designated by the emergency medical service division of the Iowa department of public health, using the facilities categorization criteria of such services that is in effect on the date of the enactment of this standard.

j. Shared service agreements—a multi-institutional arrangement for coordination or consolidation of services or sharing of support services. Among the various types of arrangements are referred services, purchased or joint contract services, multisponsored services and regional services.

k. CT consortia—a cooperative venture in which two or more institutions form a separate entity which is created for the purpose of owning, leasing, planning for, and maintaining the use of the scanner. Each facility in the consortium maintains its autonomy for all other services.

l. Applicant—an applicant may be a facility or a consortium of facilities within an area, or a physician or group of physicians.

m. General imaging procedures—a radiological diagnostic procedure performed on an X-ray machine or similar radiological diagnostic instrument.

n. Active oncology service—full, multidisciplinary cancer care, provided by a medical team that would include: surgery, gynecology, medical oncology, radiation oncology, pathology, diagnostic radiology and nuclear medicine. The surgery specialties that might be available would include: thoracic, abdominal, genitourinary and gynecological. The active oncology staff would include those specialists with training in oncology, hematology, and pathology and who spend at least half of their time at the institution.

o. Radiotherapy service—the therapeutic application of megavoltage radiation, using a linear accelerator or cobalt unit. The availability of such service at a hospital would necessitate personnel trained in the therapeutic application of radiology.

p. Chemotherapy service—the treatment of cancer by chemical agents.

203.4(3) *Determination of need.*

a. Applicants who do not now have a scanner, or who have a scanner and seek a certificate for one or more additional scanners.

(1) Applicants in areas with no other scanners.

i. Applicants must have performed at least 30,000 general imaging procedures during the past
calendar year or 12 months, or

ii. Demonstrate that during the past calendar year or 12 months, the applicant performed diagnostic procedures equivalent to 1500 HECTs, using the following scale:
50% of the number of radioisotopic brain scans X 1.75
25% of the number of cerebral angiograms/arteriograms X 1.75
100% of the number of pneumoencephelograms X 1.75
100% of the number of echoencephelograms X 1.17
10% of the number of skull X-rays X 1.75
100% of the number of patients referred to other facilities for CT diagnosis X 1.75 (in the case of head scans) and 2.75 (in the case of body scans)

(2) Applicants in areas with one or more scanners.

i. An applicant must meet the requirement of need, described in 203.4(3)*"a"*(1), and

ii. The average level of utilization for scanners within the area was at least 3000 HECTs (plus or minus 10 percent) for the past calendar year or 12 months. The average level of utilization will be determined by adding the number of HECTs performed during the period at all area facilities divided by the number of facilities.

iii. The University of Iowa Hospitals and Clinics is specifically exempted from consideration under ii., directly above, because it has a service area that encompasses the entire state and adjoining states. The utilization statistics for the University Hospital will therefore neither affect nor be affected by Mercy Hospital, Iowa City. Additionally, the utilization statistics for scanners at the University of Nebraska Hospitals and Clinics and St. Joseph's Hospital (both in Omaha) will not affect the need for scanners at hospitals in Council Bluffs.

b. Replacement scanners—applicants who currently have a scanner.

(1) All applicants seeking to replace a scanner with another scanner, head or body.

i. The applicant must demonstrate that the applicant's use of the applicant's current scanner was at least at the operating capacity level during the last calendar year or 12 months, or

ii. Below the operating capacity level, but above 1500 HECT level, and the applicant must demonstrate reasons for permanently utilizing their scanner below operating capacity level and demonstrate that discontinuation of their scanner service would impair the applicant's ability to respond to the emergency needs of the area. Reasons for utilizing the scanner below the capacity should include a unique patient or procedure mix which would define the capacity level differently for this applicant.

(2) Applicants seeking to replace a head scanner with a body scanner.

i. The applicant must meet the requirements listed in 203.4(3)*"a,"* and

ii. The applicant must meet the requirements for applicants seeking body scanners in 203.4(6), "Quality."

203.4(4) *Costs—whole body and head scanners.*

a. Financial feasibility. (Sections 135.64(1)*"f," "i," "p"*) CT scanners should be depreciated

over a period of not less than seven years. Remodeling shall be depreciated as appropriate by generally accepted accounting principles.

b. Cost-effectiveness.

(1) Applicants should demonstrate for themselves and the health care system that the most cost effective method of providing CT services has been chosen. If a CT scanner which requires less than 20 seconds to produce one section is chosen, the applicant should demonstrate the scanner's cost effectiveness over scanners requiring greater than 20 seconds to produce one section. If a CT scanner which requires 20 seconds to 2 minutes to produce one scan is chosen, the applicant should demonstrate the scanner's cost-effectiveness over scanners requiring greater than 2 minutes to produce one section.

(2) Proposed new and replacement CT scanner's cost per CT scan should, when compared to their peers, demonstrate cost-effectiveness.

203.4(5) *Accessibility.* (Sections 135.64(1)*"c," "d"*)

a. All scanners must be available for emergency use 24 hours a day, less any down time. (Section135.64(1)*"d."*)

b. Services should be provided to all patients regardless of the patient's ability to pay, taking into consideration the availability of those programs available in the state which serve the medically indigent.

c. Applicants will demonstrate a willingness to accept referrals for CT services from all area physicians.

d. All applicants must demonstrate through documented correspondence that an attempt has been made to form shared CT service agreements with all facilities within the area.

203.4(6) *Quality.* (Sections 135.64(1)*"i," "k"*)

a. Data on use and costs of the CT scanners should be submitted to the Iowa department of public health as a condition of approval. (Sections 135.64(1)*"a," "h"*)

b. All scanners.

(1) All applicants must demonstrate that they have on their staff or will acquire on their staff a full-time diagnostic radiologist, trained in the use of the CT scanner, or other physicians with comparable training and expertise.

(2) All applicants must document that they have on their medical staff individuals who are qualified to operate a scanner and interpret and act upon the diagnostic results. Such documentation may include reference to board certification, apprenticeship, academic credentials or such other qualifications that would prompt a medical staff to accept the responsibility for offering this new service. Applicants who intend to acquire staff with the desired expertise should provide signed letters of intent from the incoming medical personnel. Applicants who intend to upgrade the specialty skills of their staff should document a plan for training their current staff in the use of CT scanners.

(3) All applicants should have a complement of other diagnostic modalities available. Applicants seeking body scanners should also have available ultrasound, radionuclide scanning and conventional X-ray services.

(4) All applicants should have the facilities for treating the conditions diagnosed by imaging with the scanner or should demonstrate referral agreements with treatment facilities, in the event that the scanner will be used as a screening device.

(5) All applicants should have on their staff or available on a consultative basis the services of a biomedical engineer or radiation physicist, with special training in CT

applications. These functions may also be provided by contract with the scanner manufacturer.

c. Head scanner only.

(1) Applicants for a head scanner should be a facility which qualifies for EMS Level II Trauma Service.

(2) If an applicant does not qualify for Level II Trauma Services, it must demonstrate that it has or will acquire a specialty practice in the field of diagnosing neurologic disorders, exclusive of neuropsychiatric disorders.

d. Body scanner only.

(1) Applicants for a body scanner must meet the criteria for EMS Level II Trauma Service.

(2) Applicants for a body scanner must be a hospital with 200 or more acute care beds. An applicant who does not meet the 200-bed rule may qualify for a body scanner if the applicant directly provides active oncology services with radiotherapy or chemotherapy treatment services, or both.

203.4(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. The applicant should demonstrate an emphasis on the availability of outpatient CT procedures, and that an appropriate percentage of all CT procedures on head and whole body units will be done on an outpatient basis.

203.4(8) *Acceptability.* (Section 135.64(1)*"k"*) Providers of CT services should indicate a willingness to observe the rights of patients.

203.4(9) Rescinded effective 1/28/81.

641—203.5(135) Long-term care.

203.5(1) *Purpose and scope*.

a. These standards are measures of criteria found in Iowa Code sections 135.64(1)*"a"* to *"g."* 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 standards include applications to:

(1) Construct, develop, offer new, modernize, replace, renovate, or relocate intermediate care or skilled nursing care beds in nursing homes or hospitals.

(2) Expand bed capacity in intermediate care or skilled nursing care facilities or designated units in hospitals.

203.5(2) *Definitions.*

"Intermediate care facility" (ICF) means any institution, place, building, or agency providing for a period exceeding 24 consecutive hours accommodation, board, and nursing services, the need for which is certified by a physician, to three or more individuals, not related to the administrator or owner thereof within the third degree of consanguinity, who by reason of illness, disease, or physical or mental infirmity require nursing services which can be provided only under the direction of a registered nurse or a licensed practical nurse.

"Rural counties" means all counties not designated by the U.S. Census as SMA (Standard Metropolitan
Area) counties.

"Skilled nursing facility" (SNF) means any institution, place, building, or agency providing for a period exceeding 24 consecutive hours accommodation, board, and nursing services, the need for which is certified by a physician, to three or more individuals not related to the administrator or owner thereof within the third degree of consanguinity who by reason of illness, disease, or physical or mental infirmity require continuous nursing care services and related medical services, but do not require hospital care. The nursing care services provided must be under the direction of a registered nurse on a 24-hour-per-day basis.

"Urban counties" means those counties designated by the U.S. Census as SMA (Standard Metropolitan Area) counties.

203.5(3) *Availability and need.* (Iowa Code sections 135.64(1)*"c," "d," "e," "g," "h"*)

a. The following formula shall be used as a means of projecting the approximate number of intermediate and skilled nursing care beds needed to serve the projected population five years into the future:

(1) Rural counties:
[.09(65 + population) + .0015 (64 – population)] X 110% equals total long-term care bed need Combined SNF and ICF bed need equals 2/3 (total long-term care bed need) Assumed RCF bed need equals 1/3 (total long-term care bed need).

2) Urban counties:
[.07(65 + population) + .0015 (64 – population)] X 110% equals total long-term care bed need Combined SNF and ICF bed need equals 2/3 (total long-term care bed need) Assumed RCF bed need equals 1/3 (total long-term care bed need).

(3) Department of economic development population projections are adopted for use in the determination of long-term care bed need.

(4) The department of public health will calculate long-term care bed need figures annually, using population projections five years into the future.

b. For purposes of comparing "need" to "existing" beds in a given county, the following shall be considered in the calculation of "existing" beds:

(1) ICF and SNF beds licensed at freestanding facilities in the county.

(2) Additional ICF and SNF beds previously approved through certificate of need but not yet licensed.

(3) ICF and SNF beds in designated units in hospitals in the county.

c. The statistical calculation of bed need shall serve as a guideline for the health facilities council in reviewing need for the proposed long-term care beds. Other factors which may be considered by the council include, but are not limited to:

(1) The availability and utilization of other ICF and SNF services in the county, or within the applicant's service area.

(2) The availability and utilization of other long-term care services in nearby hospitals, such as skilled care available through the swing bed program.

(3) The availability of supportive living arrangements which may or may not be licensed as residential care facilities (RCF).

(4) The availability of home health and other in-home services.

(5) The availability of other services to the elderly.

(6) The availability of ICF and SNF services in neighboring counties.

(7) Utilization by out-of-state residents of facilities in counties bordering other states, where the applicant provides evidence that in-migration of long-term care patients exceeds out-migration to the bordering state.

(8) Programs and services directed at special populations whose needs cannot otherwise be met, or whose needs cannot be met cost-effectively at other facilities.

d. In documenting need for a project, the applicant shall identify the service area and target population, including a description of the methodology used by the applicant in determining need for the requested beds and the expected sources of referrals. The applicant shall document that the number of beds requested is appropriate to address the identified need. The applicant shall also identify how the target population is currently being cared for, and what hardship is being experienced by the absence of the proposed beds.

203.5(4) *Quality.* (Iowa Code sections 135.64(1)*"i," "k"*) The applicant shall document that the applicant has contacted the health facilities division of the department of inspections and appeals to conform with physical standards, staffing requirements, and other licensing requirements to assess the potential for provision of quality care at the facility. When necessary, the applicant shall attempt to arrange an on-site visit to the facility to determine compliance with physical requirements, and shall provide documentation of this site visit or attempts to arrange such a site visit.

203.5(5) *Continuity.* (Iowa Code sections 135.64(1)*"g," "h," "k"*)

a. The applicant shall document the relationship of the facility's proposed services to other health and long-term care services in the community such as physician and hospital services, habilitation, rehabilitation, transportation or other services. The facility should be capable of providing or arranging for the provision of a continuum of long-term care services.

b. The facility should be capable of providing or arranging for the provision of a comprehensive program of coordinated patient services. The applicant shall provide evidence of contracts for services, appropriate staffing patterns and ratios, and licensure of personnel as necessary.

203.5(6) *Accessibility and acceptability.* (Iowa Code sections 135.64(1)*"c," "d"*)

a. Population subgroups which have traditionally been underserved, such as adolescents, the elderly, women, racial minorities, mentally ill, mentally retarded, and developmentally disabled should be considered when planning for or reviewing long-term care facilities.

b. The applicant shall document to what extent Medicaid patients will be served by the proposed beds, using past Medicaid utilization as an indicator or, in the case of a new facility, projecting anticipated Medicaid utilization.

203.5(7) *Costs and financial feasibility.* (Iowa Code sections 135.64(1)*"e," "f," "i," "p"*)

a. The applicant shall identify capital and operating costs associated with the project, identify sources of funding to cover those costs, and demonstrate that the project is financially feasible.

b. Construction costs shall be in line with construction costs of other similar projects.

c. The applicant shall provide budgets for the first three years of operation, including documentation of all assumptions used. The budget shall include anticipated sources of revenue, including the percentage of revenue from private pay, Medicaid, Medicare and other patient revenues.

d. Proposed charges per patient day should be justifiable when compared to current charges of other similarly licensed facilities in the applicant's service area, or other similar facilities elsewhere in the state. If charges are significantly higher or lower, the applicant shall provide a description of proposed programs or services which explain the difference in charges.

641—203.6(135) Bed need formula for mentally retarded.

203.6(1) *Age—ten years to sixty-five years.* It was determined that services for mentally retarded under age 10 would in most cases be met in the home and that in many cases not identified until approximately that age. For age 65 and older, the services needed would in most cases be similar to those of geriatric needs.

203.6(2) *Levels of retardation in population.*

a. Mildly retarded 2.6%

b. Moderately retarded .3%

c. Severely and profoundly retarded .1%

% of mentally retarded in total population 3%
90% of "*c*" need services outside of home
50% of "*b*" need services outside of home
0% of "*a*" need services outside of home

203.6(3) *Formula.*

.1% (90%) = .09 .3% (50%) = .15 .24 X .03 = 8%
(8% of mentally retarded population need services outside of home)
8% of mentally retarded population = number of ICF/RCF beds
20% of all beds = ICF/MR beds at state-operated institution
30% of all beds = ICF/MR community-based facilities
50% of all beds = residential type services for all types of facilities.

641—203.7(135) End-stage renal disease standards.

203.7(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.*" 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 end-stage renal disease standards include:

(1) Proposals to expand the number of renal dialysis stations or renal transplant services.

(2) Proposals to add new transplant or dialysis services.

(3) Any other applications which relate to end-stage renal disease services.

203.7(2) *Definitions.*

a. Dialysis. A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis which are currently in common clinical practice are hemodialysis and peritoneal dialysis. In these rules a dialysis is used to mean one treatment.

b. Dialysis station. Any permanent or portable dialysis machine to a health care facility which is set up to service mainly ESRD patients. Back-up dialysis machines which are used for isolation and acute cases are excluded from the definition of dialysis station except where specifically mentioned in particular standards.

c. End-state renal disease (ESRD). That stage of renal impairment which is virtually always irreversible and permanent, and requires dialysis or kidney transplantation to ameliorate uremic symptoms and maintain life.

d. ESRD facility. A facility which is approved to furnish at least one specific ESRD service (see June 3, 1976 Federal Register 405.2102(f)). Such facilities are:

(1) Renal transplantation center. A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A renal transplantation center may also be a renal dialysis center.

(2) Renal dialysis center. A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic (including inpatient dialysis furnished directly or under arrangement), and rehabilitative services, except renal transplantation required for the care of ESRD dialysis patients.

(3) Renal dialysis facility. A unit which is approved to furnish dialysis services to ESRD patients. Renal dialysis facilities may be hospital or nonhospital based.

e. ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:

(1) Transplantation services. A process by which a kidney is excised from a live or cadaveric donor. Such kidney is implanted in an ESRD patient and supportive care is furnished to the living donor and to the recipient following implantation.

(2) Dialysis service.

1. Outpatient dialysis. Self-dialysis, which is performed with little or no professional assistance by a patient with appropriate training; and staff-assisted dialysis which is performed by the staff of the center or facility.

2. Inpatient dialysis. Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary basis in a hospital.

3. Home dialysis. Dialysis performed at home by an appropriately trained ESRD patient.

f. Network, ESRD. An approved organized group of ESRD facilities in a designated geographic area which by their type and location, and because of local referral patterns, collectively furnish the necessary care for ESRD patients in the population served.

g. Organ procurement agency. An organization which performs, or coordinates the performance of, all the following services:

(1) Harvesting of donated kidneys;

(2) Preservation of donated kidneys;

(3) Transportation of donated kidneys;

(4) Maintenance of a system to locate prospective recipients for harvested organs.

203.7(3) *Availability of services.*

a. Renal dialysis centers and renal dialysis facilities. (Sections 135.64(1)*"c," "d," "e," "g,""h"*)

(1) Renal dialysis centers and renal dialysis facilities located within a standard metropolitan statistical area (SMSA) of 500,000 population or greater, which perform greater than 20 percent of dialyses on ESRD outpatients should have a minimum of six stations performing a minimum of 4.5 dialyses per station per week within three years of beginning operation or expanding.

(2) Renal dialysis centers and renal dialysis facilities, located within a SMSA or other service area of less than 500,000 population, which perform greater than 20 percent of

dialyses on outpatients, should have a minimum of three stations performing a minimum of 4.0 dialyses per station per week within three years of beginning operation or expanding.

(3) Self-dialysis training stations which are used to successfully train at least six self-care or home dialysis ESRD patients per calendar year, and the dialyses performed on these stations, may be excluded from the calculation of utilization rates in standards (1) and (2).

(4) There should be no renal dialysis centers or renal dialysis facilities performing less than 20 percent outpatient dialyses.

(5) Each renal dialysis center and renal dialysis facility may have a reasonable number of back-up dialysis stations for isolation and acute cases.

b. Renal transplantation centers should perform 25 or more transplants annually and have a service area population of at least 2 million people.

c. Expansions. (Sections 135.64(1)*"c," "d," "e," "g," "h"*)

(1) There should be no additional renal dialysis centers or renal dialysis facilities, unless all stations within 90 minutes travel time are performing at a rate of at least 7 dialyses per station per week.

(2) There should be no expansions of an existing renal dialysis center or facility, unless that facility is performing at least 7 dialyses per station per week and the applicant's projected cost studies demonstrate that an expansion of service capacity is more cost-effective (when operating capital costs are weighed) than offering the service at current capacity for two shifts per day.

(3) Self-dialysis training stations which are used to successfully train at least six self or home dialysis ESRD patients per calendar year, and the dialyses performed on these stations are to be excluded from the calculation of the previous standards (1) and (2).

(4) There should be no increase in the number of dialysis stations or centers if less than 35 percent of ESRD patients in the catchment area of that center or facility are on home or self-care dialysis, unless 100 percent of the ESRD dialysis patients at that center or facility have been evaluated by personnel or an appropriate training center for and where feasible entered into a program of home or self-dialysis training.

(5) New renal dialysis facilities or centers should be initiated only if the applicant can demonstrate a reasonably large unserved population within 90 minutes travel time of the proposed site.

(6) Each transplant center in the ESRD Network should perform a minimum of 50 transplants annually before additional transplant centers are open. (For the purpose of this document, the Veteran's Administration Hospital at Iowa City and the University of Iowa Hospitals and Clinics are considered to be one transplant center.)

203.7(4) *Cost.* (Sections 135.64(1)*"f," "i," "p"*) Proposed new or expanded renal dialysis facility's or renal dialysis center's estimated cost per dialysis treatment should when compared to their peers, demonstrate cost-effectiveness.

203.7(5) *Accessibility.* (Sections 135.64(1)*"c," "d"*) The service area for renal dialysis facilities and centers should be that area within 90 minutes travel time by auto of that facility or center.

203.7(6) *Quality.* (Sections 135.64(1)*"i," "k"*) ESRD services shall meet all applicable federal quality control standards, as published in the June 3, 1976 Federal Register, "Renal Disease: Implementation of Coverage of Suppliers of End-Stage Services," and "Federal Health Insurance for the Aged and Disabled: Requirements for Self-Dialysis Units and Self-

Dialysis Services," sections 405.2134, 405.2135, 405.2136, 405.2137, 405.2139, 405.2140, 405.2160, 405.2161, 405.2162, 405.2163, 405.2171.

203.7(7) *Continuity.* (Sections 135.64(1)*"g," "h," "i," "k"*) Proposed new ESRD facilities and those ESRD facilities proposing expansions should have membership in an ESRD network.

203.7(8) *Acceptability.* (Section 135.64(1)*"k"*) Patients' rights and responsibilities should be assured in accordance with the June 3, 1976 Federal Register, "Renal Disease: Implementation of Coverage of Suppliers of End-Stage Services," section 405.2138. These rules are intended to implement Iowa Code section 135.72.

641—203.8(135) Financial and economic feasibility.

203.8(1) *Purpose and scope.*

a. These standards are measures of some of those criteria 1*(a to q) found in Iowa Code section 135.64. Criteria 1*(a to q) which are measured by a standard are cited below: Financial feasibility subrule 203.8(3), paragraph *"b,"* criteria 1**"b," "c," "p"*; subrule 203.8(3), paragraph *"c,"* criteria 1**"f," "p"*; subrule 203.8(3), paragraph *"d,"* criteria 1**"c," "f," "p," "q."* Economic feasibility subrule 203.8(4), paragraph *"a,"* criteria 1**"e," "f," "g," "i," "p," "q."*

b. Certificate of need applications which are to be evaluated against these financial and economic feasibility standards include institutional health facilities, as defined in Iowa Code section 135.61.

203.8(2) *Definitions.*

a. Project. The remodeling, replacing or equipping of existing buildings, as well as the building or equipping of new structures.

b. Financial feasibility. The applicant's demonstration that it has the money, or that it can reasonably expect to obtain moneys equal to the estimated project costs, to any debt associated with the project, and to the annual expenses of providing the service, as well as the demonstration of overall institutional financial strength.

c. Financial ratio analysis. Evaluation of the financial position of an organization through creating indexes of income, revenue, assets, liabilities, etc. Financial ratios can be classified into liquidity, capital structure, activity and profitability ratios. Financial ratios measure financial feasibility.

(1) Net margin. The net income (after taxes if the applicant is not tax-exempt) minus nonoperating revenue divided by gross revenue.

(2) Net operating margin. Net income (after taxes if the applicant is not tax-exempt) minus nonoperating revenue divided by total operating revenue. *Iowa Code section 135.64(1).

(3) Current asset ratio (current ratio). Current assets divided by current liabilities.

(4) Debt ratio. Total long-term debts divided by total fixed assets.

(5) Debt service coverage. The total of net income, interest expense, amortization of financing costs, and depreciation plus amortization and interest divided by the annual debt service.

(6) Days revenue in accounts receivable. Gross accounts receivable divided by gross patient revenue divided by 365.

d. Debt financing. Any portion of the cost of projects to be financed through borrowing either at the time the project is undertaken or at anytime subsequent thereto.

e. (Gross) revenue. Total of operating and nonoperating revenues.

f. Nonoperating revenues. Revenues not related to patient care or normal day-to-day operations, including unrestricted gifts, unrestricted endowments, income from the sale of a fixed asset, unrestricted income from a restricted or unrestricted fund, rental of facilities not used in operation, etc. (restricted funds are specifically excluded, unless expended during the accounting period, in which case they are accounted for either as operating or nonoperating revenues).

g. Operating revenues. Net patient service revenues (patient revenues minus deduction for charity, contractual and bad debt allowances) and other operating revenues.

h. Excess (or deficiency) of gross revenues over (or under) expenses. Net income.

i. Excess (or deficiency) of operating revenues over (or under) expenses. Net operating income.

j. Economic feasibility. The applicant's demonstration that its project will provide for the allocation of scarce resources within a community in a manner that is of maximum benefit to that community, in other words demonstration that the project will be cost-effective and will contain health care costs to the greatest extent possible.

k. Expense. An expired cost (cost = price paid for operations and assets, including leased assets vis-a-vis cash outlay, indebtedness incurred, or cash equivalent) incurred directly or indirectly in earning revenue. Expenditures may be expended over many years.

l. Asset. Economic potentials from which future benefits are expected to result, include leased capital equipment.

m. Liabilities. Debts or obligations.

n. Gross patient revenues. Patient service revenues before allowances for bad debt and charity and contracts.

o. Debt service. The payment of matured interest and principal; the outlay needed, supplied, or accrued for meeting such payments during any given accounting period; a budget or operating statement heading such items.

p. Current assets. Liquid assets which can be expected to directly or indirectly be converted into cash within one year or the operating cycle, whichever is longer (includes leased assets).

203.8(3) *Financial feasibility analysis.*

a. The applicant will provide financial feasibility analysis of the project's (facility's) past and projected costs, as requested by the Iowa department of public health.

b. The applicant shall show evidence of sound financial planning.

(1) If the sponsor has a long-range institutional plan, the project should be consistent with it. If the sponsor has no long-range institutional plan, the applicant shall demonstrate that the proposal helps meet the long-range needs of the community.

(2) The project should be consistent with the sponsor's three-year capital expenditure plan which all hospital and skilled nursing facilities must have.

c. The applicant shall demonstrate the financial feasibility of the services (institution) at completion and, shall show evidence of sound historical, financial, and operational management.

(1) The net operating margin should be positive. If a net loss is projected following completion of the project, an explanation of source funds should be given. Institutions funded by tax levy or endowment shall demonstrate that money from those sources has been historically applied to cover operating expenses if those institutions have a negative net operating margin.

(2) The net margin should be positive. If net loss is projected an explanation of source funds should be given.

(3) The past and projected current ratio should be at least 2:1.

(4) Past and projected debt service coverage ratio should be at least 2:1.

(5) The debt financing of a project should not increase the debt ratio above .8 unless debt service payments will derive from sources other than operating revenues.

(6) Days revenues in accounts receivable should not have been more than 65 days.

(7) If third party payment can be expected for the project, then some documentation indicating that the type of project which is proposed is generally third party reimbursable should be provided.

d. Sponsors shall show evidence of past efficient utilization. Standards (1) and (2) below apply to hospital project applications for:

—Construction of new acute care beds;

—Modernization or renovation of acute care beds/patient nursing units;

—Conversion of acute care beds from one service use to another;

—Addition to the square footage space of the hospital, where it might be architecturally feasible and cost-effective to convert excess bed space.

(1) Hospitals should have been no lower than 5 percent below the implicit target occupancy rate according to the bed need formula for the last year. Additionally hospitals with lower than target occupancy rates should show a trend during the last three years of increasing occupancy rates. This 5 percent refers to deviation on a scale of 1-100 percent and not to 5 percent of the target occupancy rate itself. Long-term care facilities should have had a 90 percent average occupancy for the last three years.

(2) Hospitals should have an average length of stay by service no greater than 10 percent above the average of their size category for the last three years.

Standards (1) and (2) above do not amend rule 641—203.1(135) acute bed care need methodology. But are additional measures of financial viability which supplement rule 641—203.1(135).

(3) Prior to the project's initiation, the full-time equivalent employees per adjusted patient day as reported in the most recent American Hospital Association Hospital Statistics should be no greater than 110 percent of the state average for hospitals of similar size. Categories of hospitals of similar size are:

Beds
6-24
25-49
50-99
100-199
200-299
300-399
400-499
500+

Adjusted patient day as used here is defined in Hospital Statistics, AHA, 1978.

Nursing homes shall meet regulations for licensure personnel requirements.

(4) Prior to initiation of a project, the cost per patient day of a hospital should be within 10 percent of the state average for hospitals within that size category. (See standard 203.8(3)"*d*"(3) for size categories.) An applicant's costs, which are incurred as a result of

shared service contracts with other entities, and which are not charged to patients within the applicant's facility should not be included in the estimation of costs per patient day.

203.8(4) *Economic feasibility.*

a. The project as proposed shall be cost-effective.

(1) The applicant should demonstrate that the project represents the most cost-effective alternative. Such alternatives include, among others, new construction versus renovation and new service versus shared or contracted services.

(2) The applicant should demonstrate that of the financing methods available, the financing method chosen is the least costly alternative.

(3) Applicants shall demonstrate that construction or renovation costs are reasonable when compared to similar projects of the most recent year.

(4) The net operating margin should not exceed a percentage sufficient to provide for the organization's financial requirements, as defined in "Financial Requirements of Health Care Institutions and Services" (American Hospital Association, S031, February 1979), and limited by existing reimbursement payors.

(5) Facilities should show evidence that they have considered alternate energy sources within
their institutions; and energy efficiency in project construction design.

b. Reserved.

This rule is intended to implement Iowa Code section 135.74.

641—203.9 Obstetrical services and neonatal intensive care unit standards.

203.9(1) *Purpose and scope.*

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

b. Certificate of need applications for new institutional, or changed institutional health services, which are to be evaluated by the standards in this section, are those applications to:

(1) Offer new, discontinue, or change the level of perinatal services;

(2) Construct, develop, offer new, modernize, replace, renovate or relocate neonatal intensive care services;

(3) Expand bed capacity in neonatal intensive care units.

203.9(2) *Definitions.*

a. "*Perinatal services"* means the facilities, equipment and personnel which provide fetal, neonatal, and maternal care from the first indication of pregnancy up through and including birth and to the time when mother and infant are in stable health. Perinatal services in acute care facilities are classified by the Iowa department of public health into three levels of centers. For detailed descriptions of what constitutes levels of obstetrical and neonatal services, reference Standards for Perinatal Centers (most recent edition), Iowa department of public health.

(1) Level I perinatal centers are hospitals whose function it is to provide neonatal nursery and obstetrical services for uncomplicated newborn and maternity patients. Certain level I centers with large numbers of births may offer some of those neonatal and obstetrical services associated with regional level II perinatal centers.

(2) Regional level II perinatal centers are designated hospitals whose responsibility is to provide care for the majority of complicated/high-risk fetal, neonatal and maternal patients in their areas. Regional level II referral area facilities have:

1. A defined referral area;
2. An educational outreach program; and
3. Staffing for maternal and neonatal emergency transport in the referral area.

Regional level II perinatal centers also provide level I neonatal and obstetrical services.

(3) Level III perinatal centers are designated hospitals whose priority responsibility is to provide tertiary care for all types of fetal neonatal and maternal illnesses and abnormalities. Tertiary responsibilities are to provide:

1. Consultation to level I and level II centers;
2. Transportation from level I and level II centers;
3. Continuing education and training for level I and level II centers.

Level III centers also provide level I and level II perinatal services.

b. "*Obstetrical unit"* means the labor, delivery, post partum, auxiliary facilities and primary care nursery unit in any perinatal center. The intensity of obstetrical services differs between the three levels of perinatal centers. Intensity means the kinds of personnel and equipment, and to a lesser extent physical facilities available, and is related to the number of births occurring at a facility. Auxiliary facilities include, but are not limited to, scrub facilities, equipment rooms, formularies, sterilization facilities, and drug distribution stations.

c. "*Neonatal intensive care unit"* means a nursery unit for neonates who are critically ill or of extremely high risk.

203.9(3) *Availability.*

a. Relationship of perinatal centers to Iowa department of public health's perinatal standards committee.

(1) Each hospital submitting an application shall identify in writing the level of care at which the state health plan classifies that hospital's perinatal services, as identified by the Iowa department of public health's perinatal standards committee.

(2) In addition to meeting the standards which follow, each applicant which seeks to change the level of care at which the state health plan classifies its perinatal services should submit to the department, during the letter of intent period, additional information in which the applicant describes the degree of conformance with the perinatal standards for the level of care that it seeks to deliver.

(3) Upon receipt of the additional information, the staff to the health facilities council shall seek a recommendation of the perinatal standards committee as to the applicant's conformance to the standards.

b. Minimum utilization—neonatal intensive care units. Each regional perinatal center service area should have no more than four neonatal intensive care beds per 1,000 live births.

c. Expansions. Applications for expanding or starting new neonatal intensive care units should not receive approval unless they have received the endorsement of the Iowa department of public health's perinatal standards committee. Such endorsement should be accompanied by an analysis of the impact the new beds will have on the occupancy rates of other neonatal intensive care units in the same referral area.

203.9(4) *Costs.* See financial and economic feasibility standards, 641—203.8(135).

203.9(5) *Accessibility.*

a. Travel time to a level I obstetrical unit should not exceed 30 minutes for 80 percent of the population served by that unit.

b. Services should be provided regardless of ability to pay, in consideration of those programs available in the state which serve the medically indigent.

203.9(6) *Quality.* Facilities should meet those Standards for Perinatal Centers (most recent edition), Iowa department of public health, for the levels of care which they provide.

203.9(7) *Continuity.* Facilities should meet those Standards for Perinatal Centers (most recent edition), Iowa department of public health, for the levels of care which they provide.

203.9(8) *Acceptability.* Facilities with neonatal and obstetrical services shall document a willingness to observe and respect the rights of patients. Provisions for counseling services shall be available.This rule is intended to implement Iowa Code section 135.64.

641—203.10(135) Designated pediatric units standards.

203.10(1) *Purpose and scope.*

a. These standards are measures of some of those criteria 1*(a to q) found in Iowa Code section 135.64. Criteria 1*(a to q) which are measured by a standard are cited in parentheses, following each standard. *Iowa Code section 135.64(1).

b. Certificate of need applications for new institutional or changed institutional health services, which are to be evaluated by the standards in this rule, are those applications to:

(1) Construct, develop, offer new, modernize, replace, renovate or relocate designated pediatric units, services and equipment;

(2) Expand bed capacity in designated pediatric units.

203.10(2) *Definitions.*

a. Designated pediatric units. A designated set of hospital facilities with equipment and personnel planned for the care of infants (other than newborn) and children (usually less than 16 years of age). According to 641—Chapter 51 of the Iowa Administrative Code, pediatric units constructed after 1976 have in addition to patient rooms, nurseries, nursery workrooms, examination and treatment room for nurseries; multipurpose rooms for dining, education and play; space for preparation and storage of infant formula; patient toilet room(s) convenient to multipurpose room equipment; and storage space for replacement of youth and adult beds to provide for swing capacity. Nurse staffing for pediatric units should have special training in pediatrics. While usable bed capacity in a section of a facility may be a designated pediatric unit, beds in that unit may be swung when peak patient census demands such.

b. Swing bed. Acute care beds which may serve adult medical/surgical patients, and pediatric patients, depending upon the patient census.

203.10(3) *Availability.*

a. Minimum utilization. (Sections 135.64(1)*"c," "g," "h"*)

(1) All designated pediatric units should operate at least at the following minimum occupancy rates:

Beds	% Occupancy	Beds	% Occupancy
< 10	60%	32-35	68%
11-13	61%	36-39	69%
14-15	62%	40-47	70%
16-17	63%	48-55	71%
18-19	64%	56-63	72%
20-23	65%	64-71	73%
24-27	66%	72-79	74%
28-31	67%	80+	75%

Facilities which cannot justify a designated pediatrics unit based on the above minimum occupancy rates are encouraged to care for pediatric patients in medical surgical beds.

b. Expansions. (Sections 135.64(1)*"c," "d," "e," "g," "h"*)

(1) Designated pediatric units in a multihospital community should be operating at least at the minimum occupancy levels of 203.10(3)*"a"*(1) before additional beds are approved. Expansion of designated pediatric units in a multihospital community which has units running at less than the minimum occupancy rates of 203.10(3)*"a"*(1) and expansion of designated pediatric units which would likely cause other units in the community to operate at less than the minimum occupancy rates should be approved only if such expansions reflect the outcome of a community planning effort which includes recommendations to adopt the least long run cost method of providing designated pediatric services in the community.

203.10(4) *Costs*. See financial and economic feasibility standards, 641—203.8(135).

203.10(5) *Accessibility.* (Sections 135.64(1)*"c," "d"*)

a. Surface travel time to a designated pediatric unit in a service area should not exceed 60 minutes for 80 percent of Iowa's population.

b. Services should be provided regardless of ability to pay, in consideration of those programs available in the state which serve the medically indigent.

203.10(6) *Quality.* (Sections 135.64(1)*"i," "k"*) The proposal should meet all applicable licensure regulations.

203.10(7) *Continuity.* (Sections 135.64(1)*"g," "h," "i," "k"*)

a. The applicant should provide documentation that physician's services are available 24 hours a day, and that registered nursing services are available on-site 24 hours a day.

b. Facilities with designated pediatric units should include mechanisms for comprehensive medical follow-up, including medical records exchange.

203.10(8) *Acceptability.* (Section 135.64(1)*"c"*) Facilities with pediatric services shall document 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. This rule is intended to implement Iowa Code sections 135.61 to 135.83.

641—203.11 Designated inpatient substance abuse treatment unit standards.

203.11(1) *Purpose and scope.*

a. These standards are measures of some of those criteria found in Iowa Code section 135.64(1)*"a"* to *"g."* 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 standards include applications to:

(1) Construct, develop, offer new, modernize, replace, renovate, or relocate designated inpatient substance abuse treatment units and services.

(2) Expand bed capacity in designated inpatient substance abuse treatment units.

203.11(2) *Definition.* Designated inpatient substance abuse treatment unit is a designated set of hospital facilities with patient beds, equipment and personnel designed for the treatment and rehabilitation of patients for whom the primary diagnosis is alcohol abuse or dependence or other drug abuse or dependence. Units designated strictly for detoxification are not considered a treatment unit as defined in this standard.

203.11(3) *Availability and need.* (Iowa Code sections 135.64(1)*"c," "d," "e," "g," "h"*)

a. The following formula shall be used as a means of projecting current utilization of inpatient substance abuse treatment services into the future and shall serve as an approximation of the number of beds needed to serve the projected population.

$$\text{Bed Need} = \frac{\text{Population by Thousand}}{\text{80\% Occupancy}} \times \frac{\text{Patient Days per Thousand Population}}{365}$$

The formula shall be calculated separately for community hospitals and state mental health institutes. The methodology for applying the formula shall be as follows.

(1) Bed need shall be calculated annually for a period five years into the future.

(a) "Population by thousand" refers to department of economic development population projection for five years into the future.

(b) For calculating community hospital bed need, "patient days per thousand population" is calculated by dividing the total patient days in all community hospital-based substance abuse treatment units during the past year (as reported on the annual hospital survey by the department of health) by the state population for that year as projected by the department of economic development.

(c) Applying the figures from (1)(a) and (1)(b) in the formula will project a statewide total of likely bed need for community hospital substance abuse treatment units, based on current utilization.

(d) For calculating mental health institute bed need, "patient days per thousand population" is calculated by dividing the total patient days in the four mental health institute substance abuse treatment units (as reported to the department of human services) by the state population for that year as projected by the department of economic development.

(e) Applying the figures from (1)(a) and (1)(d) in the formula will project a statewide total of likely bed need for mental health institute substance abuse treatment units based on current utilization.

(2) For purposes of comparing "need" to "existing" beds in community hospitals, the state shall be divided into eight planning districts, as used by the department of human services.

(a) The total number of beds derived in (1)(c) above for likely bed need for community hospital units shall be divided by the projected state population in thousands to derive beds needed per thousand population.

(b) For each district, the factor in (2)(a) above shall be multiplied by the projected population by thousand in that district for a district bed need.

(c) To determine number of existing beds in a given district, the number of substance abuse treatment beds at all community hospitals in that district shall be added together. The number of beds at each facility shall be the number of licensed or registered beds in the substance abuse treatment unit, as reported on the annual hospital survey to the Iowa department of public health.

(3) For purposes of comparing "need" to "existing" beds in mental health institutes, the total number of beds derived in (1)(e) above for likely bed need for MHI units will be compared to the total of the existing substance abuse treatment beds at the four MHIs in the state as reported on the Iowa department of public health annual survey.

b. In documenting need for a project, the applicant shall identify the service area and target population, including a description of the methodology used by the applicant in determining need for the requested beds, the expected sources of referrals, and expected average length of stay. The applicant shall document that the number of beds requested is appropriate to the modality of treatment being proposed. The applicant shall also identify where the target population has received services in the past.

c. The availability and utilization of other services in the area (e.g., inpatient, outpatient, and residential services) shall be considered in the determination of need. The applicant shall describe the relationship of the proposed service to existing services and describe what impact the proposed service will have on similar or alternate services in the district.

d. Existing hospital-based substance abuse treatment programs in the district should be running at least 85 percent occupancy in units of less than 20 beds and at least 90 percent occupancy in units of 20 beds or more before any additional inpatient substance abuse treatment beds are approved.

e. A hospital seeking expansion of a substance abuse treatment unit must demonstrate that its occupancy has been greater than 90 percent for the past two years.

f. Applicants must be able to project an annual 70 percent occupancy rate in the unit for the second year of operation and must be able to project an 80 percent occupancy rate in the unit by the third year of operation.

203.11(4) *Quality.* (Iowa Code sections 135.64(1)*"i," "k"*)

a. Staffing for an inpatient substance abuse treatment unit should minimally consist of:

(1) Medical director. The applicant shall document that the physician has specific knowledge and special interest in the area of substance abuse and several years of experience and training in the treatment of substance abusers. Physician backup must be available on a 24-hour basis.

(2) Administrative director. The applicant shall document that the director, if other than the medical director, has experience in hospital administration or substance abuse treatment and rehabilitation.

(3) Nursing personnel must staff the unit on a 24-hour basis. The applicant shall document that the RNs and LPNs have had or will be provided with specific training in the area of substance abuse treatment.

(4) Counselors. The applicant shall document the availability of chemical dependency counselors who are certified or have equivalent qualifications in training, education, and experience.

(5) Psychiatrist or psychologist should be available on staff or on a contract basis. The applicant shall document that the psychiatrist or psychologist has shown a continued interest in the area of substance abuse treatment and has experience in dealing with chemically dependent patients.

(6) Family therapist(s): The program shall employ or contract with a family therapist(s) that has completed a chemical dependency counselor training program with emphasis on family involvement; or has a master's level in family social work, family counseling or other appropriate fields; or has the equivalent in training or experience.

(7) Other ancillary personnel. The program should have access to other personnel such as social workers, dieticians, recreational therapists, occupational therapists, physical therapists, and other ancillary services as needed.

b. All inpatient programs shall develop and utilize specific written admission criteria. A good example of such criteria is that developed by the Iowa Foundation for Medical Care.

c. The program shall have a written evaluation system and be capable of providing treatment process and outcome data to evaluate the quality and effectiveness of the program at least once annually.

203.11(5) *Continuity.* (Iowa Code sections 135.64(1)*"g," "h," "k"*)

a. The applicant shall have formal referral arrangements with existing diagnosis and referral services, and detoxification services.

b. If outpatient services are available, the applicant shall provide a description of the circumstances under which a client would be accepted for inpatient treatment rather than entered into the outpatient program. The applicant shall also describe the circumstances under which a patient would be referred from inpatient to outpatient care and should have referral arrangements for outpatient services.

c. The applicant shall document that aftercare or continuing care services will be provided by the facility on a long-term basis or that such services will be provided through referral arrangements. For patients leaving the vicinity of the hospital to return to their home communities, the applicant shall indicate what arrangements will be made to provide for aftercare.

203.11(6) *Accessibility and acceptability.* (Iowa Code sections 135.64(1)*"c," "d"*) Population subgroups which have traditionally been underserved, such as adolescents, the elderly, women, and racial minorities, should be considered when planning for or reviewing inpatient treatment programs.

203.11(7) *Costs and financial feasibility.* (Iowa Code sections 135.64(1)*"e," "f," "i," "p"*)

a. The applicant shall document that for the target population, hospital-based inpatient care is warranted. The applicant shall demonstrate that alternatives were considered and that there is no less costly acceptable mode of treatment.

b. Charges per patient day should be justifiable when compared to current charges of other inpatient substance abuse treatment programs in the state.

c. The applicant should outline the anticipated sources of reimbursement in preparing the program's projected budget, indicating the percentage of patient days allocated to indigent clients, Medicare clients, private pay clients, privately insured clients or others.

d. Conversion projects will be considered preferable to new construction unless documentation of cost-savings is presented, or other factors to be specified by the applicant prohibit such conversion. This rule is intended to implement Iowa Code section 135.64.

641—203.12(135) Magnetic resonance imaging services standards.

203.12(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code sections 135.64(1)*"a"* to *"q."* 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 standards include:

(1) Proposals to commence or expand the capacity of magnetic resonance imaging services.

(2) Proposals to replace a magnetic resonance imaging unit.

(3) Any other applications which relate to magnetic resonance imaging.

203.12(2) *Definitions.*

"Area" means the community or a metropolitan statistical area (as defined by the U.S. Office of Management and Budget and used by the U.S. Census Bureau).

"CT (computed tomography) procedure" means a CT study of a single site of anatomic interest during an individual patient visit.

"Magnetic resonance imaging (MRI)" means a diagnostic modality which employs a combination of magnetic and radio frequency fields and computers to produce images of body organs and tissues.

"MRI procedure" means each discrete MRI study of one patient.

"MRI unit" means the essential equipment and facility necessary to operate one MRI system.

203.12(3) *Availability and need.* (Iowa Code sections 135.64(1)*"c," "d," "e," "g," "h"*)

a. Applicants in areas with no other MRI units. Applicant must document a CT procedure volume of at least 4,500 CT procedures during the most recent calendar or fiscal year period. For purposes of calculating the volumes required, the applicant may use the combined total of more than one facility if the application involves joint ownership of the equipment, or the applicant provides evidence of referral arrangements for the proposed MRI service from the facilities whose procedure or patient volumes are included in the calculations.

b. Applicants in areas with one or more MRI units currently in operation or approved by certificate of need for operation.

(1) Applicant must meet the requirement of need described in 203.12(3)*"a"* and

(2) The other MRI unit(s) within the area must have been operating at a minimum of 3,000 MRI procedures annually (or 750 in three months), or proportionately more if the MRI unit runs more than one ten-hour shift.

(3) If the annual utilization of the other MRI unit(s) within the area has been below 3,000 procedures, future utilization above that current level must be reasonably projected or reasons for permanently utilizing the equipment below the 3,000 procedure level must be demonstrated.

c. Applicants seeking to replace an MRI unit.

(1) The applicant must demonstrate that the existing MRI unit has been operating at the level of at least 3,000 procedures during the most recent annual period.

(2) If the applicant's annual utilization has been below 3,000 procedures, the applicant must reasonably project future utilization above that level or demonstrate reasons for permanently utilizing the equipment below that level.

d. Applicants seeking to add an additional MRI unit.

(1) The applicant must demonstrate that the existing MRI unit(s) has been operating at the level of at least 3,500 procedures during the most recent annual period.

(2) The applicant must demonstrate that the demand significantly exceeds the 3,500 procedures annually.

e. The provisions of subrule 203.12(3) shall be effective until June 30, 1995. Prior to that time the Iowa department of public health shall reconvene a task force to recommend continuing use of the need methodology outlined or develop a new or revised methodology to use in projecting future MRI needs. The department shall promulgate a new subrule 203.12(3) accordingly.

203.12(4) *Quality and continuity.* (Iowa Code sections 135.64(1)*"g," "h," "i," "k"*)

a. The proposed MRI unit must function as a component of a comprehensive inpatient or outpatient diagnostic service. The proposed MRI unit must have the following modalities on-site or through referral arrangements:

(1) Ultrasound

(2) Computed tomography — whole body unit

(3) Angiography

(4) Nuclear medicine

(5) Conventional radiography

b. The proposed MRI unit must be located in a facility which has, either in-house or through referral arrangement, the resources necessary to treat most of the conditions diagnosed or confirmed by MRI. The following medical specialties must be available during MRI service hours on-site or by referral arrangements: neurology or neurosurgery, oncology and cardiology.

c. A proposal to provide new or expanded MRI must include satisfactory assurances that the services will be offered in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing agencies' requirements.

d. The applicant must provide evidence that the proposed MRI equipment has been certified for clinical use by the U.S. Food and Drug Administration or will be operated under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations.

e. Applicants for MRI shall document that the necessary qualified staff are available to operate the proposed unit. The following minimum staff shall be available to the MRI unit:

1. A full-time board eligible or board certified radiologist or nuclear medicine imaging physician or any other board eligible or board certified licensed physician whose exclusive responsibility for at least a two-year period prior to submission of a certificate of need request has been in the acquisition and interpretation of clinical images. This individual shall have a knowledge of MRI through training, experience, or documented postgraduate education. The individual shall also have training with a functional MRI facility.

2. Qualified engineering personnel, available to the institution during MRI service hours, with training and experience in the operation and maintenance of the MRI equipment.

3. Diagnostic radiologic technologists or other certified technologists with expertise in computed tomography or other cross-sectional imaging methods, at a staffing level consistent with the hospital's expected MRI service volume.

4. Other appropriate physicians shall be available during MRI service hours in clinical specialties such as neurology or neurosurgery, oncology and cardiology.

f. The applicant shall demonstrate how emergencies within the MRI unit will be managed in conformity with accepted medical practice.

203.12(5) *Accessibility and acceptability.* (Iowa Code sections 135.64(1)*"c," "d"*)

a. MRI facilities should have adequate scheduled hours to avoid an excessive backlog of cases and MRI shall be available 24 hours a day, seven days a week on an emergency (on-call) basis.

b. Selection of patients for clinical MRI studies must guarantee equal access to all persons regardless of insurance coverage or ability to pay.

c. In addition to accepting patients from participating institutions, facilities performing clinical MRI procedures shall accept appropriate referrals from other local providers. These patients shall be accommodated to the extent possible by extending the hours of service and by prioritizing patients according to standards of need and appropriateness rather than source of referral.

203.12(6) *Costs and financial feasibility.* (Iowa Code sections 135.64(1*)"e," "f," "i," "p"*)

a. The applicant shall identify capital and operating costs associated with the proposed MRI unit, identify sources of funding to cover those costs, and demonstrate that the project is financially feasible.

b. The applicant shall provide budgets for the first three years of operation, including documentation and justification of all assumptions used.

c. The applicant must document its projected average cost per procedure and charge per procedure for the first three years. Charges for MRI should be reasonably related to service cost, and comparable to MRI charges at other facilities in the state.

d. The applicant shall demonstrate that alternatives were considered and the proposed application is the most cost-effective and will accomplish the goals of the project.

e. To provide a data base for evaluation of subsequent MRI applications by the health facilities council, applicants granted a certificate of need shall provide to the certificate of need office the following data upon request of the Iowa department of public health. The department will request the following data on an annual basis.

1. Total number of procedures performed;
2. Total number of inpatient procedures;
3. Total number of outpatient procedures;
4. Average charge per procedure;
5. Hours of operation of the MRI unit;
6. Total revenues and expenses for the MRI unit for the year.

This rule is intended to implement Iowa Code section 135.64.

641—203.13(135) Positron emission tomography services standards.

203.13(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code sections 135.64(1)*"a"* to *"q."* 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 standards include:

(1) Proposals to commence or expand the capacity of positron emission tomography services.

(2) Proposals to replace a positron emission tomography unit.

(3) Any other applications which relate to positron emission tomography.

203.13(2) *Definitions*.

"Area" means the community or a metropolitan statistical area (as defined by the U.S. Office of Management and Budget and used by the U.S. Census Bureau).

"CT (computed tomography)" means an imaging method in which a cross-sectional image of the structures in a body plane is reconstructed by a computer program from the X-ray absorption of beams projected through the body in the image plane.

"Cyclotron" means an apparatus for accelerating protons or neutrons to high energies by means of a constant magnet and an oscillating electric field.

"MRI (magnetic resonance imaging)" means a diagnostic modality which employs a combination of magnetic and radio frequency fields and computers to produce images of body organs and tissues.

"Radiopharmaceutical" means a radioactive pharmaceutical used for diagnostic or therapeutic purposes.

"PET procedure" means an image-scanning sequence derived from a single administration of PET, equated with a single injection of the tracer.

"Positron emission tomography (PET)" means an imaging method in which positron-emitting radionuclides, which are produced either by a cyclotron or generator, and a nuclear camera are used to create pictures of organ function rather than structure. PET installations generally take one of two forms: a PET scanner using only generator-produced tracers (basic PET unit), or a PET scanner with a cyclotron (enhanced PET unit).

"SPECT (single photon emission computed tomography)" means a camera-based imaging system using the radionuclides in the routine practice of nuclear medicine.

203.13(3) *Availability and need.* (Iowa Code sections 135.64(1)*"c," "d," "e," "g," "h"*)

a. Applicants in areas with no other basic or enhanced PET units.

(1) Applicants should demonstrate a reasonable potential utilization of a PET unit based on diversified inpatient and outpatient case mix thresholds including:

1. Intracranial cases

_ Primary brain tumors 50/year

_ Metastasis 100/year

_ Cerebral vascular disease 200/year

_ Organic brain disease and dementia/psychiatric diagnoses (including epilepsy-seizure disorders) 500/year

_ Spinal 100/year

2. Cardiovascular cases

_ Ischemic heart disease (including acute and chronic infarction) 1200/year

3. Neoplasms (head, neck, thorax (excluding heart), abdomen, pelvic and musculoskeletal 1300/year

4. If the application is for a basic unit, the above case mix and numbers should be adjusted according to the proposed use of the unit.

(2) Applicants should have other diagnostic capabilities, on-site or through referral arrangements, with appropriate volumes including:

	Proposed Threshold
Nuclear medicine imaging services	7,000
Single photon emission computed tomography (including brain, bone, liver, Gallium and Thallium stress)	2,000
CT	10,000
MRI	3,000
Cardiac angiography	1,500
Cardiac ultrasound	7,000

(3) Applicants must demonstrate secondary and tertiary service capability, on-site or through referral arrangements, including cardiac surgery, cardiology, internal medicine, general surgery, hematology/oncology, neurology, pathology, thoracic surgery and psychiatry.

b. Applicants in areas with one or more basic or enhanced PET units currently in operation or
approved by the certificate of need program for operation.

(1) Applicant should have access to cyclotron-produced radiopharmaceuticals.

(2) Existing PET units within the area (whether basic or enhanced) must have been operating at a minimum of 1000 PET procedures during the most recent annual period as reported to the certificate of need program according to 203.13(6)*"e."*

c. The provisions of subrule 203.13(3) shall be effective until June 30, 1995. Prior to that time the Iowa department of public health shall reconvene a task force to recommend continuing use of the need methodology outlined or develop a new or revised methodology to use in projecting future PET needs. The department shall promulgate a new subrule 203.13(3) accordingly.

203.13(4) *Quality and continuity.* (Iowa Code sections 135.64(1)*"g," "h," "i," "k"*)

a. The proposed PET unit must function as a component of a comprehensive inpatient or outpatient diagnostic service. The proposed PET unit must have the following modalities (and capabilities) on-site or through referral arrangements:

(1) Computed tomography — (whole body)

(2) Magnetic resonance imaging — (brain and whole body)

(3) Nuclear medicine — (cardiac, SPECT)

(4) Conventional radiography

b. The proposed PET unit must be located in a facility which has, either in-house or through referral arrangement, the resources necessary to treat most of the conditions diagnosed or confirmed by PET. The following medical specialties must be available during PET service hours on-site or by referral arrangements: cardiology, neurology, neurosurgery, oncology, and psychiatry.

c. A proposal to provide new or expanded PET must include satisfactory assurances that services will be offered in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing agencies' requirements. The following areas are to be addressed:

(1) Quality control and assurance of radiopharmaceutical production of generator or cyclotronproduced agents;

(2) Quality control and assurance of PET tomograph and associated instrumentation;

(3) Radiation protection and shielding;

(4) Radioactive emissions to the environment.

d. The applicant must provide evidence that the proposed PET equipment has been certified for clinical use by the U.S. Food and Drug Administration or will be operated under an institutional review
board whose membership is consistent with U.S. Department of Health and Human Services regulations.

e. Applicants for PET shall document that the necessary qualified staff are available to operate the proposed unit. The applicants shall document the PET training and experience of the staff. The following minimum staff shall be available to the PET unit:

(1) One or more nuclear medicine imaging physician(s) available on a full-time basis to the PET unit who have been licensed by the state for the handling of medical radionuclides and whose primary responsibility for at least a one-year period prior to submission of the certificate of need application has been in acquisition and interpretation of tomographic images. This individual shall have knowledge of PET through training, experience, or documented postgraduate education. The individual shall also have training with a functional PET facility.

(2) Qualified PET radiochemist or radiopharmacist personnel, available to the facility during PET service hours, with at least one year of training and experience in the synthesis of short-lived positronemitting radiopharmaceuticals. The individual(s) shall have experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical syntheses.

(3) Qualified engineering and physics personnel, available to the facility during PET service
hours, with training and experience in the operation and maintenance of the PET equipment.

(4) Qualified radiation safety personnel, available to the facility at all times, with training and experience in the handling of short-lived positron-emitting nuclides.

(5) Certified nuclear medicine technologists with expertise in computed tomographic nuclear
medicine imaging procedures, at a staffing level consistent with the proposed center's expected PET service volume.

(6) Other appropriate physicians shall be available during PET service hours which may include certified nuclear medicine technologists, computer programmers, nurses, and radiochemistry technicians.

f. The applicant shall demonstrate how emergencies within the PET unit will be managed in conformity with accepted medical practice.

203.13(5) *Accessibility and acceptability.* (Iowa Code sections 135.64(1)*"c," "d"*)

a. PET facilities should have adequate scheduled hours to avoid an excessive backlog of cases.

b. Selection of patients for clinical PET studies must guarantee equal access to all persons regardless of insurance coverage or ability to pay.

c. In addition to accepting patients from participating institutions, facilities performing clinical PET procedures shall accept appropriate referrals from other local providers. These patients shall be accommodated to the extent possible by extending the hours of service and by prioritizing patients according to standards of need and appropriateness rather than source of referral.

203.13(6) *Costs and financial feasibility.* (Iowa Code sections 135.64(1)*"e," "f," "i," "p"*)

a. The applicant shall identify capital and operating costs associated with the proposed PET unit, identify sources of funding to cover those costs, and demonstrate that the project is financially feasible.

b. The applicant shall provide budgets for the first three years of operation, including documentation and justification of all assumptions used.

c. The applicant must document its projected average cost per procedure and charge per procedure for the first three years. Charges for PET should be reasonably related to service cost and comparable to PET charges at other facilities in the state.

d. The applicant shall verify whether the service is eligible for reimbursement by public and private third-party payers.

e. The applicant shall demonstrate that alternatives were considered and the proposed application is the most cost-effective and will accomplish the goals of the project.

f. To provide a data base for evaluation of subsequent PET applications by the health facilities council, applicants granted a certificate of need shall provide to the certificate of

need office the following data upon request of the Iowa department of public health. The department will request the following data on an annual basis.

(1) Total number of procedures performed;

(2) Total number of inpatient procedures (indicate type of procedure);

(3) Total number of outpatient procedures (indicate type of procedure);

(4) Average charge per specific procedure;

(5) Hours of operation of the PET unit;

(6) Total revenues and expenses for the PET unit for the year.

This rule is intended to implement Iowa Code section 135.64.

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