441—124.1(135) Computerized tomography standards.

124.1(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code section 135.63(1)*"a"* through *"l."* Criteria that are measured by a standard are cited in parentheses following each standard.

b. Certificate of need applications that are to be evaluated against these computerized tomography standards include:

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

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

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

"Applicant" means a facility or a consortium of facilities within an area or a physician or group of physicians.

"Computerized tomographic (CT) scanner" means a diagnostic tool that rotates around the body and that sends X-ray beams through the body or brain. The X-ray beams that 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 volume or cross-section. The images on the detector are transmitted to a computer that displays on a monitor a reconstructed cross-sectional slice or volume. Contrast media is often injected to alter absorption of the detector. If the scan is repeated, it is called enhancement. Studies of the heart, arteries and veins may be done with contrast only.

"CT consortia" means a cooperative venture in which two or more institutions form a separate entity that 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.

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

"Enhanced scan" means a scan performed on a patient who has been administered a contrast medium so that specific organs or areas of the body will be displayed more distinctly on the scan image.

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

"Head scanner" means a scanner capable of imaging only the brain and structures adjacent to the head.

"Minimum shared-market area for a scanner" (hereafter referred to as "area") means the smallest geographic area within which any scanner installation is judged to affect the utilization rate of any other scanner in the community (as defined by the U.S. Bureau of the Census) or a standard metropolitan statistical area (where an area is so designated).

"Radiotherapy service" means 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.

"Shared service agreement" means 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.

"Whole body scanner" means a scanner capable of imaging the entire body.

124.1(3) *Determination of need.*

a. An applicant who does not have a scanner or an applicant who has a scanner and seeks a certificate for one or more additional scanners.

(1) An applicant in areas with no other scanners.

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

2. An applicant must demonstrate that during the past calendar year or 12 months, the applicant has performed diagnostic procedures equivalent to 1,500 head equivalent CTs (HECTs), using the following: 100 percent of the number of patients referred to other facilities for CT diagnosis × 1.75 (in the case of head scans) and 2.75 (in the case of body scans).

(2) An applicant in an area with one or more scanners.

1. An applicant must meet the requirement of need described in subparagraph 124.2(3)*"a"*(1), and

2. The average level of utilization for scanners within the area was at least 3,000 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.

3. University of Iowa Health Care is specifically exempted from consideration under numbered paragraph 124.3(2)*"a"*(2)"2" because it has a service area that encompasses the entire state and adjoining states. The utilization statistics for scanners at the University of Nebraska Medical Center and Creighton University Medical Center – Bergan Mercy (both in Omaha) will not affect the need for scanners at hospitals in Council Bluffs.

b. Replacement scanners—applicant who currently has a scanner.

(1) An applicant seeking to replace a scanner with another scanner, head or body.

1. An 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

2. An applicant must demonstrate that the applicant's use of the applicant's current scanner was at least below the operating capacity level, but above the 1,500 CT scan level, and the applicant must demonstrate reasons for permanently utilizing the applicant's scanner below operating capacity level and demonstrate that discontinuation of the applicant's 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 that would define the capacity level differently for the applicant.

(2) Reserved.

124.1(4) *Costs and financial feasibility.* (Iowa Code section 135.63(1)*"f," "i,"* and *"p"*)

a. 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. An applicant should demonstrate for the applicant and the health care system that the most cost-effective method of providing CT services has been chosen. A proposed new and replacement CT scanner's cost per CT scan should, when compared to the applicant's peers, demonstrate cost-effectiveness.

124.1(5) *Accessibility.* (Iowa Code section 135.63(1)*"c"* and *"d"*)

a. All scanners must be available to meet the needs of the communities the scanners are meant to serve.

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

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

124.1(6) *Quality.* (Iowa Code section 135.63(1)*"i"* and *"k"*)

a. Data on use and costs of the CT scanners should be submitted to the Iowa department of health and human services as a condition of approval. (Iowa Code section 135.63(1)*"a"* and *"h"*)

b. All scanners.

(1) An applicant must demonstrate that the applicant has on its staff or will acquire on its staff a full-time diagnostic radiologist trained in the use of the CT scanner or other physicians with comparable training and expertise.

(2) An applicant must document that the applicant has on its 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. An applicant that intends to acquire staff with the desired expertise should provide signed letters of intent from the incoming medical personnel. An applicant that intends to upgrade the specialty skills of its staff should document a plan for training its current staff in the use of CT scanners.

(3) An applicant should have a complement of other diagnostic modalities available. An applicant seeking body scanners should also have available ultrasound and conventional X-ray services.

(4) An applicant 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) An applicant should have on its staff or available on a consultative basis the services of a biomedical engineer or medical physicist with special training in CT applications. These functions may also be provided by contract with the scanner manufacturer.

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

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

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

c. An applicant should demonstrate an emphasis on the availability of outpatient CT procedures and that an appropriate percentage of all CT procedures will be done on an outpatient basis.

124.1(8) *Acceptability.* (Iowa Code section 135.63(1)*"k"*) Providers of CT services should indicate a willingness to observe the rights of patients.

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