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Certificate of Need Standards for the Acquisition of Imaging Equipment

Sec. 1. Computed Tomography Scanners

(a) Definitions.

- (1) "Computed tomography" or "CT" means the use of radiographic and computer techniques to produce cross-sectional images of the head or body;
- (2) "Computed tomography scanner" means x-ray CT scanning systems, including axial, spiral, helical or electron beam CT systems (except as set forth in 19a-638(b)(19)), capable of performing CT scans of the head, other body parts, or full body patient procedures, or any equipment that is classified by the United States Food and Drug Administration as a computed tomography device;
- (3) "Primary service area" means that geographic area (by town), for the service location in the application, consisting of the lowest number of contiguous zip codes from which the applicant draws at least 75% of its patients for this service at such location.

(b) Information Supporting Need Analysis

- (1) Identify the Primary Service Area.
- (2) Identify existing services (i) of the applicant, and (ii) of other providers in the Primary Service Area.
- (3) Provide capacity of existing services identified in subsection (b)(2), if available.
- (4) Explain the likely impact on existing services identified in subsection (b)(2).
- (5) Provide actual and proposed hours of operation for services.
- (6) Provide 3 year projection of utilization, with reasonable assumptions on CT scan volume and capacity.
- (7) Demonstrate need as described in (c).

(c) Need Analysis – Statewide Benchmark

- (1) Assumptions:
 - i. "Utilization Rate per Capita" means the number of scans/ 1000 population as determined by data collected and published by the Office of Healthcare Access Division of the Department of Public Health through its data collection and survey processes. If such data are not available from the Office, the applicant is responsible for including reliable statistics, with citations, to establish the utilization rate;
 - ii. "Utilization Rate" means the procedure per year for the PSA calculated by multiplying the "Utilization Rate per Capita" by the population in the PSA using the most recently available census data.

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- iii. "Current Estimated Capacity" is 9,000 scans per year multiplied by the number of hospital based scanners in the PSA at the time of the application for the acquisition of a hospital based scanner and 5,000 scans per year multiplied by the number of outpatient scanners in the PSA at the time of the application for the acquisition of an outpatient scanner; and
- iv. "Percent Utilization of Current Capacity" means the Utilization Rate/Current Estimated Capacity.

(2) Need Methodology

The Applicant shall demonstrate that the proposed scanner meets the following criteria:

- i. The applicant is generally expected to demonstrate that the Percent Utilization of Current Capacity in the Primary Service Area exceeds 85%.
 - ii. If the applicant has a CT scanner in the Primary Service Area, the applicant is generally expected to demonstrate that its Percent Utilization of Current Capacity exceeds 85%.
- (3) If the applicant is unable to demonstrate a clear public need for the proposed scanner based upon the assumptions and need methodology in subsection (c)(1) and subsection (c)(2) have been met, the Applicant may rely upon any other relevant factors, including those described in subsection (f), to demonstrate need among the population it intends to serve.

(d) Quality and Accessibility

Applicants shall demonstrate compliance with the following criteria:

- (1) Hospital applicants shall be accredited by The Joint Commission or certified by Medicare directly or through a deeming agency;
- (2) Non-hospital facilities shall obtain accreditation from either the American College of Radiology or the Intersocietal Commission on the Accreditation of Computed Tomography Laboratories within eighteen months of that date on which the imaging activities are first conducted;
- (3) The CT unit shall be operated safely by trained physicians and/or radiologic technologists who are licensed in Connecticut and who meet the minimum criteria set forth by the appropriate accrediting organization including but not limited to the American College of Radiology, the American Registry of Radiologic Technologists, and the American Registry of Clinical Radiography;
- (4) All applicants must employ or contract with a radiation physicist to review the quality and safety of the operation of the CT scanner.
- (5) When imaging is performed a physician must be available either on-site or with immediate access to remote viewing of images as they are acquired. The physician in this case must be qualified to interpret images, make adjustments to imaging parameters or protocols, make decisions regarding radiation dose, and consult with the technologists on technical

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factors related to the study acquisition. This physician must be board certified to perform and interpret the examinations so produced;

- (6) When contrast is administered, a physician capable of addressing any contrast reactions or adverse events must be on site and immediately physically available to assist in the imaging suite. This physician must be in proximity such that he/she can respond immediately if called. This is not intended to require the physical presence of a physician in the room or suite at all times.
- (7) The facility or provider shall not deny CT scanner services to any individual based upon the ability to pay or source of payment, including uninsured, underinsured and Medicaid patients;
- (8) The facility or provider must have a policy that explains what steps will be taken to respond in the event of a medical emergency for patients undergoing CT scans, including the plan for responding to allergic reactions related to contrast media or other drugs or biologicals used in connection with the scan.

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(e) Financial criteria.

The Applicant shall demonstrate that it has sufficient capital to finance the project and provide projections concerning the revenue and expenses for the first three years of the proposal.

(f) Other Factors.

The office may also take the following criteria into consideration during its review of an application:

- (1) The capabilities of the proposed CT scanner as compared to existing scanners;
- (2) The ability of the applicant to serve an underserved population and not jeopardize the financial viability of the project;
- (3) The impact on existing services, including avoiding delays in timely diagnosis or treatment;
- (4) The use of the scanner for clinical research;
- (5) The history of the applicant in running accredited, financially successful facilities;
- (6) The applicant's ability to make radiation dose exposure decisions; and
- (7) For hospital applicants only, unique patient populations or specific clinical needs for specialty scanners or specific clinical applications, including scanners with multiple use applications; complexity of scanning procedures, including the impact on available scanner access due to lengthy procedures; necessity for back-up and redundant equipment to meet the needs of emergency departments.

Sec. 2 Magnetic Resonance Imaging Scanners

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(a) Definitions.

- (1) "Magnetic resonance imaging" or "MRI" means the use of magnetic fields and radio waves to produce cross sectional images similar to those displayed by computed tomography (CT);
- (2) "Magnetic resonance imaging scanner" means the magnetic resonance system consisting of an integrated set of machines and related equipment necessary to produce the images and/or spectroscopic quantitative data from scans, or any equipment that is classified by the United States Food and Drug Administration as a magnetic resonance diagnostic device; and
- (3) "Primary service area" means that geographic area (by town), for the service location in the application, consisting of the lowest number of contiguous zip codes from which the applicant draws at least 75% of its patients for this service at such location.

(b) Information Supporting Need Analysis

- (1) Identify the Primary Service Area.
- (2) Identify existing services (i) of the applicant, and (ii) of other providers in the Primary Service Area.
- (3) Provide capacity of existing services identified in subsection (b)(2), if available.
- (4) Explain the likely impact on existing services identified in subsection (b)(2).
- (5) Provide actual and proposed hours of operation for services.
- (6) Provide 3 year projection of utilization, with reasonable assumptions on MRI scan volume and capacity.
- (7) Demonstrate need as described in (c).

(c) Need Analysis – Statewide Benchmark

(1) Assumptions

- i. "Utilization Rate per Capita" means the number of scans/1000 population as determined by data collected and published by the Office of Healthcare Access Division of the Department of Public Health through its data collection and survey processes. If such data are not available from the Office, the applicant is responsible for including reliable statistics, with citations, to establish the utilization rate;
- ii. "Utilization Rate" means procedure per year for the PSA calculated by multiplying the Utilization Rate per Capita by the population in the PSA using the most recently available census data;
- iii. "Current estimated capacity" means 7,000 scans/year multiplied by the number of hospital based scanners in the PSA at the time of the application for the acquisition of a hospital based scanner and 3,100 scans/year multiplied by the number of outpatient scanners in the PSA at the time of the application for the acquisition of an outpatient scanner;

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iv. "Percent Utilization of Current Capacity" means the Utilization Rate/Current Estimated Capacity.

(2) Need Methodology

The Applicant shall demonstrate that the proposed scanner meets the following criteria:

- i. The applicant is generally expected to demonstrate that the Percent Utilization of Current Capacity in the Primary Service Area exceeds 85%.
- ii. If the applicant has an MRI scanner in the Primary Service Area, the applicant is generally expected to demonstrate that its Percent Utilization of Current Capacity exceeds 85%.

(3) If the applicant is unable to demonstrate a clear public need for the proposed scanner based upon the assumptions and need methodology in subsection (c)(1) and subsection (c)(2) have been met, the Applicant may rely upon any other relevant factors, including those described in subsection (f), to demonstrate need among the population it intends to serve.

(d) Quality and Accessibility.

The Applicant shall demonstrate the following:

- (1) Hospital applicants shall be accredited by The Joint or certified by Medicare directly or through a deeming agency;
- (2) Non-hospital facilities shall obtain accreditation from the American College of Radiology within eighteen months of the date on which imaging activities are first conducted;
- (3) A full-time board certified radiologist, who is a member in good standing with the American College of Radiology, shall be responsible for managing the operation of the MRI scanner and for the written interpretation of the MRI scan;
- (4) Personnel shall be trained, consistent with guidance of the American College of Radiology, in the use of the MRI scanner and the safety procedures to follow in the event of an emergency;
- (5) When imaging is performed a physician must be available either on-site or with immediate access to remote viewing of images as they are acquired. The physician in this case must be qualified to interpret images, make adjustments to imaging parameters or protocols, make decisions regarding magnetic field strength risks, and consult with the technologists on technical factors related to the study acquisition. This physician must be board certified to perform and interpret the examinations so produced;
- (6) When contrast is administered, a physician capable of addressing any contrast reactions or adverse events must be on site and immediately physically available to assist in the imaging suite. This physician must be in proximity such that he/she can respond immediately if called. This is

not intended to require the physical presence of a physician in the room or suite at all times.

- (7) The facility or provider shall not deny MRI scanner services to any individual based upon the ability to pay or source of payment, including uninsured, underinsured and Medicaid patients;
- (8) The facility or provider must have a policy that explains what steps will be taken to respond in the event of a medical emergency for patients undergoing MRI scans, including the plan for responding to allergic reactions related to contrast media or other drugs or biologicals used in connection with the scan.

(e) Financial Criteria.

The Applicant shall demonstrate that it has sufficient capital to finance the project and provide projections concerning the revenue and expenses for the first three years of the proposal.

(f) Other factors.

The office may also take the following criteria into consideration during its review of an application:

- (1) The capabilities of the proposed MRI scanner as compared to existing MRI scanners;
- (2) The ability of the applicant to serve an underserved population and not jeopardize the financial viability of the project;
- (3) The impact on existing services, including avoiding delays in timely diagnosis or treatment;
- (4) The use of the MRI scanner for clinical research;
- (5) The history of the applicant in running accredited, financially successful facilities;
- (6) The applicant's ability to make radiation dose exposure decisions; and
- (7) For hospital applicants only, unique patient populations or specific clinical needs for specialty scanners or specific clinical applications, including scanners with multiple use applications; complexity of scanning procedures, including the impact on available scanner access due to lengthy procedures; necessity for back-up and redundant equipment to meet the needs of emergency departments.

Sec. 3 Positron Emission Tomography Scanners and Positron Emission Tomography/Computed Tomography Scanners

(a) Definitions.

- (1) "Positron emission tomography" or "PET" is a non-invasive diagnostic technology which enables the body's physiological and biological processes to be observed through the use of positron emitting radiopharmaceuticals which are injected into the body and whose interaction with body tissues and organs is able to be pictured through a computerized positron transaxial reconstruction tomography scanner;

- (2) "Positron emission tomography scanner " means an FDA-approved full or partial ring scanner or coincidence system that has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and digital detectors and iterative reconstruction, or any equipment that is classified by the United States Food and Drug Administration as an emission computed tomography device;
- (3) "Positron emission tomography-computed tomography scanner" or "PET-CT scanner" is a medical imaging device which combines in a single gantry system both a positron emission tomography (PET) and a computed tomography (CT), so that images acquired from both devices can be taken sequentially, in the same session from the patient and combined into a single superposed image;
- (4) "Primary service area" means that geographic area (by town), for the service location in the application, consisting of the lowest number of contiguous zip codes from which the applicant draws at least 75% of its patients for this service at such location.

(b) Information Supporting Need Analysis

- (1) Identify the Primary Service Area.
- (2) Identify existing services (i) of the applicant, and (ii) of other providers in the Primary Service Area.
- (3) Provide capacity of existing services identified in subsection (b)(2), if available.
- (4) Explain the likely impact on existing services identified in subsection (b)(2).
- (5) Provide actual and proposed hours of operation for services.
- (6) Provide 3 year projection of utilization, with reasonable assumptions on PET or PET-CT scan volume and capacity.
- (7) Demonstrate need as described in (c).

(c) Need Analysis – Statewide Benchmark

(1) Assumptions

- i. "Utilization Rate per Capita" means the number of scans/1000 population as determined by data collected and published by the Office of Healthcare Access Division of the Department of Public Health through its data collection and survey processes. If such data are not available from the Office, the applicant is responsible for including reliable statistics, with citations, to establish the utilization rate;
- ii. "Utilization Rate" means procedure per year for the PSA calculated by multiplying the Utilization Rate Per Capita by the population in the PSA using the most recently available census data;
- iii. "Current estimated capacity" means 950 scans per year multiplied by the number of scanners in the service area;

- iv. "Percent Utilization of Current Capacity" means the utilization rate/current estimated capacity.

(2) Need Methodology

The Applicant shall demonstrate that the proposed scanner meets the following criteria:

- i. The applicant is generally expected to demonstrate that the Percent Utilization of Current Capacity in the Primary Service Area exceeds 85%.
 - ii. If the applicant has a PET or PET/CT scanner in the Primary Service Area, the applicant is generally expected to demonstrate that its Percent Utilization of Current Capacity exceeds 85%.
- (3) If the applicant is unable to demonstrate a clear public need for the proposed scanner based upon the assumptions and need methodology in subsection (c)(1) and subsection (c)(2) have been met, the Applicant may rely upon any other relevant factors, including those described in subsection (f), to demonstrate need among the population it intends to serve.

(d) Quality and Accessibility.

The Applicant shall demonstrate that the proposal meets the following criteria:

- (1) Hospital applicants shall be accredited by The Joint or certified by Medicare directly or through a deeming agency;
- (2) Non-hospital facilities shall obtain accreditation from either the American College of Radiology or the Intersocietal Commission on the Accreditation of Nuclear Laboratories within eighteen months of the date on which imaging activities are first conducted;
- (3) A physician who is board-certified by the applicable accrediting organization, and who is qualified and licensed to handle radionuclides, shall be available to supervise during service hours;
- (4) Qualified engineering and physics personnel with training in the operation and maintenance of PET equipment shall be available to the facility during service hours;
- (5) Qualified radiation safety personnel with training and experience in the handling of short-lived position emitting nuclides shall be available during services hours; and
- (6) The facility or provider shall not deny PET or PET-CT scanner services to any individual based upon the ability to pay or source of payment, including uninsured, underinsured and Medicaid patients;
- (7) The facility must have a policy that explains what steps will be taken to respond in the event of a medical emergency for patients undergoing PET or PET-CT scans, including the plan for responding to allergic reactions related to contrast media or other drugs or biologicals used in connection with the scan.

(e) Financial Criteria.

The Applicant shall demonstrate that it has sufficient capital to finance the project and provide projections concerning the revenue and expenses for the first three years of the proposal.

(f) Other factors.

The office may also take the following criteria into consideration during its review of an application:

- (1) The capabilities of the proposed PET or PET-CT scanner as compared to existing PET or PET-CT scanners;
- (2) The ability of the applicant to serve an underserved population and not jeopardize the financial viability of the project;
- (3) The impact on existing services, including avoiding delays in timely diagnosis or treatment;
- (4) The use of the PET or PET-CT scanner for clinical research;
- (5) The history of the applicant in running accredited, financially successful facilities;
- (6) The applicant's ability to make radiation dose exposure decisions; and
- (7) For hospital applicants only, unique patient populations or specific clinical needs for specialty scanners or specific clinical applications, including scanners with multiple use applications; complexity of scanning procedures, including the impact on available scanner access due to lengthy procedures; necessity for back-up and redundant equipment to meet the needs of emergency departments.

(g) Replacement of PET scanners.

- (1) A facility or provider may replace a PET scanner with a PET-CT scanner, without obtaining a CON, provided that the CT scanner will not be used independently of the PET component of the PET-CT scanner.
- (2) A facility or provider may replace a mobile PET scanner or PET/CT scanner, without obtaining a CON, with a fixed PET or PET/CT scanner.