

## **COMPUTED TOMOGRAPHY SERVICES**

### **I. INTRODUCTION**

A primary goal of the health planning process is the establishment of a rational allocation of services and resources. Planning for the provision of health care services is frequently associated with prohibiting the development of duplicative services and cost containment. However, the West Virginia Health Care Authority (“Authority”) is charged with balancing these traditional Certificate of Need goals with providing access to care for patients, including shorter travel times and the opportunity for patients to receive all necessary medical services in one visit.

The area of diagnostic imaging has grown at a rapid rate with the onset of new technology. In response, the WV Legislature approved rules adopted by the Authority requiring Certificate of Need review for Computed Tomography (hereinafter “CT”) services. 65 C.S.R. 7 and 65 C.S.R. 17. Subsequent to legislative approval of these rules, the Authority engaged in stakeholder meetings over a period of approximately ten months to gather facts and to hear the diverse perspectives of the participants. A preliminary draft of the CT Standards was submitted for public comment and the Authority received comments from approximately 44 interested groups and individuals.

Based upon a review of current medical literature and materials received during the stakeholder meetings, the Authority determined CT technology has become increasingly specialized. Accordingly, the Standards include three separate sections based upon the type of CT scan being provided.

## II. DEFINITIONS

- A. Billable procedure: A CT procedure or set of procedures commonly billed as a single unit.
- B. Capital Expenditure: Capital Expenditure is defined in W.Va. Code § 16-2D-2(g).
- C. Cardiac Computed Tomography Angiography (CCTA): A CT scan of the heart.
- D. CT Scanning: A scan which uses computer technology and radiographic techniques to produce cross-sectional images of the head and body.
- E. Low dose CT scanner: A CT unit used for a specific and limited purpose generally associated with scans of the head and neck, the effective dose for which is estimated to be less than or equal to 1.0 millisieverts (“mSv”) or a unit requiring five (5) kilowatts or less.
- F. Millisieverts: A measure of radiation dosage.

- G. Mobile CT: A diagnostic service using computed tomography with a mobile CT scanner at two or more sites.
- H. Multiple Use CT: A unit capable of performing scans of multiple areas of the body.
- I. Stationary CT: A diagnostic service using computed tomography with a fixed CT scanner.
- J. Use Rate: The number of CT Equivalent units per thousand population.

### **III. ASSUMPTIONS**

#### Effective Radiation Dosage:

Radiation dosage is measured in millisieverts (mSv). Information about radiation dosage and average times associated with CT scans is available from a website jointly maintained by the American College Of Radiology and the Radiological Society of North America (RSNA) known as RadiologyInfo. The information is available at [http://www.radiologyinfo.org/en/safety/index.cfm?pg=sfty\\_xray](http://www.radiologyinfo.org/en/safety/index.cfm?pg=sfty_xray) and <http://www.radiologyinfo.org/en/sitemap/modal-alias.cfm?modal+CT&bhcp+1>.

RadiologyInfo states that we are exposed to radiation from natural sources all the time. The average person in the U.S. receives an effective dose of about 3 mSv per year from naturally occurring radioactive material and cosmic radiation from outer space. These natural “background” doses vary throughout the country. The following chart shows, for selected procedures, the comparison of

effective radiation dose with background radiation exposure for several radiological procedures and the average scan times.

<b>Procedure</b>	<b>Effective radiation dose</b>	<b>Comparable to natural background radiation for</b>	<b>Average scan times</b>
Computed Tomography (CT) Abdomen	10 mSv	3 years	30 minutes
Computed Tomography (CT) Body	10 mSv	3 years	5 to 30 minutes
Computed Tomography (CT) Colonography	5 mSv	20 months	15 minutes
Computed Tomography (CT) Head	2 mSv	8 months	20 minutes
Computed Tomography (CT) Spine	10 mSv	3 years	30 minutes
Computed Tomography (CT) Chest	8 mSv	3 years	30 minutes total Scan time 30 seconds
Computed Tomography (CT) Sinuses	0.6 mSv	2 months	45 minutes total Scanning time <1 minute
Cardiac CT for Calcium Scoring	2 mSv	8 months	10 minutes
Radiography-Chest	0.1 mSv	10 days	
CTCA	9-29 mSv*	2.5 years to 8 years	20 minutes

#### **IV. LOW DOSE CT SERVICES**

An applicant who proposes to provide low dose CT services as defined in these Standards must provide the following:

- A. A minimum of thirty days notice to the Authority before implementation of the service; and
- B. Documentation that the proposed capital expenditure is less than \$2,000,000.

---

\* "Estimating Risk of Cancer Associated with Radiation Exposure from 64-slice Computed Tomography Coronary Angioplasty", JAMA, July 18, 2007, vol. 298, No. 3, p. 317.

A low dose CT scanner cannot be upgraded through replacement to a multiple use and/or CCTA scanner without meeting the requirements in these Standards applicable to multiple use and/or CCTA scanners.

## **V. NEED METHODOLOGY**

An applicant who proposes to provide CCTA services or multiple use CT services must delineate the proposed service area for the service by documenting the expected areas around where the proposed unit will be located and from which the unit is expected to draw patients. An applicant for mobile services must justify each proposed site. The applicant may submit testimony or documentation regarding the expected service area, based upon national data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services. Any assumptions must be reasonable and supported by the evidence in the record.

The applicant must document expected utilization for the service to be provided for the population within the service area. As used in this section, “expected utilization”, in addition to the expected demand for the service, may be expressed as the number of providers typically required to service any given population, or as the number of persons in a population that are typically serviced by a single provider. Where a population is known to have specific characteristics, such as age, or disease rates, that affect utilization, then those characteristics may be taken into consideration.

- A. Cardiac CT Angiography (CCTA) Services: An existing provider with a multiple use CT unit(s) that proposes to provide CCTA services is not required to undergo further Certificate of Need review for a new service. However, the Authority strongly recommends that the provider comply with the Quality and Accessibility Section of these Standards.

The following criteria are applicable to applicants who propose to initiate CCTA services:

The actual scan time for CCTA is 10 to 25 minutes and the entire process is usually completed within one hour according to information from RadiologyInfo. The information can be found at: <http://www.radiologyinfo.org/en/sitemap/modal-alias.cfm?modal+CT&bhcp+1>.

Information submitted by letter and in numerous work group meetings held by the HCA indicated that some CCTA scans may take up to 4 hours, depending on the need to administer medication to achieve the necessary heart beat to perform the study, perform the scan, and prepare for the next scan. Therefore, the HCA will assume an average time for CCTA of 2 hours.

Based on 2 hours per scan, the unit would be able to perform 4 scans per day. Operating at 250 days per year, the CT unit would be able to perform 1,000 scans. However, due to downtime, maintenance, cancelled appointments, etc. a more

realistic projection is to operate at 70% of capacity. Thus, the Authority expects the unit to perform 700 scans per year.

Therefore, based on the above, an applicant proposing to provide CCTA must demonstrate that it can perform 700 CCTA scans annually by the end of the third year of operation.

A non-hospital applicant who proposes to accept referrals must address the criteria set forth in W.Va. C.S.R. § 65-17, Health Services Offered by Health Professionals.

An applicant who proposes to place the CT unit outside of the physician's office or the hospital's campus must address the Standards for Ambulatory Care Centers.

A provider proposing to perform only CCTA may not expand the use of the CT scanner to perform scans other than CCTA unless it obtains a Certificate of Need for multiple use CT scan services.

A provider proposing to perform CCTA and other CT services must meet the need methodology for multiple use CT Services.

- B. Multiple Use CT Services: An applicant for multiple use CT services must:

1. Identify the patient base it serves;
2. Multiply the patient base by the use rate per 1,000 population (WV or national) to get a projected number of users;
3. Take the number of projected users and demonstrate the number of projected users the applicant would be expected to serve based on historical data of referrals or mobile CT utilization; and,
4. Project 3,000 scans annually by the end of the third year of operation.

## **VI. REPLACEMENT CT SERVICES**

The replacement/upgrade of an existing CT unit shall not be subject to these Standards if the capital expenditure is less than \$2,000,000. An applicant proposing to replace/upgrade an existing CT scanner where the capital expenditure exceeds \$2,000,000 shall demonstrate the financial feasibility of the proposed replacement/upgrade. Equipment that is upgraded or replaced shall be removed from service. Applicants seeking approval for low dose CT or CCTA may not replace their CT unit to a multiple use unit without undergoing further CON review.



## **VII. ADDITIONAL CT SERVICES**

The acquisition of an additional CT unit by an existing provider shall not be subject to these Standards if the applicant documents that the capital expenditure is less than \$2,000,000 and the type of CT services provided will not change. A provider may not add a different type of CT scanner without meeting the criteria contained in these Standards.

## **VIII. QUALITY AND ACCESSIBILITY**

Applicants seeking to provide CT services subject to this Standard must demonstrate compliance with the following criteria:

- A. Hospital applicants must be accredited by the Joint Commission on Accreditation of Healthcare Organizations or certified by Medicare;
- B. Non-hospital facilities must apply for CT accreditation from either the American College of Radiology or the Intersocietal Commission for the Accreditation of Computed Tomography Laboratories within the first year of operation. Non-hospital facilities must obtain this accreditation by the third year of operation, unless the facility can demonstrate good cause for its failure to obtain the accreditation.
- C. Non-hospital applicants for multiple use and/or low dose CT scanners must meet the training requirements of their specialty society;

- D. Applicants for CCTA must meet the following requirements:
1. Cardiologists must meet the American College of Cardiology (ACC) criteria for CCTA; and
  2. Radiologists must meet the American College of Radiology (ACR) criteria for CCTA.
- E. All applicants must demonstrate the proposed services will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements;
- F. All applicants must demonstrate that the CT scanner unit to be used for patient care must have pre-market approval by the FDA for clinical use prior to the submission of the application;
- G. All applicants must provide documentation that personnel will be trained in the use of the specific equipment and the safety procedures to follow in the event of an emergency. If pharmaceuticals are administered, the applicant must provide equipment and supplies, including but not limited to a Crash Cart containing a defibrillator and intravenous medications such as epinephrine and atropine, sufficient to handle clinical emergencies that might occur and facility staff trained in CPR and other appropriate emergency interventions;

- H. All applicants must have a physician on site or immediately available to the CT scanner at all times when patients are undergoing CT scans;
- I. All applicants must provide a safety manual governing the equipment and its location. The manual must cover hazards and security measures, including, at a minimum, fire precautions and evacuations, to ensure the safety of the patients, staff and others;
- J. All applicants must document that, if approved, the CT unit will be operated safely by trained physicians and/or radiologic technologists who are licensed by the appropriate licensure organization including but not limited to the American College of Cardiology, the American College of Radiology, the American Registry of Radiologic Technologists, the American Registry of Clinical Radiography, or the West Virginia Medical Imaging and Radiation Therapy Technology Board of Examiners;
- K. All applicants must employ or contract with a radiation physicist to review the quality and safety of the operation of the CT scanner;
- L. All applicants must demonstrate that the CT services are accessible to the disabled in compliance with applicable state and federal laws; and,

- M. All applicants must demonstrate how the project enhances geographic access to the service.
- N. To assure that the CT scanner will be utilized by all segments of the West Virginia population, a provider of CT services:
1. must participate in all state sponsored healthcare coverage plans;
  2. shall not deny CT scanner services to any individual based on the ability to pay or source of payment, including uninsured, underinsured and Medicaid patients;
  3. must provide to participants in the Medicaid program a number of CT scans at a level not less than 33% of the statewide median number of Medicaid visits provided by West Virginia hospitals. This percentage, based upon 2006 data, is 5.7%. This benchmark will be updated by the Authority on an annual basis;
  4. must provide charity care and uncompensated care in an amount not less than 33% of the statewide median of charity care and uncompensated care, as a percentage of gross patient revenues, provided by West Virginia hospitals. This percentage, based upon 2006 data, is 2.1%. This benchmark will be updated by the Authority on an annual basis;

5. must submit its written charity care policy; and,
6. must maintain and report annually: gross revenue by payor; total cost; volume by payor and non-paying sources; charity care and bad debt; volume of inpatient and outpatient procedures; volume of fixed and mobile procedures. The provider must maintain and report charity care and bad debt separately. This information is currently provided by hospitals in the Uniform Financial Report filed annually with the Authority.

## **IX. FINANCIAL FEASIBILITY**

Applicants must demonstrate that sufficient capital is available to finance the project, or demonstrate that financing arrangements are reasonable and secure. Applicants must also demonstrate financial feasibility by presenting a three year projection of revenues and expenses.