

DRAFT

Approved by Governor
Date:XXXXX

COMPUTED TOMOGRAPHY SERVICES

Exemptions from Certificate of Need (CON) which require submission of information to the Health Care Authority (Authority).

Those providing Computed Tomography (CT) Services, which meet the following criteria, will not be required to address the standards.

West Virginia Code § 16-2D-11(b)(1) states:

The acquisition and utilization of one computed tomography scanner with a purchase price up to \$750,000 that is installed in a private office practice where at minimum seventy-five percent of the scans are performed on the patients of the practice. The private office practice shall obtain and maintain accreditation from the American College of Radiology prior to, and at all times during, the offering of this service. The authority may at any time request from the private office practice information relating to the number of patients who have been provided scans and proof of active and continuous accreditation from the American College of Radiology. If a physician owns or operates a private office practice in more than one location, this exemption shall only apply to the physician's primary place of business and if a physician wants to expand the offering of this service to include more than one computed tomography scanner, he or she shall be required to obtain a certificate of need prior to expanding the service. All current certificates of need issued for computed tomography services, with a required percentage threshold of scans to be performed on patients of the practice in excess of seventy-five percent, shall be reduced to seventy-five percent: Provided, that these limitations on the exemption for a private office practice with more than one location shall not apply to a private office practice with more than twenty locations in the state on April 8, 2017.

West Virginia Code § 16-2D-11(b)(5) states:

Shared Health services between two or more hospitals licensed in West Virginia providing health services made available through existing technology that can reasonably be mobile. This exemption does not include providing mobile cardiac catheterization.

West Virginia Code § 16-2D-11(b)(9) states:

The replacement of major medical equipment with like equipment, only if the replacement major medical equipment cost is more than the expenditure

minimum.

The expenditure minimum is updated annually by the Authority and can be found on the Authority's website at www.hca.wv.gov.

Like Equipment means medical equipment in which functional and technological capabilities are similar to the equipment being replaced; and the replacement equipment is to be used for the same or similar diagnostic, therapeutic, or treatment purposes as currently in use; and it does not constitute a substantial change in health services or a proposed health service.

Major Medical Equipment means a single unit of medical equipment or a single system of components with related functions which is used for the provision of medical and other health services and costs in excess of the expenditure minimum. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services if the clinical laboratory is independent of a physician's office and a hospital and it has been determined under the Title XVIII of the Social Security Act to meet the requirements of paragraphs ten and eleven, Section 1861(s) of such act, Title 42 U.S.C. §1395x. In determining whether medical equipment is major medical equipment, the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition of such equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

West Virginia Code § 16-2D-11(b)(27) states:

The acquisition and utilization of one computed tomography scanner and/or one magnetic resonance imaging scanner with a purchase price of up to \$750,000 by a hospital.

Those meeting the requirements of § 16-2D-11(b)(1), § 16-2D-11(b)(5), § 16-2D-11(b)(9), or § 16-2D-11(b)(27) will be eligible for an exemption from CON, which requires the submission of information to the Authority. In accordance with W. Va. Code § 16-2D-11(a), in order to obtain an exemption from CON, a person shall file an exemption application and provide a statement detailing which exemption applies and the circumstances justifying the exemption.

The exemption application is available on the Authority's website at: <https://hca.wv.gov/certificateofneed/Pages/Exemptions.aspx>.

The provision of CT Services that does not qualify for one of the above exemptions must submit an expedited application that addresses the standards below.

I. 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.
- C. CT Scanning: A scan which uses computer technology and radiographic techniques to produce cross-sectional images of the head and body.
- D. 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.
- E. Millisieverts: A measure of radiation dosage.
- F. Mobile CT: A diagnostic service using computed tomography with a mobile CT scanner at two or more sites.
- G. Multiple Use CT: A unit capable of performing scans of multiple areas of the body.
- H. Stationary CT: A diagnostic service using computed tomography with a fixed CT scanner.
- I. Use Rate: The number of CT scans per thousand population.

II. ASSUMPTIONS

Effective Radiation Dosage:

Radiation dosage is measured in millisieverts (mSv). Information about radiation dosage 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 <https://www.radiologyinfo.org/en/info/safety-xray> 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.

Procedure	Effective radiation dose	Comparable to natural background radiation for
Computed Tomography (CT) Abdomen and pelvis	7.7 mSv	2.6 years
Computed Tomography (CT) Brain	1.6 mSv	7 months
Computed Tomography (CT) Colonography	6 mSv	2 years
Computed Tomography (CT) Head and Neck	1.2 mSv	5 months
Computed Tomography (CT) Spine	8.8 mSv	3 years
Computed Tomography (CT) Chest	6.1 mSv	2 years
Computed Tomography (CT) Lung Cancer Screening	1.5 mSv	6 months
Cardiac CT for Calcium Scoring	2 mSv	8 months
Radiography-Chest	0.1 mSv	10 days

III. 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 the capital expenditure minimum. .

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

IV . NEED METHODOLOGY

An applicant who proposes to provide 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. 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.

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.

V. 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 or any other accepted accrediting agency or be 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. 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;
- E. 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;
- F. 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;
- G. All applicants must have a physician on site or immediately available to the CT scanner at all times when patients are undergoing CT scans;
- H. 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;
- I. 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, or the West Virginia Medical Imaging and Radiation Therapy Technology Board of Examiners;
- J. All applicants must employ or contract with a radiation physicist to review the quality and safety of the operation of the CT scanner;
- K. All applicants must demonstrate that the CT services are accessible to the disabled in compliance with applicable state and federal laws; and,
- L. All applicants must demonstrate how the project enhances geographic access to the service.
- M. 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 as a percentage of the statewide median number of total visits, provided by West Virginia hospitals. This percentage is 7.5% based upon 2020 data;
4. must provide charity care and uncompensated care in an amount not less than 33% of the statewide median of charity care and bad debt combined, as a percentage of the statewide median gross patient revenues, provided by West Virginia hospitals. This percentage, based upon 2020 data, is 1.0%; and,
5. must submit its written charity care policy.

VI . 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.