

LETTER OF INTENT



**State of Tennessee
Health Facilities Commission**

502 Deaderick Street, Andrew Jackson Building, 9th Floor, Nashville, TN 37243

www.tn.gov/hsda

Phone: 615-741-2364

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LETTER OF INTENT

The Publication of Intent is to be published in The Nashville Tennessean, which is a newspaper of general circulation in Robertson County, Tennessee, on or before 03/15/2024 for one day.

This is to provide official notice to the Health Facilities Commission and all interested parties, in accordance with T.C.A. §68-11-1601 et seq., and the Rules of the Health Facilities Commission, that Tennessee Oncology White House, a/an Ambulatory Surgical Treatment Center (ASTC) – Single Specialty owned by Tennessee Oncology White House, LLC with an ownership type of Limited Liability Company and to be managed by itself intends to file an application for a Certificate of Need for the establishment of a licensed ambulatory surgical treatment center limited to outpatient megavoltage radiation therapy with a linear accelerator, and to initiate outpatient linear accelerator services in the city of White House, in Robertson County. The address of the project will be currently unaddressed site on the west side of North Sage Road, approximately 70 yards south of North Sage Road’s intersection with Hampton Place, White House, Robertson County, Tennessee, 37188. The estimated project cost will be \$23,001,275.

The anticipated date of filing the application is 04/01/2024

The contact person for this project is Consultant John Wellborn who may be reached at Development Support Group - 4505 Harding Pike Suite 53-E, Nashville, Tennessee, 37205 – Contact No. 615-665-2022.

John Wellborn

03/09/2024

john.wellborn.dsg@gmail.com

Signature of Contact

Date

Contact’s Email Address

The Letter of Intent must be received between the first and the fifteenth day of the month. If the last day for filing is a Saturday, Sunday, or State Holiday, filing must occur on the next business day. Applicants seeking simultaneous review must publish between the sixteenth day and the last day of the month of publication by the original applicant.

The published Letter of Intent must contain the following statement pursuant to T.C.A. §68-11-1607 (c)(1). (A) Any healthcare institution wishing to oppose a Certificate of Need application must file a written notice with the Health Facilities Commission no later than fifteen (15) days before the regularly scheduled Health Facilities Commission meeting at which the application is originally scheduled; and (B) Any other person

wishing to oppose the application may file a written objection with the Health Facilities Commission at or prior to the consideration of the application by the Commission, or may appear in person to express opposition. Written notice of opposition may be sent to: Health Facilities Commission, Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243 or email at hsda.staff@tn.gov .



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PUBLICATION OF INTENT

The following shall be published in the “Legal Notices” section of the newspaper in a space no smaller than two (2) columns by two (2) inches.

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Facilities Commission and all interested parties, in accordance with T.C.A. §68-11-1601 et seq., and the Rules of the Health Facilities Commission, that Tennessee Oncology White House, a/an Ambulatory Surgical Treatment Center (ASTC) – Single Specialty owned by Tennessee Oncology White House, LLC with an ownership type of Limited Liability Company and to be managed by itself intends to file an application for a Certificate of Need for the establishment of a licensed ambulatory surgical treatment center limited to outpatient megavoltage radiation therapy with a linear accelerator, and to initiate outpatient linear accelerator services in the city of White House, in Robertson County. The address of the project will be currently unaddressed site on the west side of North Sage Road, approximately 70 yards south of North Sage Road’s intersection with Hampton Place, White House, Robertson County, Tennessee, 37188. The estimated project cost will be \$23,001,275.

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CRITERIA AND **STANDARDS**

Attachment 1NR – State Health Plan Criteria and Standards



**STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA**

**Megavoltage Radiation Therapy Services
(Revised on Supplemental, Round 2)**

Standards and Criteria

1. **Determination of Need:** The following table outlines the utilization standards that should be used to determine need in the proposed service area.

a. These utilization standards were developed based on the following assumptions related to operating time:

- i. 8 hours per day,
- ii. 5 treatment days per week,
- iii. 52 weeks per year, and
- iv. 95% average up-time.

Type of Linear Accelerator	Estimated Patients Per Day	Capacity		
		Minimum (40%)	Optimal (80%)	Maximum (100%)
Non-IMRT, Non-IGRT	32	3162	6323	7904
IMRT only without OBI	32	3162	6323	7904
IMRT with OBI	38	3754	7509	9386
SRS only	14	1383	2766	3458
SBRT only	16	1581	3162	3952
Hybrid MRTs	32	3162	6323	7904

Response: This project will be in the category of “Hybrid MRTs”.

b. Applicants should use the treatment codes provided on the HSDA website to calculate utilization.

Response: The applicant used the treatment codes it employs for its current radiation therapy patients, which are the same codes as those on the HSDA website. Please note that this application is not to demonstrate an unmet area need for RT care. It is to shorten patient drive times for this type of care by offering them another linear accelerator more conveniently located north of Davidson and Sumner Counties. The utilization of this project will not be currently unserved patients, but rather current patients who want to avoid onerous daily drives to and from hospital-based MRT units south of this project.

An applicant proposing a new Linear Accelerator should project a minimum of at least 3,162 MRT procedures in the first year of service in its proposed Service Area, building to a minimum of 6,323 procedures per year by the third year of service and for every year thereafter.

Response: The projected utilization complies with the Year One target in the Guidelines. Projected utilization of the project is as follows:

Table MRT Need 1b Part A: Projected Utilization of Tennessee Oncology White House			
Year of Operation	Year One CY2026	Year Two CY2027	Year Three CY2028
Linac Procedures	3,686	4256	4842
State Health Plan Target	3,162	NA	6,323
% of Target Met	116.6%	NA	76.6%

For an explanation of the applicant's methodology for projecting utilization, a summary of the methodology is presented immediately below (bulleted points). Following that summary are two tables showing the detailed calculations referenced in the bullets.

- The applicant identified a service area consisting of nineteen ZIP codes around the project location in White House, Robertson County. Ten of them are wholly or substantially (50+%) within a 15-mile planning radius for this project. Small portions of another nine ZIP codes are also covered by the 15-mile planning radius.
- The applicant identified patients currently referred to it from these 19 ZIP codes during CY2023.
- The ZIP codes' populations age 45 and older were identified by a commercial source (Intellimed and Esri) and the annual numerical (not percentage) increase/decrease for each ZIP code was calculated.
- The applicant used the average annual change in population for each ZIP code to project each ZIP code's likely CY2026-CY2028 patient referrals to Tennessee Oncology. This resulted in a projection of just over 1,100 patients in each of the first three years of the project's operation.
- The applicant's experience has been that 88% of patients referred to them will be found to require treatments on a linear accelerator. The number of patients requiring this service in Years One-Three would be 969, 983, and 997 RT ("radiation therapy") patients, respectively. These RT patients will be free to choose from among a variety of sites for treatments, all of which are medically supervised by their Tennessee Oncology radiation therapist.
- To project the number of RT patients who would elect to use the White House linear accelerator, rather than other less convenient urban locations, the applicant divided the RT patient projections into two groups. One was a "moderate patient shift" group of the ten ZIP codes closest to White House; the other was a "minimal patient shift" group of the other nine ZIP codes with small edges covered by the 15-mile radius.
- The applicant projects that during the project's first three years, CY2026-CY2028, that 30%, 35%, and 40% of the "moderate shift" group of RT patients will choose White House for their radiation therapy, due to its greater convenience compared to more distant hospital-based accelerators. Only 10% of the "minimal shift" group are projected to relocate to White House for their radiation therapy and would continue to obtain care at current existing units.

Table: MRT Need 1b PART B: Projected Tennessee Oncology Patient Referrals CY2023-CY2028

Zip Code	Name of Zip Code (USPO)	Patients Referred to TnOnc CY2023	Population Age 45+ Change CY2023-CY2028	Projected Patients Referred to TnOnc CY2028	2023-2028 Average Annual Patient Change	Actual Patients Referred to TnOnc CY2023	Projected Patients Referred to TnOnc CY2024	Projected Patients Referred to TnOnc CY2025	Projected Patients Referred to TnOnc	Projected Patients Referred to TnOnc	Projected Patients Referred to TnOnc
									CY2026	CY2027	CY2028
									Year One	Year Two	Year Three
37048	Cottontown	28	5.1%	29	0.3	28	28.3	28.6	28.9	29.1	29.4
37049	Cross Plains	6	4.9%	6	0.1	6	6.1	6.1	6.2	6.2	6.5
37066	Gallatin	177	13.4%	201	4.7	177	181.7	186.5	191.2	196.0	200.7
37072	Goodlettsville	81	1.8%	82	0.3	81	81.3	81.6	81.9	82.2	82.5
37073	Greenbrier	32	2.3%	33	0.1	32	32.1	32.3	32.4	32.6	32.7
37075	Hendersonville	140	6.7%	149	1.9	140	141.9	143.8	145.6	147.5	149.4
37141	Orlinda	2	-0.9%	2	0.0	2	2.0	2.0	2.0	2.0	2.0
37148	Portland	72	4.8%	75	0.7	72	72.7	73.4	74.1	74.8	75.5
37172	Springfield	74	5.8%	78	0.9	74	74.9	75.7	76.6	77.4	78.3
37188	White House	40	10.6%	44	0.8	40	40.8	41.7	42.5	43.4	44.2
				10 ZIP CODES WITH MODERATE RT PATIENT SHIFTS				SUBTOTALS	681.4	691.2	701.2
37032	Cedar Hill	14	4.0%	15	0.1	14	14.1	14.2	14.3	14.5	14.6
37080	Joelton	27	-0.1%	27	0.0	27	27.0	27.0	27.0	27.0	27.0
37115	Madison	62	6.1%	66	0.8	62	62.8	63.5	64.3	65.0	65.8
37122	Mt Juliet	157	11.1%	174	3.5	157	160.5	164.0	167.5	170.9	174.4
37138	Old Hickory	65	2.4%	67	0.3	65	65.3	65.6	65.9	66.2	66.6
37189	Whites Creek	6	5.7%	6	0.1	6	6.1	6.1	6.2	6.3	6.3
37207	Nashville	62	11.3%	69	1.4	62	63.4	64.8	66.2	67.6	69.0
42134	Franklin KY	6	5.4%	6	0.1	6	6.1	6.1	6.2	6.3	6.3
42202	Adairville KY	2	3.2%	2	0.0	2	2.0	2.0	2.0	2.1	2.1
				9 ZIP CODES WITH MINIMAL RT PATIENT SHIFTS				SUBTOTALS	419.6	425.9	432.1
				ALL 19 ZIP CODES – TOTAL PATIENTS SHIFTED (ROUNDED)					1,101	1,117	1,133

Source: Applicant's records; Intellimed for population projections.

Table: MRT Need 1b PART C: Projected Treatments at Tennessee Oncology--White House			
	Year 1 CY2026	Year 2 CY2027	Year 3 CY2028
MODERATE PATIENT SHIFT AREA (10 Zip Codes)			
Total Patients Referred to Tennessee Oncology from This Area	681.4	691.2	701.2
Referred Patients Needing MRT Treatments (88% of Referrals, Rounded)	600	608	617
% of Those MRT Patients Who Will Choose White House For This Service	30.0%	35.0%	40.0%
MRT Patients Who Will Shift To White House ("Shifting" from Hospital-Based Alternatives)	180	213	247
Treatments Needed By Shifted Patients @ 17 Treatments Per Patient	3,058	3,619	4,196
MINIMAL PATIENT SHIFT AREA (9 Zip Codes)			
Total Patients Referred to Tennessee Oncology from This Area	419.6	425.9	432.1
Referred Patients Needing MRT Treatments (88% of Referrals, Rounded)	369	375	380
% of Those MRT Patients Who Will Choose White House For This Service	10%	10%	10%
MRT Patients Who Will Shift To White House ("Shifting" from Hospital-Based Alternatives)	37	37	38
Treatments Needed By Shifted Patients @ 17 Treatments Per Patient	628	637	646
TOTAL LINAC TREATMENTS SHIFTED TO WHITE HOUSE			
	3,686	4,256	4,842
State Plan Target	3,162	NA	6,323
% of Target Met	116.6%	NA	76.6%

- c. Applicants should utilize the publicly available Tennessee’s Cancer Registry (<https://www.tn.gov/health/health-program-areas/tcr.html>) data to estimate the need within the proposed service area. These data should then be compared to the data included in the HSDA’s Medical Equipment Registry for the defined market to determine the need. To estimate the number of radiation treatment patients in its proposed service area, the applicant should multiply the number of cancer patients by 60%. A minimum of 600 cancer patients and 360 radiation patients should reside in the proposed service area. Data included in the HSDA’s Medical Equipment Registry may also be used to determine the need for radiation services in the proposed service area.

Response: The project’s utilization represents a shift of existing patients and procedures. This is based on the applicant’s actual CY2023 experience, not the sources and methodology in this Guideline. The applicant’s projection methodology uses the best and most current data available for projecting clinical “need”. The Tennessee Cancer Registry and other sources cited above are too out of date and would not reflect the service area’s actual existing patients, whose shifting will determine this project’s utilization and “need”.

However, on the following pages is a supplemental response that presents the methodology as specified in the Guidelines.

Response to State Plan Guideline 1c: The table below uses the latest available CDC age-adjusted cancer incidence rates and the 60% standard of the State Health Plan to project a need in 2028 for 55,439 treatments in this area – assuming at least 17 treatments per patient. 3,261 patients requiring radiation therapy treatments will reside in the area, far exceeding the minimum required threshold of 360 patients.

Radiation Therapy Treatments Needed for New Cancer Patients in the Primary Service Area in 2028					
PSA County	2028 Population (in 100,000s) - 4 Years from Current Year	New Cancer Rate/100K Population (CDC Age Adjusted)	Projected New Cancer Patients/Year	Patients Needing RT Treatments (60%)	RT Treatments Needed at 17/Patient
Davidson	7.70119	434.1	3343.1	2005.9	34099.5
Robertson	0.78642	477.0	375.1	225.1	3826.2
Sumner	2.13896	464.6	993.8	596.3	10136.4
Wilson	1.62237	445.8	723.3	434.0	7377.2
Total PSA (Rounded)			5,435	3,261	55,439
Data Source:	Tennessee State Data Center, Population Projections 2016-2030	National Cancer Institute, State Cancer Profiles			

- d. **An exception to the standard number of procedures may occur as new or improved technology and equipment or new treatment applications for Linear Accelerators develop. Any applications seeking an exception to the standards and criteria must include information on the projected impact on existing services in the proposed service area. Data reported in the HSDA’s Medical Equipment Registry should also be used to estimate the impact of the proposed project on existing services for the proposed service area.**

Response: All patients at the White House facility will benefit from the features available on the selected Truebeam unit. It will be equipped with Varian’s IDENTIFY system, a surface-guided patient position monitoring system for radiotherapy with automatic beam hold functionality. If a patient moves out of tolerance, the beam of radiation will turn off, eliminating the risk of radiating tissue outside the intended treatment target. The IDENTIFY positioning system will be utilized on every patient, improving treatment accuracy, and promoting patient safety. The package selected for this machine also includes gated conebeam CT (CBCT) scanning, which provides the ability to acquire images synchronized with patient respiration. This unit will also have iterative CBCT imaging which provides improved detectability of stationary soft tissue anatomy.

Facilities proximal to the White House location also utilize Truebeam units, but based on the information provided on the state registry, it is unclear whether their machines are equipped with the same upgraded features.

2. **Relationship to Existing Similar Services in the Proposed Service Area: Applicants should provide an inventory of and assess all available technologies and utilization in the service area. Additionally, the applicant should provide evidence that volumes in the proposed service area will support the introduction of new MRT services without causing existing providers to fall below the minimum thresholds outlined in the following table.**

Type of Linear Accelerator	Minimum (40)%
Non-IMRT, Non-IGRT	3162
IMRT only	3162
IMRT with OBI	3754
SRS only	1383
SBRT only	1581
Hybrid MRTs*	3162*

Applicants should use the treatment codes provided on the HSDA website to calculate utilization.

Response: The treatment codes utilized in this application came from the HSDA Medical Equipment Utilization Survey list: 77372, 77373, 77385, 77386, 77402, 77407, 77412, G6004, G6005, G6008, G6012, G6015. They were used by the applicant to calculate utilization.

Within the declared service area there is only one linear accelerator, located at Carpenter Cancer Center of Sumner Regional Medical Center. The Registry reports its utilization for the past three years as:

Table Need-2: Utilization of Existing Linear Accelerators in the Project Service Area (Carpenter Cancer Center, Gallatin)			
Procedures	CY2020	CY2021	CY2022
Minimum Utilization Standard (40%)	3,162	3,162	3,162
Reported Procedures (HFC Registry)	5,672	6091	6,861
Percent of 40% Utilization Standard	179.4%	192.6%	217.0%

The CY2022 utilization of the Carpenter linear accelerator was 3,699 treatments above the 40% minimum utilization protected by this criterion (6,861-3,162 = 3,699). The Tennessee Oncology White House’s entire Year One treatment shifts from all of its 19 service area zip codes will be only 3,690 treatments. They will be shifted from several

existing sites, not just from Carpenter Cancer Center. All of them would have to be shifted from Carpenter to lower Carpenter's utilization to the minimum 40% protected level. It is not reasonable to imagine that this could happen.

- a. **Applicants should utilize the data included in the HSDA's Medical Equipment Registry along with the publicly available Tennessee's Cancer Registry (<http://tn.gov/health/health-program-areas/tcr.html>) to estimate the capacity for all existing units located within the applicant's proposed service area.**

Response: There is only one linear accelerator in the defined ZIP code service area. Its utilization in this application is from the HFC Medical Equipment Registry. The linear accelerator selected for White House is a Varian Truebeam, which is considered a hybrid linear accelerator, capable of 3D, IMRT, SRS, and SBRT treatment delivery. According to the most recent state equipment registry, 7 of the 8 centers located in Sumner, Davidson, and Wilson counties operate a Varian Truebeam unit. Machine capacity is comparable across all locations.

- b. **An exception to the need standards may occur as new or improved technology and equipment or new treatment applications for MRT Units develop. An applicant must demonstrate that the proposed MRT Unit offers a unique and necessary technology for the provision of health care services in the proposed service area.**

Response: The applicant is not requesting an exception based on new technology.

3. **Establishment of Service Area: For linear accelerators that do not perform SRT or SBRT procedures, the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services.**

Response: The application's declared service area is based on zip codes rather than on counties.

Applicants should utilize the publicly available Tennessee's Cancer Registry (<https://www.tn.gov/health/health-program-areas/tcr.html>) data to estimate the need within the proposed service area. These data should then be compared to the data

included in the HSDA's Medical Equipment Registry for the defined market to determine the need.

To estimate the number of radiation treatment patients in its proposed service area, the applicant should multiply the number of cancer patients by 60%. A minimum of 600 cancer patients and 360 radiation patients should reside in the proposed service area. Data included in the HSDA's Medical Equipment Registry may also be used to determine the need for radiation services in the proposed service area.

Otherwise, a service area shall be the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services.

Additionally, the applicant must demonstrate that the patient origin of the proposed site aligns with other existing cancer-related healthcare services provided within the defined service.

Response: These have already been addressed in response to 1.c above.

4. Access to MRT Units

- a. **An MRT unit should be located at a site that allows reasonable access for residents of the proposed service area.**

Response: The purpose of this application is to improve patient access, by providing a new option for site of service which will reduce patient travel times for these long courses of treatment. All of the 15-mile radius service area is within a half hour one-way drive time of the project.

- b. **An applicant for any proposed new Linear Accelerator should document that the proposed location of the Linear Accelerator is within a 45 minute drive time of the majority of the proposed service area's population.**

Response: The majority of the service area's population is within a half hour's one-way drive time of the project.

- c. **Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing MRT units that service the non-Tennessee counties and the impact on MRT unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if those data are available).**

Response: Not applicable. There are no linear accelerators within 15 miles of this project, in the edges of adjoining States.

5. **Economic Efficiencies: All applicants for any proposed new MRT Unit should document that lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.**

Response: The unit proposed for this project is a standard advanced technology that is the best combination of these qualities. It is a type most in use in the Nashville area.

6. **Separate Inventories for Linear Accelerators and for other MRT Units: A separate inventory shall be maintained by the HSDA for Linear Accelerators, and, if data are available, for Linear Accelerators dedicated to SRT and/or SBRT procedures and other types of MRT Units.**

Response: The applicant is aware that the HFC Registry maintains applicable data for this criterion. That data has been used in this application.

7. **Patient Safety and Quality of Care: The applicant shall provide evidence that any proposed MRT Unit is safe and effective for its proposed use.**

- a. **The United States Food and Drug Administration (FDA) must certify the proposed MRT Unit for clinical use.**

Response: The type of linear accelerator specified for this project is a proven, FDA-approved unit already in wide use in a number of sites in an around greater Nashville. Its FDA approval letters are provided in supplemental Attachment Additional Document 3.

- b. **The applicant should demonstrate that the proposed MRT Units shall be housed in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.**

Response: Upon approval of the CON application, the applicant will engage architectural and engineering consultants who will commit to conform this facility's environment to all applicable federal standards, manufacturer's specifications, and licensing requirements.

- c. **The applicant should demonstrate how emergencies within the MRT Unit facility will be managed in conformity with accepted medical practice.**

Response: in the event of a health emergency, a technologist will immediately notify the onsite radiation oncologist or notify the front office to call for him/her. The tech will stay with the patient and evaluate the patient's condition. The onsite radiologist will authorize notification of Emergency Medical Serviced if needed and will stabilize the patient until the EMS team arrives. The radiation oncologist or tech under his/her supervision may defibrillate or administer emergency drugs. After the patient has been stabilized and/or transported to the nearest emergency facility by EMS, the technologist will fill out an incident report online in the Adverse Event program accessible through the Tennessee Oncology Intranet.

- d. **The applicant should establish protocols that assure that all MRT Procedures performed are medically necessary and will not unnecessarily duplicate other services.**

Response: Tennessee Oncology physicians manage the care of thousands of patients a year, at Middle Tennessee hospitals that have well-established procedures for utilization review and for documenting the necessity of performing procedures. The applicant will adapt these processes for this project.

- e. An applicant proposing to acquire any MRT Unit shall demonstrate that it meets the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) or a similar accrediting authority such as the National Cancer Institute (NCI). Applicants should provide evidence of accreditation by ASTRO, ACR, or other similar accrediting authority either as a stand-alone facility or through that of a parent organization with oversight capabilities.**

Response: The applicant's staffing pattern has been provided in the body of the application. It will conform to ASTRO accreditation requirements.

- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject's transfer agreement hospital medical staff.**

Response: This is a new facility. It will seek appropriate transfer agreements with Sumner Regional Medical Center and Skyline Medical Center. Almost all of the applicant's radiation oncologists are already active members of the medical staffs of multiple local hospitals, in their capacity as Medical Directors of radiation oncology services.

- g. All applicants should demonstrate the ability to provide simulations and treatment planning services to support the volumes they project and any impact such services may have on volumes and treatment times.**

Response: Tennessee Oncology physicians provide medical direction to 9 or the 13 linear accelerators in the greater Nashville area and are highly experienced in providing the simulation and treatment planning services that this project requires. The simulator and the linear accelerator are both located on the premises of the project.

- h. Applicants should provide evidence of plans for the radiation oncology physician treating patients to participate in consultative services and a multi-**

disciplinary cancer committee to ensure high quality treatment for the patients. Additionally, each center should have a dedicated radiation oncologist to serve as medical director with defined responsibilities overseeing quality assurance for the site.

Response: This is standard practice at the many radiation therapy sites where the applicant's physicians serve as Medical Directors (9 accelerators at 6 provider locations). This will be the case at the White House facility as well.

- i. Treatment planning at off-site centers should be coordinated with a multi-disciplinary cancer center.**

Response: Not applicable. Treatment planning will take place at this site.

- 8. Data Requirements: Applicants shall agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.**

Response: The applicant agrees to this.

- 9. Services to High-Need and Underserved Populations: Special consideration should be given to applicants providing services fulfilling the unique needs and requirements of certain high-need populations, including uninsured, low-income, and underserved geographic regions, as well as to other underserved population groups. This includes any applicant:**

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration,**

Response: Robertson County in the service area is designated as a medically underserved area.

- b. Who is a “safety net hospital” or a “children’s hospital” as defined by the Bureau of TennCare Essential Access Hospital payment program, and/or**
- c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.**

Response: The applicant will contract with the three TennCare MCO’s active in this service area and will participate in the Medicare program.

10. Access: An applicant should demonstrate an ability and willingness to serve equally all of the service area in which it seeks certification.

Response: The applicant’s organization has a long record of willingness and ability to serve equally well all of the service area for which it seeks approval. These are already patients of the applicant, being served by the applicant at many locations in the greater Nashville area. The project will allow some of them to shift their service site to an easily accessible location north of Nashville, saving time and effort in accessing care at existing hospital-based units.

11. Adequate Staffing: An applicant shall document a plan demonstrating the intent and ability to recruit, hire, train, assess competencies of, supervise, and retain the appropriate numbers of qualified personnel to provide the services described in the application and that such personnel are available in the proposed service area.

Response: This has been addressed in responses above.

12. Assurance of Resources: The applicant shall document that it will provide the resources necessary to properly support the applicable level of services. Included in such documentation shall be a letter of support from the applicant’s governing board of directors, Chief Executive Officer, or Chief Financial Officer documenting the full commitment of the applicant to develop and maintain the facility resources, equipment, and staffing to provide the appropriate services. The applicant shall also document the financial costs of maintaining these resources and its ability to sustain them.

Response: That commitment of support is made in a letter from the applicant's Chief Executive Officer, provided in the supplemental attachment Additional Documentation 2.

13. Quality Control and Monitoring: The applicant shall identify and document its existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring systems.

Response: The applicant will develop and implement these plans. They will include standard business controls and process monitoring (including standard controls for patient data processing and integrity). Nursing policies to ensure and improve quality will be put in place. Specific quality processes for physics, dosimetry and treatment planning will be developed in conformity with accreditation guidelines of national organizations such as ASTRO, ACRO, and the American College of Radiology.

14. Licensure and Quality Considerations: Any existing applicant for this CON service category shall be in compliance with the appropriate rules of TDH. The applicant shall also demonstrate its accreditation status with the Joint Commission or other applicable accrediting agency.

Response: The applicant is not an existing facility, and does not own an interest in any operational facility of this type. It owns a linear accelerator facility under construction in Lebanon (Wilson County), scheduled to open in October of 2024. As committed in that project's approved CON application, ASTRO accreditation of the Lebanon service will be sought.

ADDITIONAL INFORMATION FROM SUPPLEMENTALS

MRT Criterion #1c, Determination of Need

Radiation Therapy Treatments Needed for New Cancer Patients in the Primary Service Area in 2028					
PSA County	2028 Population (in 100,000s) - 4 Years from Current Year	New Cancer Rate/100K Population (CDC Age Adjusted)	Projected New Cancer Patients/Year	Patients Needing RT Treatments (60%)	RT Treatments Needed at 17/Patient
Davidson	7.70119	434.1	3343.1	2005.9	34099.5
Robertson	0.78642	477.0	375.1	225.1	3826.2
Sumner	2.13896	464.6	993.8	596.3	10136.4
Wilson	1.62237	445.8	723.3	434.0	7377.2
Total PSA (Rounded)			5,435	3,261	55,439
Data Source:	Tennessee State Data Center, Population Projections 2016-2030	National Cancer Institute, State Cancer Profiles			

MRT Criterion #2 Relationship with Existing Service Providers

What type of linear accelerator unit is located at Carpenter Cancer Center in Gallatin?

Response: According to the most recent state equipment registry (11/01/23), the Carpenter Cancer Center is utilizing a Varian Truebeam to delivery radiation therapy treatments.

Are all projected patients expected to shift from Carpenter Cancer Center in Gallatin or are residents of the 19 ZIP Code service area also expected to shift from other providers in the service area counties? If other shifts are expected, please identify where those patients are being referred to currently.

Response: In 2023, Tennessee Oncology radiation oncologists treated 1,053 patients from the 19 ZIP Codes. Of these patients, 327 were treated at Carpenter Cancer Center in Gallatin and 304 were treated at TriStar Skyline. The other 422 patients received treatment at the following facilities:

- Ascension Saint Thomas Midtown. Nashville, TN
 - TriStar Centennial Medical Center. Nashville, TN
 - Memorial Hospital. Chattanooga, TN
 - Ascension Saint Thomas Rutherford. Murfreesboro, TN
 - Tennessee Oncology Proton Center. Franklin, TN
 - TriStar StoneCrest Medical Center. Smyrna, TN
 - Ascension Saint Thomas West. Nashville, TN
 - TriStar Summit Medical Center. Hermitage, TN
- Based on Tennessee Oncology 2023 patient data, 125 patients outside the target 19 ZIP Codes selected for this application received treatment at Carpenter Cancer Center; TriStar Skyline treated an additional 88 patients from ZIP codes outside the 19 selected for this application.

Based on Tennessee Oncology 2023 patient data, 125 patients outside the target 19 ZIP Codes of this application received treatment at Carpenter Cancer Center; TriStar Skyline treated an additional patients from ZIP codes outside the 19 selected for this application.

Due to proximity, the applicant anticipates the majority of projected patients will likely shift from Carpenter Cancer Center and TriStar Skyline, though patients receiving treatment at other facilities may also choose to transition to the proposed White House location. But, the proposed project will minimally impact these facilities. In fact, assuming each patient receives 17 fractions, it is possible for Carpenter Cancer Center and TriStar Skyline to lose 65% of their patients from the 19 target ZIP Codes only and still **remain above the 3,162 minimum treatment volume threshold**. Carpenter Cancer Center would have to lose 82% of its patients from the target 19 ZIP Codes before it drops below the minimum treatment threshold.

Tennessee Oncology Patients Treated at Carpenter Cancer Center & TriStar Skyline (January 2023 to December 2023)			Assuming <u>65%</u> Shift of Patients from 19 Target ZIP Codes:	
	Carpenter Cancer Center	TriStar Skyline	Carpenter Cancer Center	TriStar Skyline
Referrals from <u>Non-Target</u> ZIP Codes	125	88	125 (unchanged)	88 (unchanged)
<i>Estimated # of treatments, assuming 17 fractions per patient</i>	2125	1496	2125 (unchanged)	1496 (unchanged)
Referrals from <u>19 Target</u> ZIP Codes	327	304	Decreased to 114	Decreased to 106
<i>Estimated # of treatments, assuming 17 fractions per patient</i>	5559	5168	1946	1809
All Referrals from <u>ALL</u> ZIP Codes	452	392	239	194
<i>Estimated # of treatments, assuming 17 fractions per patient</i>	7684	6664	4071	3305

MRT Criterion #4 Access to MRT Units

Please respond to Criterion #4 by completing the template included with the following link:
https://www.tn.gov/content/dam/tn/hfc/documents/HFC-IN-Megavoltage_Radiation_Therapy.xlsx

Response:

Access to MRT Units					
Service Area County	Driving Distance from the Center of the County to Proposed MRT Facility	Projected Number of Cases Year 1 (2028 RT patient metrics from section 1d)	% of Projected Cases Year 1	Percent of Service Provided <u>OUTSIDE</u> County	Potential Projected Cases to Seek Treatment <u>OUTSIDE</u> of Home County
Davidson	24.2 miles	2005.9	62%	5.9%	118.3
Robertson	13.2 miles	225.1	7%	100.0%	225.1
Sumner	12.7 miles	596.3	18%	40.6%	242.1
Wilson	39.7 miles	434.0	13%	68.9%	299.0
TOTAL		3261			884.6

Are there any MRT units located in KY that are located within a shorter drive time distance than the proposed facility?

Response: No, the closest facilities with MRT units in Kentucky are in Bowling Green, which is 39.4 miles from White House.



STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

Ambulatory Surgical Treatment Centers (Revised on Supplemental, Round 2)

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to establish or expand Ambulatory Surgical Treatment Centers (ASTCs). Existing ASTCs are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for the establishment or expansion of an ASTC.

These standards and criteria are effective immediately as of May 23, 2013, the date of approval and adoption by the Governor of the State Health Plan changes for 2013. Applications to establish or expand an ASTC that were deemed complete by the HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

- 1. "Ambulatory Surgical Treatment Center" (ASTC) shall have the meaning set forth in the Rules of the Tennessee Department of Health, Board for Licensing Health Care Facilities, Chapter 1200-08-12, or its successor.**
- 2. "Full Capacity" shall mean:
For a dedicated outpatient Operating Room: 1,263 Cases per year¹
For a dedicated outpatient Procedure Room: 2,667 Cases per year**
- 3. "Operating Room" shall mean a room at an ASTC where general and/or Monitored Anesthesia Care (MAC) (the ability to administer general anesthesia) is employed. Any**

¹ From information provided at the Public Meeting, the Division of Health Planning believes the previous 1,333 number is high and is lowering this calculation by increasing the estimated average time per Case in an Operating room from 60 to 65 minutes, resulting in a "Full Capacity" number of 1,266 Cases for an

level of sedation or anesthesia can be utilized in Operating Rooms as the anesthesia equipment is present in the room.

4. "Procedure Room" shall mean a room at an ASTC where local and/or intravenous sedation is employed.
 1. If an applicant intends to utilize an Operating Room or Procedure Room for types of sedation other than are set forth in the above definitions or for no type of sedation, it must provide information in its application setting forth the reasons for employing such different sedation type(s) (or lack thereof) and identify the types of Cases so impacted..
5. "Optimum Utilization" shall mean:
 2. For a dedicated outpatient Operating Room, 70% of Full Capacity
 3. For a dedicated outpatient Procedure Room: 70% of Full Capacity
6. "Service Area" shall mean the county or counties represented by the applicant as the reasonable area to which the facility intends to provide services and/or in which the majority of its service recipients reside.
7. "Specialty ASTC" shall mean an ASTC that limits its Surgical Cases to specific types.
8. "Case" shall mean one visit to an Operating Room or to a Procedure Room by one patient, regardless of the number of surgeries or procedures performed during that visit.

Assumptions in Determination of Need

The need for an ambulatory surgical treatment center shall be based upon the following assumptions:

1. Operating Rooms

- a. An operating room is available 250 days per year, 8 hours per day.
- b. The estimated average time per Case in an Operating Room is 65 minutes.
- c. The average time for clean up and preparation between Operating Room Cases is 30 minutes.
- d. The optimum utilization of a dedicated, outpatient, general-purpose Operating Room is 70% of full capacity. $70\% \times 250 \text{ days/year} \times 8 \text{ hours/day}$ divided by 95 minutes = 884 Cases per year.

Response: This is not applicable to a radiation therapy facility, which does not have operating rooms.

2. Procedure Rooms

- a. A procedure room is available 250 days per year, 8 hours per day.
- b. The estimated average time per outpatient Case in a procedure room is 30 minutes.
- c. The average time for clean up and preparation between Procedure Room Cases is 15 minutes.

d. The optimum utilization of a dedicated, outpatient, general-purpose outpatient Procedure Room is 70% of full capacity. $70\% \times 250 \text{ days/year} \times 8 \text{ hours/day}$ divided by 45 minutes = 1867 Cases per year.

Response: This is not applicable to a radiation therapy facility, which does not have procedure rooms.

Determination of Need

- 1. Need.** The minimum numbers of 884 Cases per Operating Room and 1867 Cases per Procedure Room are to be considered as baseline numbers for purposes of determining Need.² An applicant should demonstrate the ability to perform a minimum of 884 Cases per Operating Room and/or 1867 Cases per Procedure Room per year, except that an applicant may provide information on its projected case types and its assumptions of estimated average time and clean up and preparation time per Case if this information differs significantly from the above-stated assumptions. It is recognized that an ASTC may provide a variety of services/Cases and that as a result the estimated average time and clean up and preparation time for such services/Cases may not meet the minimum numbers set forth herein. It is also recognized that an applicant applying for an ASTC Operating Room(s) may apply for a Procedure Room, although the anticipated utilization of that Procedure Room may not meet the base guidelines contained here. Specific reasoning and explanation for the inclusion in a CON application of such a Procedure Room must be provided. An applicant that desires to limit its Cases to a specific type or types should apply for a Specialty ASTC.

Response: This is not applicable to an outpatient radiation therapy facility, which does not perform surgical operations and has no operating or procedure rooms. However, the applicant may request a surgery center license restricted to radiation therapy procedures, as have a number of linear accelerator providers across Tennessee. A separate license requires certain space separations between the licensed area and the medical practice, and these will be provided to allow for a licensure option. Having a licensed facility

separate from the owners' medical practice has some advantages, such as flexibility in personnel management, management of liabilities, and similar factors.

- 2. Need and Economic Efficiencies. An applicant must estimate the projected surgical hours to be utilized per year for two years based on the types of surgeries to be performed, including the preparation time between surgeries. Detailed support for estimates must be provided.**

Response: This is not applicable to an outpatient radiation therapy facility, which does not perform surgical operations and has no operating and procedure rooms.

- 3. Need; Economic Efficiencies; Access. To determine current utilization and need, an applicant should take into account both the availability and utilization of either: a) all existing outpatient Operating Rooms and Procedure Rooms in a Service Area, including physician office based surgery rooms (when those data are officially reported and available³) OR b) all existing comparable outpatient Operating Rooms and Procedure Rooms based on the type of Cases to be performed. Additionally, applications should provide similar information on the availability of nearby out-of-state existing outpatient Operating Rooms and Procedure Rooms, if that data are available, and provide the source of that data. Unstaffed dedicated outpatient Operating Rooms and unstaffed dedicated outpatient Procedure Rooms are considered available for ambulatory**

surgery and are to be included in the inventory and in the measure of capacity.

Response: Not applicable. This type of facility does not have operating rooms or procedure rooms.

- 4. Need and Economic Efficiencies. An applicant must document the potential impact that the proposed new ASTC would have upon the existing service providers and their referral patterns. A CON application to establish an ASTC or to expand existing services of an ASTC should not be approved unless the existing ambulatory surgical services that provide comparable services regarding the types of Cases performed, if those services are known and relevant, within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above.**

Response: Not applicable. Within the service area there is only one provider of radiation therapy services and it is operating under its hospital's license, not as a licensed specialty ASTC. It is Carpenter Cancer Center in Gallatin. Its historic utilization has been presented and discussed in the application's response to the State Plan Guidelines for Radiation Therapy facilities.

- 5. Need and Economic Efficiencies. An application for a Specialty ASTC should present its projections for the total number of cases based on its own calculations for the projected length of time per type of case, and shall provide any local, regional, or**

national data in support of its methodology. An applicant for a Specialty ASTC should provide its own definitions of the surgeries and/or procedures that will be performed and whether the Surgical Cases will be performed in an Operating Room or a Procedure Room. An applicant for a Specialty ASTC must document the potential impact that the proposed new ASTC would have upon the existing service providers and their referral patterns. A CON proposal to establish a Specialty ASTC or to expand existing services of a Specialty ASTC shall not be approved unless the existing ambulatory surgical services that provide comparable services regarding the types of Cases performed within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above. An applicant that is granted a CON for a Specialty ASTC shall have the specialty or limitation placed on the CON.

Response: Not applicable. The State Plan Guidelines for a radiation therapy facility do not provide this standard.

Other Standards and Criteria

- 6. Access to ASTCs. The majority of the population in a Service Area should reside within 60 minutes average driving time to the facility.**

Response: All of the service area population identified in the project's 19 ZIP codes is well within a 60-minute one-way drive time of the project. The service area has been defined as zip codes within 15 miles' drive of the project site.

- 7. Access to ASTCs. An applicant should provide information regarding the relationship of an existing or proposed ASTC site to public transportation routes if that information is available.**

Response: The project location is not served by a public transportation service.

- 8. Access to ASTCs. An application to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project the origin of potential patients by percentage and county of residence and, if such data are readily available, by zip code, and must note where they are currently being served. Demographics of the Service Area should be included, including the anticipated provision of services to out-of-state patients, as well as the identity of**

other service providers both in and out of state and the source of out-of-state data. Applicants shall document all other provider alternatives available in the Service Area. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

Response: The applicant does not have access to information on which existing hospital-based linear accelerator sites are currently being used by the RT patients who will be shifted to this project.

9. Access and Economic Efficiencies. An application to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project patient utilization for each of the first eight quarters following completion of the project. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

Table B-Need-State Health Plan ASTC Criterion 9: Projection of Quarterly Cases, Years One and Two					
	Q1 Procedures	Q2 Procedures	Q3 Procedures	Q4 Procedures	Total Procedures
2027	921	921	922	922	3686
2028	1064	1064	1064	1064	4256

The table above projects an approximately equal distribution of annual cases among quarters in both years, without a significant ramp-up period in Year One. This is reasonable because the applicant already serves these patients at other locations.

10. Patient Safety and Quality of Care;

Health Care Workforce.

- a. An applicant should be or agree to become accredited by any accrediting organization approved by the Centers for Medicare and Medicaid Services, such as the Joint Commission, the Accreditation Association of Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgical Facilities, or other nationally recognized accrediting organization.

Response: Not applicable. The applicant's accreditation will be from ASTRO, as a megavoltage radiation facility rather than a surgical facility.

- b. An applicant should estimate the number of physicians by specialty that are expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel. An applicant should provide documentation on the availability of appropriate and qualified staff that will provide ancillary support services, whether on- or off-site.

Response: Not applicable. The facility will not be a surgical facility; it will be a radiation therapy facility staffed by one radiation oncologist.

11. Access to ASTCs. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, Every citizen should have reasonable access to health care. the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

Response: Robertson County is a designated medically underserved area.

- b. Who is a “safety net hospital” or a “children’s hospital” as defined by the Bureau of TennCare Essential Access Hospital payment program;

Response: Not applicable.

- c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program; or

Response: The applicant has committed to contract with all area MCO’s as well as with the Medicare program.

- d. Who is proposing to use the ASTC for patients that typically require longer preparation and scanning times. The applicant shall provide in its application information supporting the additional time required per Case and the impact on the need standard.

e. **Response:** Not applicable to a linear accelerator facility.

ORIGINAL
APPLICATION



**State of Tennessee
Health Facilities Commission**

502 Deaderick Street, Andrew Jackson Building, 9th Floor, Nashville, TN 37243

www.tn.gov/hsda

Phone: 615-741-2364

hsda.staff@tn.gov

CERTIFICATE OF NEED APPLICATION

1A. Name of Facility, Agency, or Institution

Tennessee Oncology White House

Name

A currently unaddressed site on the west side of North Sage Road, approximately 70 yards south of North Sage Road's intersection with Hampton Place

Robertson County

Street or Route

County

White House

Tennessee

37188

City

State

Zip

N.A.

Website Address

Note: The facility's name and address **must be** the name and address of the project and **must be** consistent with the Publication of Intent.

2A. Contact Person Available for Responses to Questions

John Wellborn

Consultant

Name

Title

DSG

john.wellborn.dsg@gmail.com

Company Name

Email Address

4505 Harding Pike Suite 53-E

Street or Route

Nashville

Tennessee

37205

City

State

Zip

Consultant

615-665-2022

Association with Owner

Phone Number

3A. Proof of Publication

Attach the full page of newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper that includes a copy of the publication as proof of the publication of the letter of intent. (Attachment 3A)

Date LOI was Submitted: 03/09/24

Date LOI was Published: 03/15/24

RESPONSE: See Attachment 3A, Proof of publication.

4A. Purpose of Review (*Check appropriate box(es) – more than one response may apply*)

- Establish New Health Care Institution
- Relocation
- Change in Bed Complement
- Addition of a Specialty to an Ambulatory Surgical Treatment Center (ASTC)
- Initiation of MRI Service
- MRI Unit Increase
- Satellite Emergency Department
- Addition of Therapeutic Catheterization
- Positron Emission Tomography (PET) Service
- Initiation of Health Care Service as Defined in §TCA 68-11-1607(3)

Initiation of HealthCare services

- Burn Unit
- Neonatal Intensive Care Unit
- Open Heart Surgery
- Organ Transplantation
- Cardiac Catheterization
- Linear Accelerator
- Home Health
- Hospice
- Opiate Addiction Treatment Provided through a Non-Residential Substitution-Based Treatment Section for Opiate Addiction

Please answer all questions on letter size, white paper, clearly typed and spaced, single sided, in order and sequentially numbered. In answering, please type the question and the response. All questions must be answered. If an item does not apply, please indicate “N/A” (not applicable). Attach appropriate documentation as an Appendix at the end of the application and reference the applicable item Number on the attachment, i.e. Attachment 1A, 2A, etc. The last page of the application should be a completed signed and notarized affidavit.

5A. Type of Institution (*Check all appropriate boxes – more than one response may apply*)

- Hospital
- Ambulatory Surgical Treatment Center (ASTC) – Multi-Specialty
- Ambulatory Surgical Treatment Center (ASTC) – Single Specialty
- Home Health
- Hospice
- Intellectual Disability Institutional Habilitation Facility (ICF/IID)
- Nursing Home
- Outpatient Diagnostic Center
- Rehabilitation Facility
- Residential Hospice
-

Nonresidential Substitution Based Treatment Center of Opiate Addiction

Other

Other -

Physician's Practice Office

Hospital -

6A. Name of Owner of the Facility, Agency, or Institution

Tennessee Oncology White House, LLC

Name

2004 Hayes Street Suite 800

615-986-4120

Street or Route

Phone Number

Nashville

Tennessee

37203

City

State

Zip

7A. Type of Ownership of Control (Check One)

- Sole Proprietorship
- Partnership
- Limited Partnership
- Corporation (For Profit)
- Corporation (Not-for-Profit)
- Government (State of TN or Political Subdivision)
- Joint Venture
- Limited Liability Company
- Other (Specify)

Attach a copy of the partnership agreement, or corporate charter and certificate of corporate existence. Please provide documentation of the active status of the entity from the Tennessee Secretary of State's website at <https://tnbear.tn.gov/ECommerce/FilingSearch.aspx>. If the proposed owner of the facility is government owned must attach the relevant enabling legislation that established the facility. (Attachment 7A)

Describe the existing or proposed ownership structure of the applicant, including an ownership structure organizational chart. Explain the corporate structure and the manner in which all entities of the ownership structure relate to the applicant. As applicable, identify the members of the ownership entity and each member's percentage of ownership, for those members with 5% ownership (direct or indirect) interest.

RESPONSE: 1. Please see Attachment 7A. 2. Please see Attachment 7A for an organization Chart showing the ownership structure of the applicant, and for ownership interests in that entity. The proposed facility will be wholly owned by Tennessee Oncology White House LLC, a new entity wholly owned by Tennessee Oncology PLLC (the medical group). The LLC is established to own this White House project. The LLC does not own any other entity. No other entity owns 5% or more of the PLLC or of the applicant LLC.

8A. Name of Management/Operating Entity (If Applicable)

Name

Street or Route

County

City

State

Zip

Website Address

For new facilities or existing facilities without a current management agreement, attach a copy of a draft management agreement that at least includes the anticipated scope of management services to be provided, the anticipated term of the agreement, and the anticipated management fee payment schedule. For facilities with existing management agreements, attach a copy of the fully executed final contract. (Attachment 8A)

9A. Legal Interest in the Site

Check the appropriate box and submit the following documentation. (Attachment 9A)

The legal interest described below must be valid on the date of the Agency consideration of the Certificate of Need application.

- Ownership (Applicant or applicant’s parent company/owner) – Attach a copy of the title/deed.
 - Lease (Applicant or applicant’s parent company/owner) – Attach a fully executed lease that includes the terms of the lease and the actual lease expense.
 - Option to Purchase - Attach a fully executed Option that includes the anticipated purchase price.
 - Option to Lease - Attach a fully executed Option that includes the anticipated terms of the Option and anticipated lease expense.
 - Letter of Intent, or other document showing a commitment to lease the property - attach reference document
 - Other (Specify)
-

RESPONSE: A development company will acquire the project site to construct a two-story medical office building with a connected accelerator vault. The CON applicant will lease ground-floor shelled space in the building (including the vault) to finish, equip, and operate as a radiation therapy facility limited to radiation therapy with a linear accelerator. Attachment 9A contains a purchase agreement documenting site control by the developer that will build the MOB. It also includes a Letter of Intent from the developer, stating the terms of the developer’s lease to the CON applicant.

10A. Floor Plan

If the facility has multiple floors, submit one page per floor. If more than one page is needed, label each page. (Attachment 10A)

- Patient care rooms (Private or Semi-private)
- Ancillary areas
- Other (Specify)

RESPONSE: Please see Attachment 10A for the floor plan of this project. Tennessee Oncology’s proposed linear accelerator facility (office space and accelerator vault) will occupy approximately 10,631 RSF of space on the ground floor of a two-story, 32,724 SF building. Tennessee Oncology PLLC may lease additional space in the building, for activities that are not part of this project—such as medical oncology clinics and for diagnostic and therapeutic services other than radiation therapy. The long-term objective would be to offer a full-service community-based cancer care resource for Tennessee Oncology patients in this rapidly growing area north of Nashville. This linear accelerator project is the first step toward that objective. Tennessee Oncology PLLC may lease additional space in the building, for

activities that are not part of this project—such as medical oncology clinics and for diagnostic and therapeutic services other than radiation therapy. The long-term objective would be to offer a full-service community-based cancer care resource for Tennessee Oncology patients in this rapidly growing area north of Nashville. This linear accelerator project is the first step toward that objective.

11A. Public Transportation Route

Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients. (Attachment 11A)

RESPONSE: Please see Attachment 11A.

12A. Plot Plan

Unless relating to home care organization, briefly describe the following and attach the requested documentation on a letter size sheet of white paper, legibly labeling all requested information. It **must** include:

- Size of site (in acres);
- Location of structure on the site;
- Location of the proposed construction/renovation; and
- Names of streets, roads, or highways that cross or border the site.

(Attachment 12A)

RESPONSE: Please see Attachment 12A for the plot plan.

13A. Notification Requirements

- TCA §68-11-1607(c)(9)(B) states that “... If an application involves a healthcare facility in which a county or municipality is the lessor of the facility or real property on which it sits, then within ten (10) days of filing the application, the applicant shall notify the chief executive officer of the county or municipality of the filing, by certified mail, return receipt requested.” Failure to provide the notifications described above within the required statutory timeframe will result in the voiding of the CON application.
 - Notification Attached (Provide signed USPS green-certified mail receipt card for each official notified.)
 - Notification in process, attached at a later date
 - Notification not in process, contact HFC Staff
 - Not Applicable
- TCA §68-11-1607(c)(9)(A) states that “... Within ten (10) days of the filing of an application for a nonresidential substitution based treatment center for opiate addiction with the agency, the applicant shall send a notice to the county mayor of the county in which the facility is proposed to be located, the state representative and senator representing the house district and senate district in which the facility is proposed to be located, and to the mayor of the municipality, if the facility is proposed to be located within the corporate boundaries of the municipality, by certified mail, return receipt requested, informing such officials that an application for a nonresidential substitution based treatment center for opiate addiction has been filed with the agency by the applicant.
 - Notification Attached (Provide signed USPS green-certified mail receipt card for each official notified.)
 - Notification in process, attached at a later date
 - Notification not in process, contact HFC Staff
 - Not Applicable

EXECUTIVE SUMMARY

1E. Overview

Please provide an overview not to exceed **ONE PAGE** (for 1E only) in total explaining each item point below.

- Description: Address the establishment of a health care institution, initiation of health services, and/or bed complement changes.

RESPONSE:

The facility will be in a new office building that a developer will construct in White House, in Robertson County, north of Nashville. The applicant LLC will lease 10,631 RSF of shelled ground-floor space in the building, including a connected linear accelerator vault. The applicant will finish out, equip, and operate its leased space as an outpatient linear accelerator facility serving only Tennessee Oncology, PLLC's radiation therapy patients. If required by Licensure regulation at the time, the applicant will seek licensure from the Health Facilities Commission as an Ambulatory Surgical Treatment Center limited to outpatient radiation therapy with a linear accelerator. (The physician group Tennessee Oncology PLLC may lease additional space in that building for activities that are not part of this project—such as medical oncology clinics and diagnostic and therapeutic services other than radiation therapy. Tennessee Oncology PLLC plans to develop a full-service community-based outpatient cancer care resource for its numerous patients in this rapidly growing sector north of Nashville.)

-
- Ownership structure

RESPONSE: The applicant LLC is wholly owned by Tennessee Oncology PLLC, the largest cancer care physician group in Tennessee, and one of the largest in the United States. The PLLC is owned by 75 physician partners, each of whom owns 1.333% of the PLLC. The PLLC's radiation oncologists are the Medical Directors for for 9 of 13 linear accelerators in Davidson and Sumner County hospitals (i.e., at all sites not operated by Vanderbilt University Medical Center). In CY2022, they provided medical supervision for 63% of all linear accelerator treatments delivered in Davidson and Sumner Counties.

-
- Service Area

RESPONSE: The service area of the project will consist of 19 ZIP codes surrounding the project site in White House, north of Nashville in Robertson County. Ten of those ZIP codes are either entirely or substantially (>50%) within a 15-mile radius of the project site. Small portions of nine other ZIP codes are also covered in the 15-mile planning radius. This area north of Nashville annually refers to Tennessee Oncology more than 1,000 patients, most of whom (88%) are found to need radiation therapy treatments on linear accelerators.

-
- Existing similar service providers

RESPONSE: The 15-mile service area includes only one provider of linear accelerator services: Carpenter Cancer Center in Gallatin, which is part of LifePoint Health System, the owner of Sumner Regional Medical Center. That provider operates only one linear accelerator, which has consistently high utilization.

-
- Project Cost

RESPONSE: The applicant's estimated total project cost is \$23,001,275, of which \$10,439,762 consists of space lease payments over a 15-year period.

-
- Staffing

RESPONSE: The staff will require 7.45 FTE's in Year One. Clinical staff will consist of a physicist, a dosimetrist, an RN, 3 therapists, a 0.25 FTE PRN therapist and a 0.20 FTE dietician. A clinical services assistant will provide reception and clerical services. The applicant will explore sub-contracting certain support functions to Tennessee Oncology.

2E. Rationale for Approval

A Certificate of Need can only be granted when a project is necessary to provide needed health care in the area to be served, will provide health care that meets appropriate quality standards, and the effects attributed to competition or duplication would be positive for consumers

Provide a brief description not to exceed ONE PAGE (for 2E only) of how the project meets the criteria necessary for granting a CON using the data and information points provided in criteria sections that follow.

- Need

RESPONSE: There is an undisputed clinical need for the services projected in this application, because the patients who will use the project are already using existing linear accelerators in or near downtown Nashville. The purpose of this project is consumer-oriented and aimed at dramatically reducing the substantial travel time and expense these patients now endure driving to existing linear accelerators at area hospitals. For patients north of Nashville, close to White House, a trip to hospital-based linear accelerators (with wayfinding, parking, etc.) may require a 1-hour round-trip, but their entire course of treatment is 17 such round trips on as many consecutive weekdays. It should not be necessary to face such a travel time burden. It is also a burden for their companions who accompany them on these trips. It important to note that research has shown that drive times to RT care deter many patients from seeking timely care. Decentralizing healthcare services to keep pace with population growth and to lower travel times has been a consistent pattern in Middle Tennessee for years. It is overdue for radiation oncology, which imposes onerous drive time burdens on its patients (many of whom are elderly). For this reason, Tennessee Oncology itself is establishing radiation therapy services to the east of Nashville (Lebanon), and to the south (Tennessee Oncology Proton Center of Franklin). This project will offer similar options for patients living north of Nashville in the growing area of White House and the I-24 corridor.

- Quality Standards

RESPONSE: The White House linear accelerator service will seek accreditation by the American Society for Therapeutic Radiation Oncology (“ASTRO”) and the American College of Radiology (“ACR”). It may also seek single-specialty surgery center licensure by the State of Tennessee, if indicated as appropriate by licensing regulations at the time. The applicant has deep experience in maintaining high quality care standards Its radiation oncologists are the Medical Directors for 9 of 13 linear accelerators in Davidson and Sumner County hospitals (excluding four at Vanderbilt University Medical Center). In CY2022, these physicians provided medical supervision for 63% of all linear accelerator treatments delivered in Davidson and Sumner Counties.

- Consumer Advantage

- Choice

RESPONSE: The project will create an additional service site option option that is closer-to-home for Tennessee Oncology patients from areas north of Nashville.

- Improved access/availability to health care service(s)

RESPONSE: The new service option will significantly reduce the time that linear accelerator patients and their companions must spend in commuting for care during more than 17 daily round trips. It will offer common patient registration, billing and patient assistance processes all under the scope of Tennessee Oncology. It will further continuity of care through utilization of a common medical record. It will enhance access to Tennessee Oncology’s many support services throughout a course of cancer management regardless of treatment modality.

- Affordability

RESPONSE: The service will be competitively priced, as well as being less costly to access. As it does today, Tennessee Oncology will serve Medicare patients, and will contract with all of the area's TennCare MCOs. It will also serve patients who are uninsured or underinsured, making a charity care commitment of 2% of gross technical revenues.

3E. Consent Calendar Justification

- Letter to Executive Director Requesting Consent Calendar (Attach Rationale that includes addressing the 3 criteria)
- Consent Calendar NOT Requested

If Consent Calendar is requested, please attach the rationale for an expedited review in terms of Need, Quality Standards, and Consumer Advantage as a written communication to the Agency's Executive Director at the time the application is filed.

4E. PROJECT COST CHART

A. Construction and equipment acquired by purchase:

1. Architectural and Engineering Fees	\$160,000
2. Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	\$145,000
3. Acquisition of Site	\$0
4. Preparation of Site	\$0
5. Total Construction Costs	\$3,264,000
6. Contingency Fund	\$0
7. Fixed Equipment (Not included in Construction Contract)	\$6,406,149
8. Moveable Equipment (List all equipment over \$50,000 as separate attachments)	\$300,000
Project Management Fees, IT/telecom/furnishings/finance fees,	\$2,073,243
9. Other (Specify): <u>service contracts for linac and sim</u>	

B. Acquisition by gift, donation, or lease:

1. Facility (inclusive of building and land)	\$10,439,883
2. Building only	\$0
3. Land only	\$0
4. Equipment (Specify): _____	\$0
5. Other (Specify): _____	\$0

C. Financing Costs and Fees:

1. Interim Financing	\$168,000
2. Underwriting Costs	\$0
3. Reserve for One Year's Debt Service	\$0
4. Other (Specify): _____	\$0

D. Estimated Project Cost (A+B+C) \$22,956,275

E. CON Filing Fee \$45,000

F. Total Estimated Project Cost (D+E) **TOTAL** \$23,001,275

GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with TCA §68-11-1609(b), “no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, will provide health care that meets appropriate quality standards, and the effect attributed to completion or duplication would be positive for consumers.” In making determinations, the Agency uses as guidelines the goals, objectives, criteria, and standards adopted to guide the agency in issuing certificates of need. Until the agency adopts its own criteria and standards by rule, those in the state health plan apply.

Additional criteria for review are prescribed in Chapter 11 of the Agency Rules, Tennessee Rules and Regulations 01730-11.

The following questions are listed according to the three criteria: (1) Need, (2) the effects attributed to competition or duplication would be positive for consumers (Consumer Advantage), and (3) Quality Standards.

NEED

The responses to this section of the application will help determine whether the project will provide needed health care facilities or services in the area to be served.

- 1N.** Provide responses as an attachment to the applicable criteria and standards for the type of institution or service requested. A word version and pdf version for each reviewable type of institution or service are located at the following website. <https://www.tn.gov/hsda/hsda-criteria-and-standards.html> (Attachment 1N)

RESPONSE:

Attachment 1N contains responses to the State Health Plan's review criteria and standards for radiation therapy and for ambulatory surgical treatment centers.

- 2N.** Identify the proposed service area and provide justification for its reasonable ness. Submit a county level map for the Tennessee portion and counties boarding the state of the service area using the supplemental map, clearly marked, and shaded to reflect the service area as it relates to meeting the requirements for CON criteria and standards that may apply to the project. Please include a discussion of the inclusion of counties in the border states, if applicable. (Attachment 2N)

RESPONSE:

Please see Attachment 2N for the required map designating the project 's primary service area, which is ZIP code-based rather than county-based.

The primary service area ("PSA") consists of 19 ZIP codes that are wholly or partially within a 15-mile radius of the project site. Ten of the ZIP codes are wholly or substantially (>50%) within the 15-mile radius. Small portions of nine more ZIP codes are within the 15-mile planning radius.

In CY2023, Tennessee Oncology received 1,053 referrals of patients from these 19 ZIP codes and found that approximately 88% of them required radiation therapy on a linear accelerator – which was only available at hospital-based facilities. There is no linear accelerator in Robertson County, where this project will be located. There is only one linear accelerator in any of the 19 ZIP codes defined by the 15-mile planning radius. It is at Gallatin in Sumner County. It is highly utilized on a consistent basis.



Complete the following utilization tables for each county in the service area, if applicable.

PROJECTED UTILIZATION

Unit Type: <input checked="" type="checkbox"/> Procedures <input type="checkbox"/> Cases <input type="checkbox"/> Patients <input type="checkbox"/> Other _____		
Service Area Counties	Projected Utilization Recent Year 1 (Year = 2026)	% of Total
Robertson	3,686	100.00%
Total	3,686	100%

3N. A. Describe the demographics of the population to be served by the proposal.

RESPONSE:

The population is rapidly growing in the White House area along the 1-65 corridor, where this project is proposed. The data on a county level indicates that the service area for Robertson and Sumner Counties will increase 5.3% over the next four years, compared to a Statewide increase of 2.9%. The adult population 18+ years of age is also projected to increase more rapidly than the State: at 5.5% compared to 3.1%.

The service area has a significantly higher median household income than the State (\$78,162 compared to \$64,035 Statewide). Approximately 7.9% of the total population is below poverty level, compared to 13.3% Statewide. The service area has 17.0% of its population enrolled in TennCare, compared to a 21% enrollment Statewide.

B. Provide the following data for each county in the service area:

- Using current and projected population data from the Department of Health. (www.tn.gov/health/health-program-areas/statistics/health-data/population.html);
- the most recent enrollee data from the Division of TennCare (<https://www.tn.gov/tenncare/information-statistics/enrollment-data.html>),
- and US Census Bureau demographic information (<https://www.census.gov/quickfacts/fact/table/US/PST045219>).

RESPONSE:

See Attachment 3N-B for this demographic table. The target population is adults age 45+ years; and is for zip codes, not counties. However, only adult data 18+ years of age, for counties, was available for this table.

4N. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly those who are uninsured or underinsured, the elderly, women, racial and ethnic minorities, TennCare or Medicaid recipients, and low income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

RESPONSE:

The project will be accessible to all of these groups. It is projected to have more than a 60% payor mix of Medicare and TennCare/Medicaid patients. Charity care of 2% is committed. The project will not discriminate against the elderly, women, ethnic and racial minorities, or those with limited incomes.

Tennessee Oncology makes significant efforts in helping uninsured and underinsured patients achieve the support they need to undertake this rigorous course of treatment. The applicant has made a charitable care commitment of 2% of technical gross charges.

5N. Describe the existing and approved but unimplemented services of similar healthcare providers in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. List each provider and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: Admissions or discharges, patient days. Average length of stay, and occupancy. Other projects should use the most appropriate measures, e.g. cases, procedures, visits, admissions, etc. This does not apply to projects that are solely relocating a service.

RESPONSE:

There are no approved but unimplemented services of similar providers in the service area.

There is only one similar service on the edge of the project service area, at Carpenter Cancer Center in Gallatin, Sumner County. Its past three years of utilization and its percentage of compliance with the State Health Plan utilization target is provided below.

Table 5N: Utilization of Existing Linear Accelerators in the Project Service Area (Carpenter Cancer Center, Gallatin)			
Procedures	CY2020	CY2021	CY2022
Minimum Utilization Standard (40%)	3,162	3,162	3,162
Reported Procedures (HFC Registry)	5,672	6091	6,861

Percent of Minimum 40% Utilization Standard	179.4%	192.6%	217.0%

6N. Provide applicable utilization and/or occupancy statistics for your institution services for each of the past three years and the project annual utilization for each of the two years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

RESPONSE:

Historic Utilization: Because this is not an existing facility, there is no historic data on its utilization.

Projected Utilization: The table below shows the applicant’s projected treatments during its first three full calendar years of operation, which will be CY2026 - CY2028. It shows that the project will substantially exceed the State Health Plan’s utilization target in Year One. Year Three will be higher but below the State Health Plan’s Year Three targets, which do not accurately account for the prevailing technology’s ability to deliver needed fractions (treatments) with fewer treatments. In fact, the area average number of treatments per linear accelerator in Davidson and Sumner Counties is 4,400 treatments per unit and most are very busy.

Table 6N, Part A: Projected Utilization of Tennessee Oncology White House			
Year of Operation	Year One CY2026	Year Two CY2027	Year Three CY2028
Linac Procedures	3,686	4256	4842
State Health Plan Target	3,162	NA	6,323
% of State Health Plan Target Met	116.6%	NA	76.6%

The applicant’s methodology for projecting treatments can be summarized as follows. Tables illustrating these calculations are provided the applicant’s response to the State Plan MRT Guidelines, Attachment 1N.

The primary service area ("PSA") consists of 19 ZIP codes that are wholly or partially within a 15-mile radius of the project site. Ten of the ZIP codes are wholly or substantially (>50%) within the 15-mile radius. Small portions of nine more ZIP codes are within the 15-mile planning radius. The applicant identified patients currently referred to it from these 19 ZIP codes during CY2023.

- The ZIP codes' populations age 45 and older were identified by a commercial source (Intellimed and Esri) and the annual numerical (not percentage) increase/decrease for each ZIP code was calculated.
 - The applicant used the average annual change in population for each ZIP code to project each ZIP code's likely CY2026-CY2028 patient referrals to Tennessee Oncology. This resulted in a projection of just over 1,100 patients in each of the first three years of the project's operation.
 - The applicant's experience has been that 88% of its referred patients will be found to require treatments on a linear accelerator. The number of patients requiring this service in Years One-Three would be 969, 983, and 997 RT ("radiation therapy") patients, respectively. The RT patients will be free to choose from among a variety of sites for treatments, all of which are medically supervised by their Tennessee Oncology radiation therapist.
 - To project the number of RT patients who would elect to use the White House linear accelerator, rather than other less convenient urban locations, the applicant divided the RT patient projections into two groups. One was a "*moderate patient shift*" group of the ten ZIP codes closest to White House; the other was a "*minimal patient shift*" group of the other nine ZIP codes with small portions covered by the 15-mile radius.
 - The applicant projects that during the project's first three years, CY2026-CY2028, that 30%, 35%, and 40% of the "moderate shift" group of RT patients will choose White House for their radiation therapy, due to its greater convenience compared to more distant hospital-based accelerators. Only 10% of the "minimal shift" group are projected to relocate to White House for their radiation therapy and would continue to obtain care at current existing units.
-

7N. Complete the chart below by entering information for each applicable outstanding CON by applicant or share common ownership; and describe the current progress and status of each applicable outstanding CON and how the project relates to the applicant, and the percentage of ownership that is shared with the applicant's owners.

RESPONSE:

CON Number	Project Name	Date Approved	Expiration Date
2210-041A	Lebanon Radiation Oncology Center	1-25-2023	3-1-25

Complete the above chart by entering information for each applicable outstanding CON by applicant or share common ownership; and

Describe the current progress and status of each applicable outstanding CON and how the project relates to them.

Response: The table above has been completed.

The applicant Tennessee Oncology White House, LLC is wholly owned by Tennessee Oncology, PLLC. That PLLC owns Lebanon Radiation Oncology Center ("LROC"), which is being developed in Lebanon, Wilson County, under CN2210-041A. The project is a linear accelerator facility. It is under construction and is scheduled to open October 15, 2024. The applicant does not own an interest in any other facility, either existing or approved.

CONSUMER ADVANTAGE ATTRIBUTED TO COMPETITION

The responses to this section of the application helps determine whether the effects attributed to competition or duplication would be positive for consumers within the service area.

1C. List all transfer agreements relevant to the proposed project.

RESPONSE: Not applicable to a new facility. Transfer agreements will be sought when the project is approved.

2C. List all commercial private insurance plans contracted or plan to be contracted by the applicant.

- Aetna Health Insurance Company
- Ambetter of Tennessee Ambetter
- Blue Cross Blue Shield of Tennessee
- Blue Cross Blue Shield of Tennessee Network S
- Blue Cross Blue Shiled of Tennessee Network P

- BlueAdvantage
- Bright HealthCare
- Cigna PPO
- Cigna Local Plus
- Cigna HMO - Nashville Network
- Cigna HMO - Tennessee Select
- Cigna HMO - Nashville HMO
- Cigna HMO - Tennessee POS
- Cigna HMO - Tennessee Network
- Golden Rule Insurance Company
- HealthSpring Life and Health Insurance Company, Inc.
- Humana Health Plan, Inc.
- Humana Insurance Company
- John Hancock Life & Health Insurance Company
- Omaha Health Insurance Company
- Omaha Supplemental Insurance Company
- State Farm Health Insurance Company
- United Healthcare UHC
- UnitedHealthcare Community Plan East Tennessee
- UnitedHealthcare Community Plan Middle Tennessee
- UnitedHealthcare Community Plan West Tennessee
- WellCare Health Insurance of Tennessee, Inc.
- Others

RESPONSE: Please see Attachment 2C for a list of current and planned insurers.

- 3C. Describe the effects of competition and/or duplication of the proposal on the health care system, including the impact upon consumer charges and consumer choice of services.

RESPONSE:

The project improves consumer choice significantly by offering patients a closer-to-home option for their cancer treatment. Patients receiving treatment through the proposed project will have reduced total round-trip hours of travel time compared to what they would incur if using most existing providers closer to Nashville. Patients choosing the White House facility will avoid crowded highways and will have accessible parking and entry. Continuity of care will be enhanced as patients will continue to utilize Tennessee Oncology's unified medical records system during their treatment phase, rather than being set up under separate hospital medical records systems. In terms of charges, the White House project will not adversely impact any existing provider's charge structure, and the project's gross charge structure will compare favorably to other regional providers' gross charges. By committing 2% of technical charges to charity care, the project further improves community access to radiation therapy treatments. Finally, the project will not decrease existing providers' utilization below the State Health Plan capacity threshold.

- 4C. Discuss the availability of and accessibility to human resources required by the proposal, including clinical leadership and adequate professional staff, as per the State of Tennessee licensing requirements, CMS, and/or accrediting agencies requirements, such as the Joint Commission and Commission on Accreditation of Rehabilitation Facilities.

RESPONSE:

The physicians who will direct this service have deep experience in providing the clinical and staffing leadership required for the project. They have long played a key role in assisting their hospital-based

services to meet all requirements of licensure, CMS, and the accrediting agencies responsible for this specialized service.

- 5C. Document the category of license/certification that is applicable to the project and why. These include, without limitation, regulations concerning clinical leadership, physician supervision, quality assurance policies and programs, utilization review policies and programs, record keeping, clinical staffing requirements, and staff education.

RESPONSE:

If necessary, the proposed facility may seek licensure from the Health Facilities Commission as a single specialty ambulatory surgical treatment center limited to providing megavoltage radiation therapy with a linear accelerator.

PROJECTED DATA CHART

- Project Only
 Total Facility

Give information for the *two (2)* years following the completion of this proposal.

	Year 1	Year 2
	<u>2026</u>	<u>2027</u>
A. Utilization Data		
Specify Unit of Measure <u>Procedures</u>	<u>3686</u>	<u>4256</u>
B. Revenue from Services to Patients		
1. Inpatient Services	<u>\$0.00</u>	<u>\$0.00</u>
2. Outpatient Services	<u>\$2,762,880.00</u>	<u>\$2,994,894.00</u>
3. Emergency Services	<u>\$0.00</u>	<u>\$0.00</u>
4. Other Operating Revenue (Specify) _____	<u>\$0.00</u>	<u>\$0.00</u>
Gross Operating Revenue	<u>\$2,762,880.00</u>	<u>\$2,994,894.00</u>
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	<u>\$1,599,155.00</u>	<u>\$1,733,445.00</u>
2. Provision for Charity Care	<u>\$55,258.00</u>	<u>\$59,898.00</u>
3. Provisions for Bad Debt	<u>\$0.00</u>	<u>\$0.00</u>
Total Deductions	<u>\$1,654,413.00</u>	<u>\$1,793,343.00</u>
NET OPERATING REVENUE	<u>\$1,108,467.00</u>	<u>\$1,201,551.00</u>

PROJECTED DATA CHART

- Total Facility
 Project Only

Give information for the *two (2)* years following the completion of this proposal.

	Year 1	Year 2
	<u>2026</u>	<u>2027</u>
A. Utilization Data		
Specify Unit of Measure <u>Procedures</u>	<u>3686</u>	<u>4256</u>
B. Revenue from Services to Patients		
1. Inpatient Services	<u>\$0.00</u>	<u>\$0.00</u>
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3. Emergency Services	<u>\$0.00</u>	<u>\$0.00</u>
4. Other Operating Revenue (Specify) _____	<u>\$0.00</u>	<u>\$0.00</u>
Gross Operating Revenue	<u>\$2,762,880.00</u>	<u>\$2,994,894.00</u>
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3. Provisions for Bad Debt	<u>\$0.00</u>	<u>\$0.00</u>
Total Deductions	<u>\$1,654,413.00</u>	<u>\$1,793,343.00</u>

NET OPERATING REVENUE

\$1,108,467.00

\$1,201,551.00

7C. Please identify the project’s average gross charge, average deduction from operating revenue, and average net charge using information from the Historical and Projected Data Charts of the proposed project.

Project Only Chart

	Previous Year to Most Recent Year	Most Recent Year	Year One	Year Two	% Change (Current Year to Year 2)
Gross Charge (<i>Gross Operating Revenue/Utilization Data</i>)	\$0.00	\$0.00	\$749.56	\$703.69	0.00
Deduction from Revenue (<i>Total Deductions/Utilization Data</i>)	\$0.00	\$0.00	\$448.84	\$421.37	0.00
Average Net Charge (<i>Net Operating Revenue/Utilization Data</i>)	\$0.00	\$0.00	\$300.72	\$282.32	0.00

8C. Provide the proposed charges for the project and discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the project and the impact on existing patient charges.

RESPONSE:

See response to question 9C, immediately below.

9C. Compare the proposed project charges to those of similar facilities/services in the service area/adjoining services areas, or to proposed charges of recently approved Certificates of Need.

If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

RESPONSE:

Please see Attachment 9C for a comparison of the project's frequent treatment charges to current Medicare allowables and to the latest available published charges of selected other providers.

10C. Report the estimated gross operating revenue dollar amount and percentage of project gross operating revenue anticipated by payor classification for the first and second year of the project by completing the table below.

If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

**Applicant’s Projected Payor Mix
Project Only Chart**

Payor Source	Year-2026		Year-2027	
	Gross Operating Revenue	% of Total	Gross Operating Revenue	% of Total
Medicare/Medicare Managed Care	\$1,519,156.00	54.98	\$1,647,192.00	55.00
TennCare/Medicaid	\$141,722.00	5.13	\$152,710.00	5.10
Commercial/Other Managed Care	\$932,655.00	33.76	\$1,012,274.00	33.80
Self-Pay	\$0.00	0	\$0.00	0
Other(Specify)	\$169,347.00	6.13	\$182,718.00	6.10
Total	\$2,762,880.00	100%	\$2,994,894.00	100%
Charity Care	\$55,258.00		\$59,898.00	

**Needs to match Gross Operating Revenue Year One and Year Two on Projected Data Chart*

Discuss the project’s participation in state and federal revenue programs, including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project.

RESPONSE: As shown in the table immediately above, the project will serve Medicare and TennCare/Medicaid patients, and will commit a minimum of 2% of its gross technical revenues to charity care for medically indigent patients.

QUALITY STANDARDS

1Q. Per PC 1043, Acts of 2016, any receiving a CON after July 1, 2016, must report annually using forms prescribed by the Agency concerning appropriate quality measures. Please attest that the applicant will submit an annual Quality Measure report when due.

- Yes
- No

2Q. The proposal shall provide health care that meets appropriate quality standards. Please address each of the following questions.

- Does the applicant commit to maintaining the staffing comparable to the staffing chart presented in its CON application?
 - Yes
 - No

- Does the applicant commit to obtaining and maintaining all applicable state licenses in good 3standing?
 - Yes
 -

No

- Does the applicant commit to obtaining and maintaining TennCare and Medicare certification(s), if participation in such programs are indicated in the application?

Yes

No

3Q. Please complete the chart below on accreditation, certification, and licensure plans. Note: if the applicant does not plan to participate in these type of assessments, explain why since quality healthcare must be demonstrated.

Credential	Agency	Status (Active or Will Apply)	Provider Number or Certification Type
Licensure	<input checked="" type="checkbox"/> Health Facilities Commission/Licensure Division <input type="checkbox"/> Intellectual & Developmental Disabilities <input type="checkbox"/> Mental Health & Substance Abuse Services	Will Apply	for ASTC limited to radiation therapy
Certification	<input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> TennCare/Medicaid <input type="checkbox"/> Other _____	Will Apply Will Apply	Radiation Therapy Radiation Therapy
Accreditation(s)	Other - Specify	Will Apply	Radiation Therapy

4Q. If checked “TennCare/Medicaid” box, please list all Managed Care Organization’s currently or will be contracted.

- AMERIGROUP COMMUNITY CARE- East Tennessee
- AMERIGROUP COMMUNITY CARE - Middle Tennessee
- AMERIGROUP COMMUNITY CARE - West Tennessee
- BLUECARE - East Tennessee
- BLUECARE - Middle Tennessee
- BLUECARE - West Tennessee
- UnitedHealthcare Community Plan - East Tennessee
- UnitedHealthcare Community Plan - Middle Tennessee
- UnitedHealthcare Community Plan - West Tennessee
- TENNCARE SELECT HIGH - All
- TENNCARE SELECT LOW - All
- PACE
- KBB under DIDD waiver
- Others

5Q. Do you attest that you will submit a Quality Measure Report annually to verify the license, certification, and/or accreditation status of the applicant, if approved?

- Yes
- No

6Q. For an existing healthcare institution applying for a CON:

- Has it maintained substantial compliance with applicable federal and state regulation for the three years prior to the CON application. In the event of non-compliance, the nature of non-compliance and corrective action should be discussed to include any of the following: suspension of admissions, civil monetary penalties, notice of 23-day or 90-day termination proceedings from Medicare/Medicaid/TennCare, revocation/denial of accreditation, or other similar actions and what measures the applicant has or will put into place to avoid similar findings in the future.

- Yes
- No
- N/A

- Has the entity been decertified within the prior three years? If yes, please explain in detail. (This provision shall not apply if a new, unrelated owner applies for a CON related to a previously decertified facility.)

- Yes
- No
- N/A

7Q. Respond to all of the following and for such occurrences, identify, explain, and provide documentation if occurred in last five (5) years.

Has any of the following:

- Any person(s) or entity with more than 5% ownership (direct or indirect) in the applicant (to include any entity in the chain of ownership for applicant);
- Any entity in which any person(s) or entity with more than 5% ownership (direct or indirect) in the applicant (to include any entity in the chain of ownership for applicant) has an ownership interest of more than 5%; and/or.

Been subject to any of the following:

- Final Order or Judgement in a state licensure action;
 - Yes
 - No
- Criminal fines in cases involving a Federal or State health care offense;
 - Yes
 - No
- Civil monetary penalties in cases involving a Federal or State health care offense;
 - Yes
 - No
- Administrative monetary penalties in cases involving a Federal or State health care offense;
 - Yes
 - No
- Agreement to pay civil or administrative monetary penalties to the federal government or any state in cases involving claims related to the provision of health care items and services;
 - Yes
 - No
- Suspension or termination of participation in Medicare or TennCare/Medicaid programs; and/or
 - Yes
 - No
- Is presently subject of/to an investigation, or party in any regulatory or criminal action of which you are aware.
 - Yes
 - No

8Q. Provide the project staffing for the project in Year 1 and compare to the current staffing for the most recent 12-month period, as appropriate. This can be reported using full-time equivalent (FTEs) positions for these positions.

Existing FTE not applicable (Enter year)

Position Classification	Existing FTEs(enter year)	Projected FTEs Year 1
A. Direct Patient Care Positions		
Physicist	0.00	1.00
Dosimetrist	0.00	1.00
RN	0.00	1.00
Therapist, PRN	0.00	0.25
Dietician	0.00	0.20
Therapist	0.00	3.00
Total Direct Patient Care Positions	N/A	6.45

B. Non-Patient Care Positions		
Clinical Services Assistant	0.00	1.00
Total Non-Patient Care Positions	N/A	1
Total Employees (A+B)	0	7.45

C. Contractual Staff		
Contractual Staff Position	0.00	0.00
Total Staff (A+B+C)	0	7.45

DEVELOPMENT SCHEDULE

TCA §68-11-1609(c) provides that activity authorized by a Certificate of Need is valid for a period not to exceed three (3) years (for hospital and nursing home projects) or two (2) years (for all other projects) from the date of its issuance and after such time authorization expires; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificate of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need authorization which has been extended shall expire at the end of the extended time period. The decision whether to grant an extension is within the sole discretion of the Commission, and is not subject to review, reconsideration, or appeal.

- Complete the Project Completion Forecast Chart below. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
- If the CON is granted and the project cannot be completed within the standard completion time period (3 years for hospital and nursing home projects and 2 years for all others), please document why an extended period should be approved and document the “good cause” for such an extension.

PROJECT COMPLETION FORECAST CHART

Assuming the Certificate of Need (CON) approval becomes the final HFC action on the date listed in Item 1 below, indicate the number of days from the HFC decision date to each phase of the completion forecast.

Phase	Days Required	Anticipated Date (Month/Year)
1. Initial HFC Decision Date		05/24/24
2. Building Construction Commenced	150	10/20/24
3. Construction 100% Complete (Approval for Occupancy)	510	10/15/25
4. Issuance of License	540	11/14/25
5. Issuance of Service	555	11/29/25
6. Final Project Report Form Submitted (Form HR0055)	615	01/28/26

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

Attachment 3A
Proof of Publication



Tennessee
GANNETT

PO Box 631340 Cincinnati, OH 45263-1340

PROOF OF PUBLICATION

Development Support Group
4505 Harding Pike Ste 53-E
NASHVILLE TN 37205

STATE OF WISCONSIN, COUNTY OF BROWN

The Tennessean, a newspaper published in the city of Nashville,
Davidson County, State of Tennessee, and personal knowledge of
the facts herein state and that the notice hereto annexed was
Published in said newspapers in the issue:

03/15/2024

and that the fees charged are legal.
Sworn to and subscribed before on 03/15/2024

Legal Clerk

Rickee Jacobs
mmh

Notary, State of WI, County of Brown

8.25.26

My commission expires

Publication Cost: \$973.36

Order No: 9953095

of Copies:

Customer No: 1329917

1

PO #:

THIS IS NOT AN INVOICE!

Please do not use this form for payment remittance.

MARIAH VERHAGEN
Notary Public
State of Wisconsin

**NOTIFICATION OF INTENT TO APPLY FOR A
CERTIFICATE OF NEED**

This is to provide official notice to the Health Facilities Commission and all interested parties, in accordance with T.C.A. §68-11-1601 et seq., and the Rules of the Health Facilities Commission, that Tennessee Oncology White House, an Ambulatory Surgical Treatment Center (ASTC) - Single Specialty owned by Tennessee Oncology White House, LLC, with an ownership type of Limited Liability Company and to be managed by itself, intends to file an application for a Certificate of Need for the establishment of a licensed ambulatory surgical treatment center limited to outpatient megavoltage radiation therapy with a linear accelerator, and to initiate outpatient linear accelerator services in the city of White House, in Robertson County. The address of the project will be a currently unaddressed site on the west side of North Sage Road, approximately 70 yards south of North Sage Road's intersection with Homaton Place, White House, Robertson County, Tennessee 37188. The estimated project cost will be \$23,001,275.

The anticipated date of filing the application is 04/01/2024.

The contact person for this project is Consultant John Wellborn, who may be reached at Development Support Group, 4505 Harding Pike, Suite 53-E, Nashville, TN 37205, 615-665-2022.

Pursuant to T.C.A. §68-11-1607(c)(1), (A) Any healthcare institution wishing to oppose a Certificate of Need application must file a written notice with the Health Facilities Commission no later than fifteen (15) days before the regularly scheduled Health Facilities Commission meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application may file a written objection with the Health Facilities Commission at or prior to the consideration of the application by the Commission, or may appear in person to express opposition. Written notice of opposition may be sent to: Health Facilities Commission, Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243 or email at hdsa.staff@tn.gov.

Attachment 7AR
Legal Entity Existence Documents
and Organization Chart



Tennessee
Secretary of State
Tre Hargett

Business Services Online > Find and Update a Business Record

Business Information Search

As of March 24, 2024 we have processed all corporate filings received in our office through March 17, 2024 and all annual reports received in our office through March 18, 2024.

Click on the underlined control number of the entity in the search results list to proceed to the detail page. From the detail page you can verify the entity displayed is correct (review addresses and business details) and select from the available entity actions - file an annual report, obtain a certificate of existence, file an amendment, etc.

Search:						1-1 of 1
Search Name: <u>Tennessee Oncology White House LLC</u> <input checked="" type="radio"/> Starts With <input type="radio"/> Contains						
Control #: _____						
Active Entities Only: <input type="checkbox"/>						<u>Search</u>
Control #	Entity Type	Name	Name Type	Name Status	Entity Filing Date	Entity Status
<u>001521317</u>	LLC	Tennessee Oncology White House, LLC TENNESSEE	Entity	Active	03/12/2024	Active
						1-1 of 1

Information about individual business entities can be queried, viewed and printed using this search tool for free.

If you want to get an electronic file of all business entities in the database, the full database can be downloaded for a fee by [Clicking Here](#).

[Click Here](#) for information on the Business Services Online Search logic.



Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

Tennessee Oncology White House, LLC
C/O TAMMY VERSLUIS
STE 800
2004 HAYES STREET
NASHVILLE, TN 37203

March 13, 2024

Filing Acknowledgment

Please review the filing information below and notify our office immediately of any discrepancies.

SOS Control # :	001521317	Formation Locale:	TENNESSEE
Filing Type:	Limited Liability Company - Domestic	Date Formed:	03/12/2024
Filing Date:	03/12/2024 3:34 PM	Fiscal Year Close:	12
Status:	Active	Annual Report Due:	04/01/2025
Duration Term:	Perpetual	Image # :	B1516-0806
Managed By:	Member Managed		
Business County:	DAVIDSON COUNTY		

Document Receipt

Receipt # : 008767828	Filing Fee:	\$300.00
Payment-Check/MO - CFS, NASHVILLE, TN		\$300.00

Registered Agent Address:
NATALIE DICKSON
C/O TAMMY VERSLUIS
STE 800
2004 HAYES STREET
NASHVILLE, TN 37203

Principal Address:
STE 800
2004 HAYES STREET
NASHVILLE, TN 37203

Congratulations on the successful filing of your **Articles of Organization** for **Tennessee Oncology White House, LLC** in the State of Tennessee which is effective on the date shown above. You must also file this document in the office of the Register of Deeds in the county where the entity has its principal office if such principal office is in Tennessee. Please visit the Tennessee Department of Revenue website (www.tn.gov/revenue) to determine your online tax registration requirements. If you need to obtain a Certificate of Existence for this entity, you can request, pay for, and receive it from our website.

You must file an Annual Report with this office on or before the Annual Report Due Date noted above and maintain a Registered Office and Registered Agent. Failure to do so will subject the business to Administrative Dissolution/Revocation.

Tre Hargett
Secretary of State

Processed By: Alexis Uqdah



ARTICLES OF ORGANIZATION LIMITED LIABILITY COMPANY (ss-4270)



Business Services Division
Tre Hargett, Secretary of State
State of Tennessee
312 Rosa L. Parks AVE, 6th Fl.
Nashville, TN 37243-1102
(615) 741-2286

Filing Fee: \$50.00 per member
(minimum fee = \$300, maximum fee = \$3,000)

For Office Use Only

FILED

The Articles of Organization presented herein are adopted in accordance with the provisions of the Tennessee Revised Limited Liability Company Act.

1. The name of the Limited Liability Company is: Tennessee Oncology White House, LLC

(NOTE: Pursuant to the provisions of T.C.A. § 48-249-106, each Limited Liability Company name must contain the words "Limited Liability Company" or the abbreviation "LLC" or "L.L.C.")

2. Name Consent: (Written Consent for Use of Indistinguishable Name)

This entity name already exists in Tennessee and has received name consent from the existing entity.

3. This company has the additional designation of: _____

4. The name and complete address of the Limited Liability Company's initial registered agent and office located in the state of Tennessee is:

Name: Natalie Dickson
Address: c/o Tammy Versluis 2004 Hayes Street, Suite 800
City: Nashville State: TN Zip Code: 37203 County: Davidson

5. Fiscal Year Close Month: December

6. If the document is not to be effective upon filing by the Secretary of State, the delayed effective date and time is: (Not to exceed 90 days)

Effective Date: ____/____/____ Time: _____
Month Day Year

7. The Limited Liability Company will be: Member Managed Manager Managed Director Managed

8. Number of Members at the date of filing: 1

9. Period of Duration: Perpetual Other ____/____/____
Month Day Year

10. The complete address of the Limited Liability Company's principal executive office is:

Address: 2004 Hayes Street, Suite 800
City: Nashville State: TN Zip Code: 37203 County: Davidson
Business Email: tversluis@tnonc.com

B1516-0806 03/12/2024 3:34 PM Received by Tennessee Secretary of State Tre Hargett



ARTICLES OF ORGANIZATION LIMITED LIABILITY COMPANY (ss-4270)

Page 2 of 2



Business Services Division
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State of Tennessee
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The name of the Limited Liability Company is: Tennessee Oncology White House, LLC

11. The complete mailing address of the entity (If different from the principal office) is:

Address: _____

City: _____ State: _____ Zip Code: _____

12. Non-Profit LLC (required only if the Additional Designation of "Non-Profit LLC" is entered in section 3.)

I certify that this entity is a Non-Profit LLC whose sole member is a nonprofit corporation, foreign or domestic, incorporated under or subject to the provisions of the Tennessee Nonprofit Corporation Act and who is exempt from franchise and excise tax as not-for-profit as defined in T.C.A. § 67-4-2004. The business is disregarded as an entity for federal income tax purposes.

13. Professional LLC (required only if the Additional Designation of "Professional LLC" is entered in section 3.)

I certify that this PLLC has one or more qualified persons as members and no disqualified persons as members or holders.
Licensed Profession: _____

14. Series LLC (required only if the Additional Designation of "Series LLC" is entered in section 3.)

I certify that this entity meets the requirements of T.C.A. § 48-249-309(a) & (b)

15. Obligated Member Entity (list of obligated members and signatures must be attached)

This entity will be registered as an Obligated Member Entity (OME) Effective Date: _____
Month Day Year

I understand that by statute: THE EXECUTION AND FILING OF THIS DOCUMENT WILL CAUSE THE MEMBER(S) TO BE PERSONALLY LIABLE FOR THE DEBTS, OBLIGATIONS AND LIABILITIES OF THE LIMITED LIABILITY COMPANY TO THE SAME EXTENT AS A GENERAL PARTNER OF A GENERAL PARTNERSHIP. CONSULT AN ATTORNEY.

16. This entity is prohibited from doing business in Tennessee:

This entity, while being formed under Tennessee law, is prohibited from engaging in business in Tennessee.

17. Other Provisions: _____

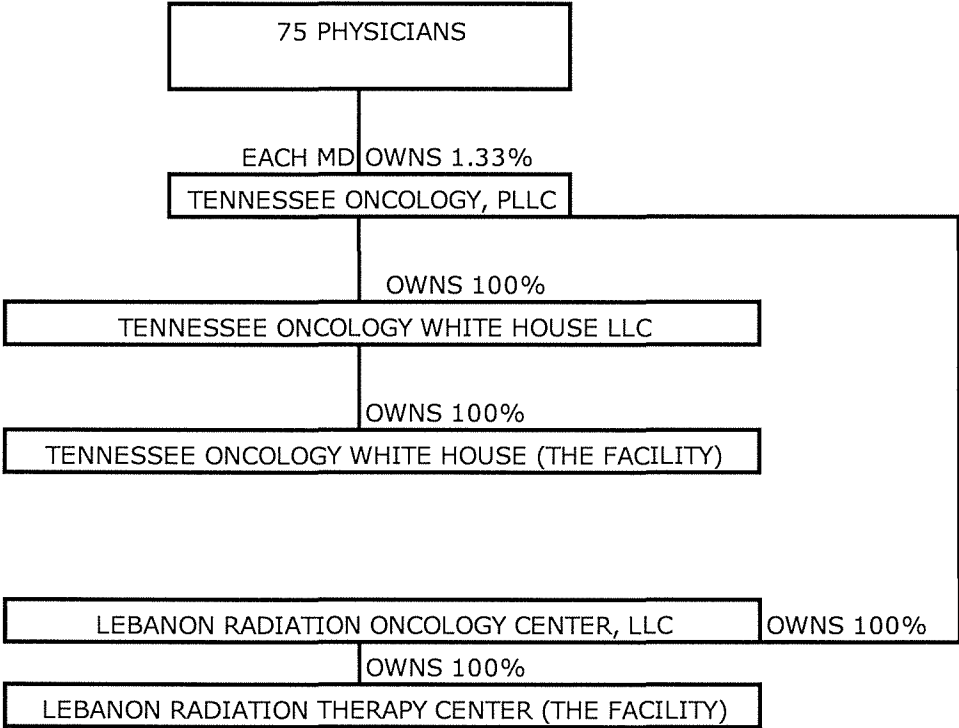
3/12/2024
Signature Date

Cynthia Y. Reisz
Signature

Signer's Capacity (if other than individual capacity)

Cynthia Y. Reisz
Name (printed or typed)

ORGANIZATION CHART--TENNESSEE ONCOLOGY WHITE HOUSE



Attachment 8A
Management Agreement
(Not applicable; facility to be self-managed)

Attachment 7A
Legal Entity Existence Documents



Tennessee
 Secretary of State
 Tre Hargett

Business Services Online > Find and Update a Business Record

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Click on the underlined control number of the entity in the search results list to proceed to the detail page. From the detail page you can verify the entity displayed is correct (review addresses and business details) and select from the available entity actions - file an annual report, obtain a certificate of existence, file an amendment, etc.

Search:						1-1 of 1
Search Name: <input type="text" value="Tennessee Oncology White House LLC"/> <input checked="" type="radio"/> Starts With <input type="radio"/> Contains						
Control #: <input type="text"/>						
Active Entities Only: <input type="checkbox"/>						<input type="button" value="Search"/>
Control #	Entity Type	Name	Name Type	Name Status	Entity Filing Date	Entity Status
<u>001521317</u>	LLC	Tennessee Oncology White House, LLC TENNESSEE	Entity	Active	03/12/2024	Active
						1-1 of 1

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Tre Hargett
Secretary of State

Division of Business Services
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March 13, 2024

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Duration Term:	Perpetual	Image # :	B1516-0806
Managed By:	Member Managed		
Business County:	DAVIDSON COUNTY		

Document Receipt

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Tre Hargett
Secretary of State

Processed By: Alexis Uqdah



ARTICLES OF ORGANIZATION LIMITED LIABILITY COMPANY (ss-4270)



Business Services Division
Tre Hargett, Secretary of State
State of Tennessee
312 Rosa L. Parks AVE, 6th Fl.
Nashville, TN 37243-1102
(615) 741-2286

For Office Use Only

FILED

Filing Fee: \$50.00 per member
(minimum fee = \$300, maximum fee = \$3,000)

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Address: c/o Tammy Versluis 2004 Hayes Street, Suite 800

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5. Fiscal Year Close Month: December

6. If the document is not to be effective upon filing by the Secretary of State, the delayed effective date and time is: (Not to exceed 90 days)

Effective Date: ___/___/___ Time: _____
Month Day Year

7. The Limited Liability Company will be: Member Managed Manager Managed Director Managed

8. Number of Members at the date of filing: 1

9. Period of Duration: Perpetual Other ___/___/___
Month Day Year

10. The complete address of the Limited Liability Company's principal executive office is:

Address: 2004 Hayes Street, Suite 800

City: Nashville State: TN Zip Code: 37203 County: Davidson

Business Email: tversluis@tnonc.com

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ARTICLES OF ORGANIZATION LIMITED LIABILITY COMPANY (ss-4270)



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I certify that this entity is a Non-Profit LLC whose sole member is a nonprofit corporation, foreign or domestic, incorporated under or subject to the provisions of the Tennessee Nonprofit Corporation Act and who is exempt from franchise and excise tax as not-for-profit as defined in T.C.A. § 67-4-2004. The business is disregarded as an entity for federal income tax purposes.

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I certify that this PLLC has one or more qualified persons as members and no disqualified persons as members or holders.

Licensed Profession: _____

14. Series LLC (required only if the Additional Designation of "Series LLC" is entered in section 3.)

I certify that this entity meets the requirements of T.C.A. § 48-249-309(a) & (b)

15. Obligated Member Entity (list of obligated members and signatures must be attached)

This entity will be registered as an Obligated Member Entity (OME) Effective Date: _____ / _____ / _____
Month Day Year

I understand that by statute: THE EXECUTION AND FILING OF THIS DOCUMENT WILL CAUSE THE MEMBER(S) TO BE PERSONALLY LIABLE FOR THE DEBTS, OBLIGATIONS AND LIABILITIES OF THE LIMITED LIABILITY COMPANY TO THE SAME EXTENT AS A GENERAL PARTNER OF A GENERAL PARTNERSHIP. CONSULT AN ATTORNEY.

16. This entity is prohibited from doing business in Tennessee:

This entity, while being formed under Tennessee law, is prohibited from engaging in business in Tennessee.

17. Other Provisions: _____

3/12/2024

Signature Date

Cynthia Y. Reisz

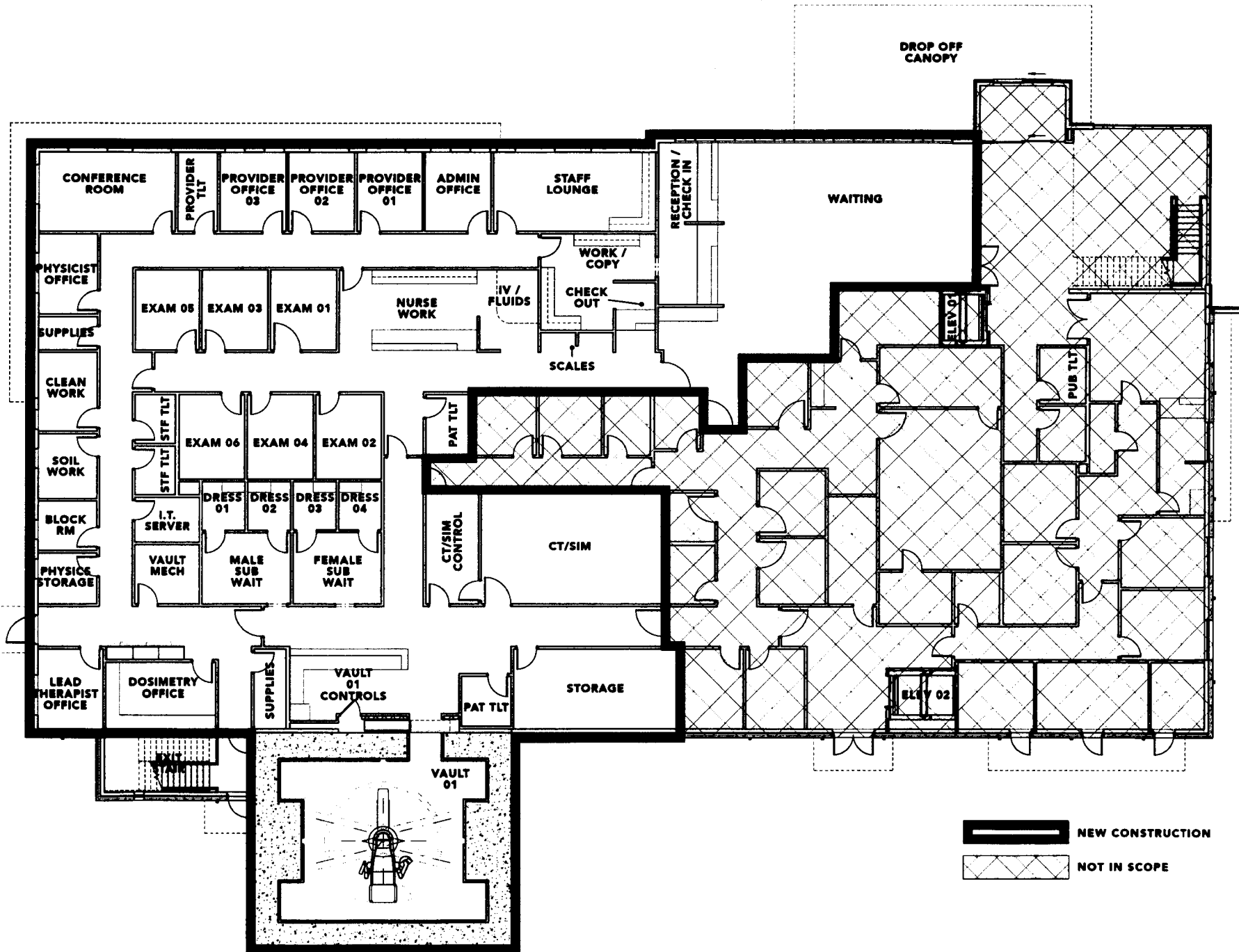
Signature

Signer's Capacity (if other than individual capacity)

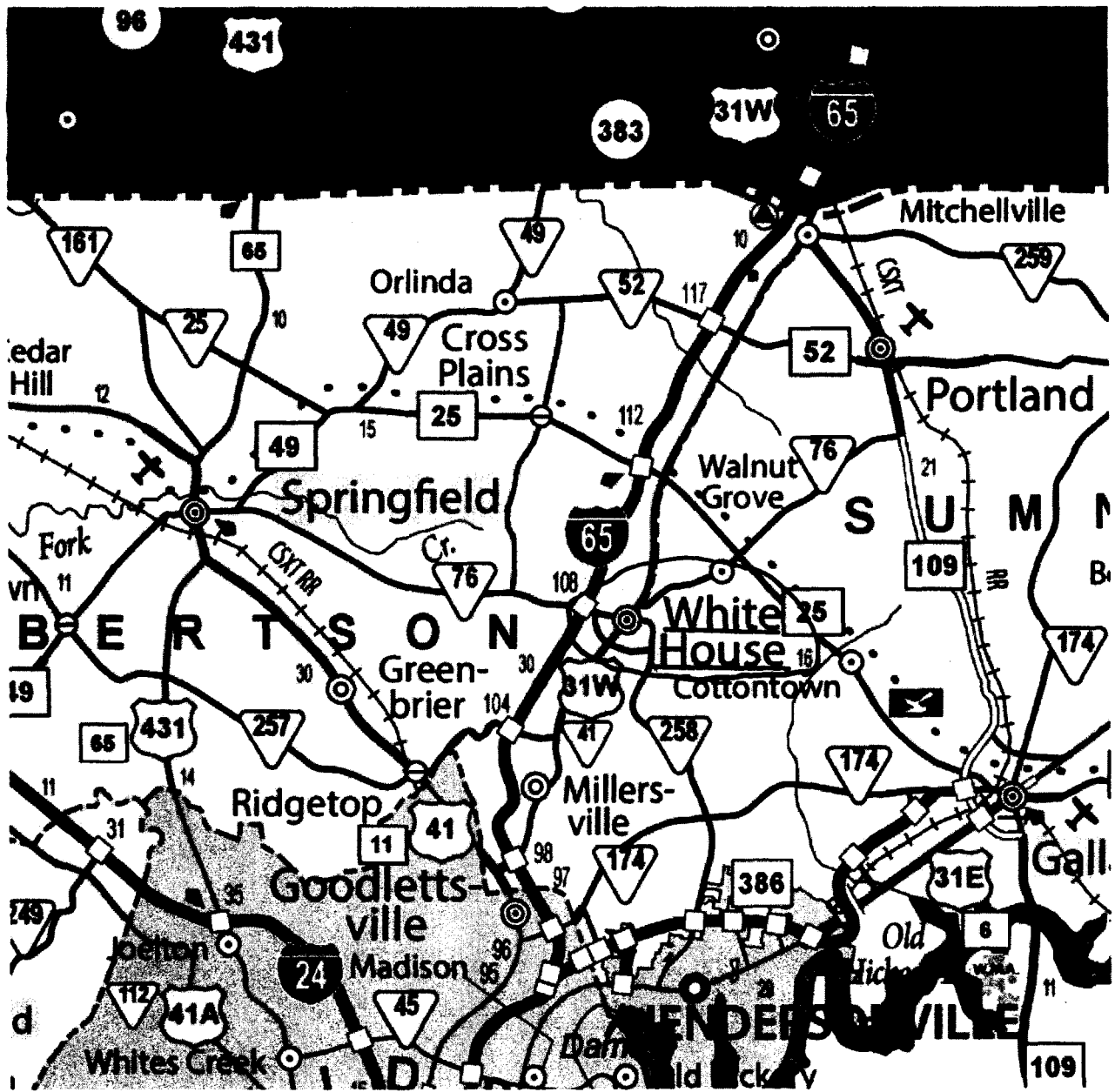
Cynthia Y. Reisz
Name (printed or typed)

B1516-0807 03/12/2024 3:34 PM Received by Tennessee Secretary of State Tre Hargett

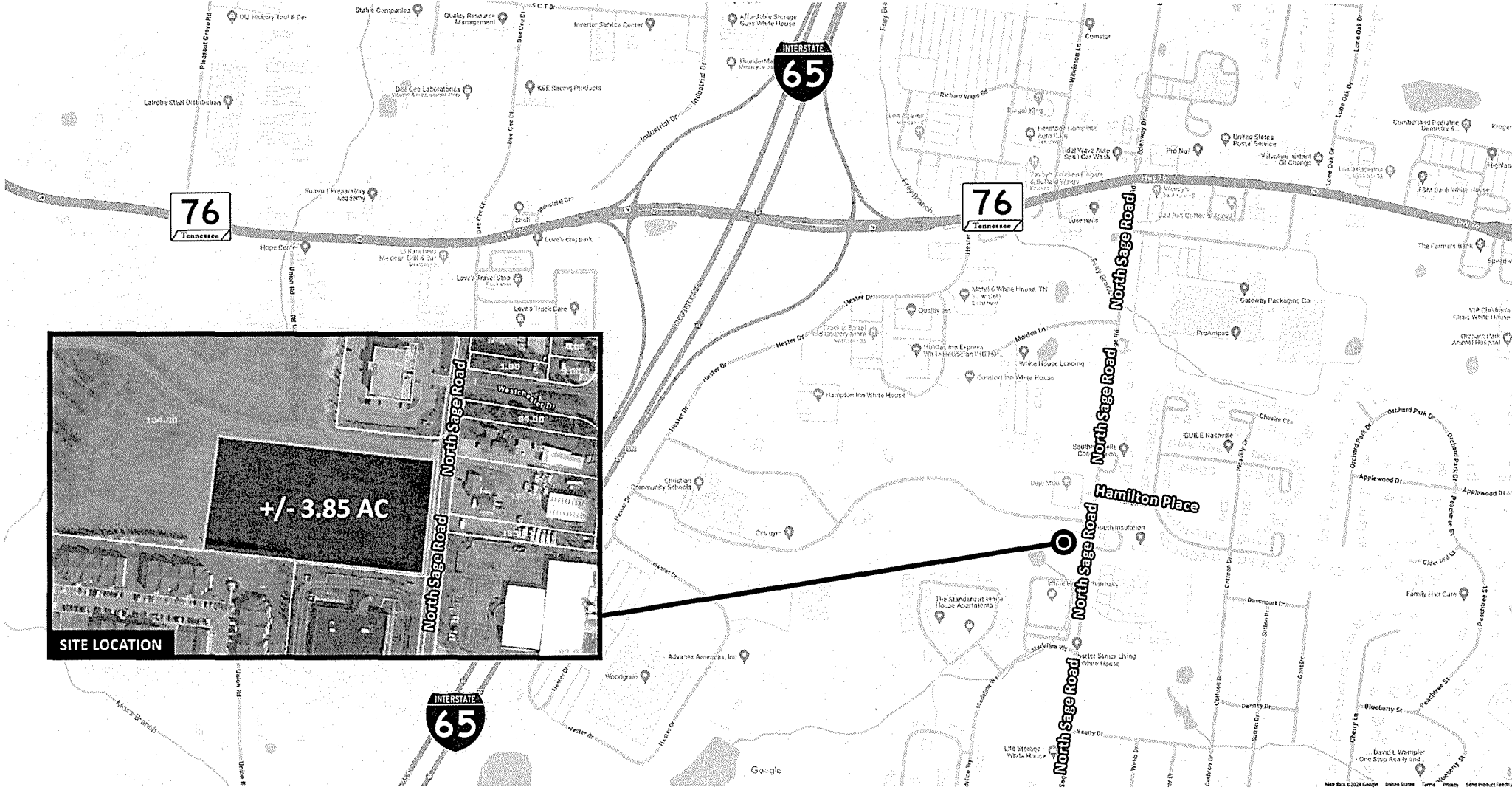
Attachment 10A
Floor Plan



Attachment 11A
Public Transportation Route



Attachment 12AR
Plot Plan



SITE LOCATION

76
Tennessee

76
Tennessee

INTERSTATE
65

INTERSTATE
65

Hamilton Place

North Sage Road

North Sage Road

North Sage Road

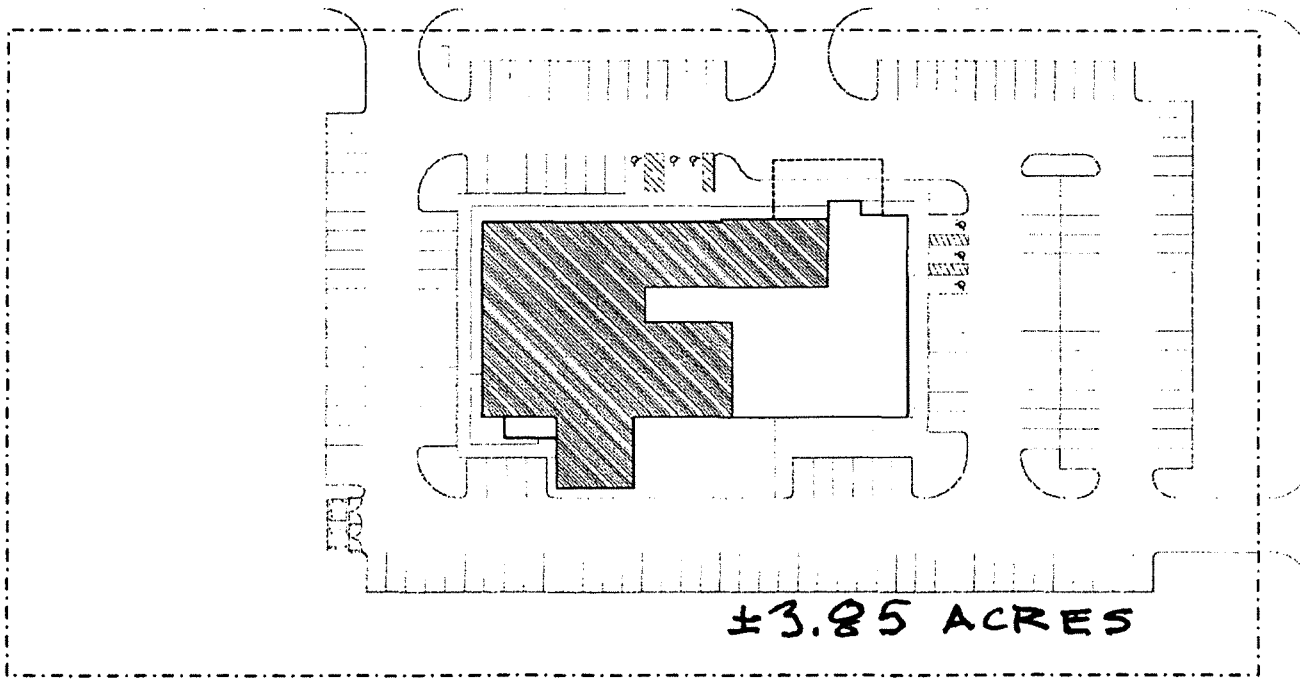
North Sage Road

Exhibit B

TENNESSEE ONCOLOGY

a partner of  OneOncology

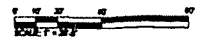
 RADIATION ONCOLOGY SUITE



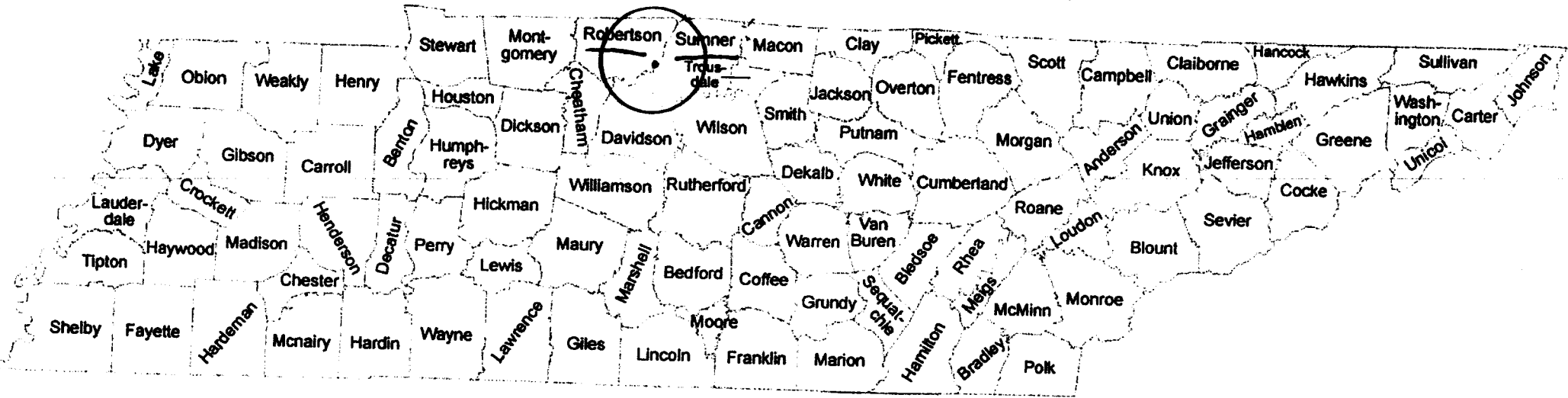
NORTH SAGE ROAD

±3.85 ACRES

NORTH

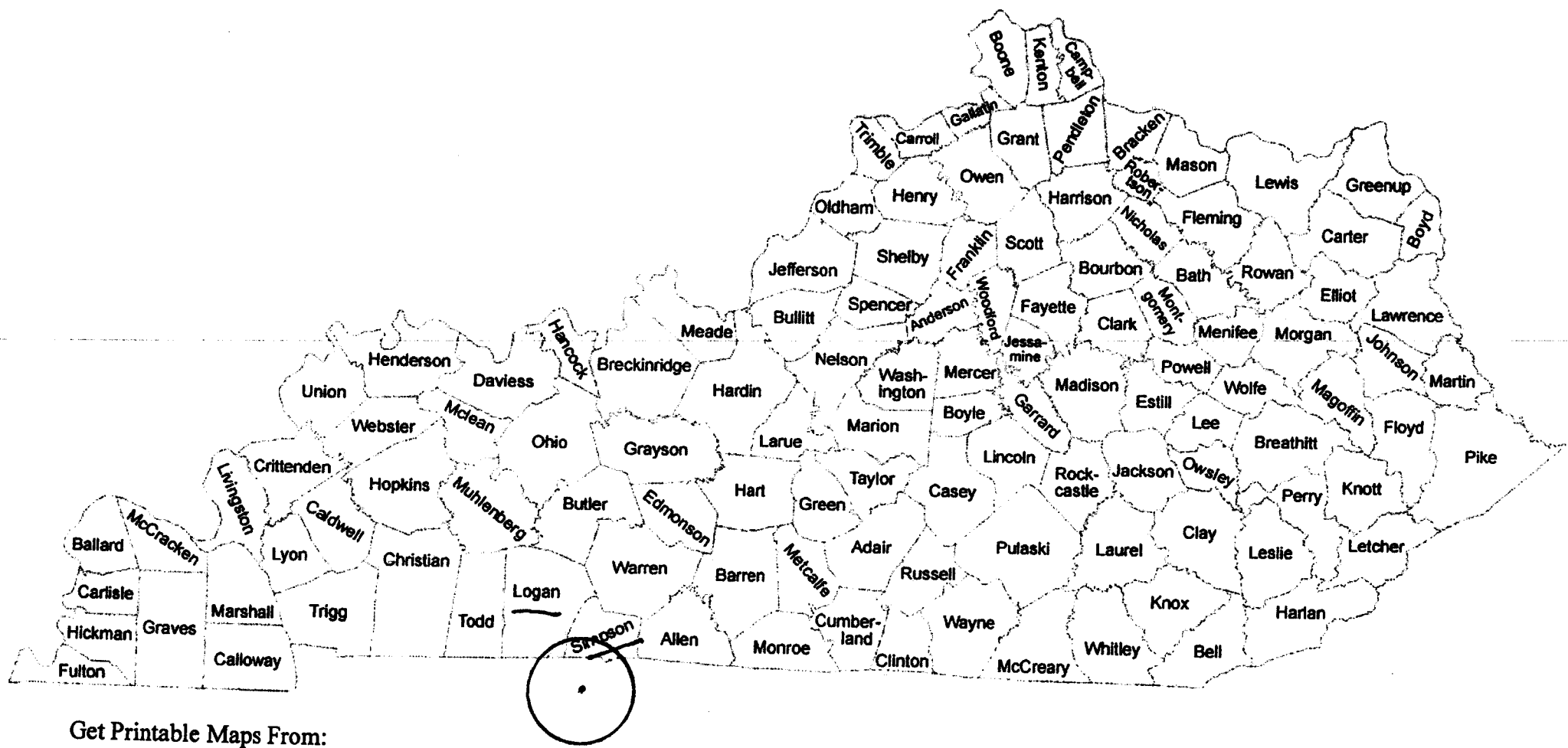


Attachment 2N
Counties Wholly or Partially Included in the
Project Service Area
(Tennessee and Kentucky)



Get Printable Maps From:
Waterproof Paper.com

**TENNESSEE ONCOLOGY WHITE HOUSE
PRIMARY SERVICE AREA**



Get Printable Maps From:
[Waterproof Paper.com](http://WaterproofPaper.com)

**TENNESSEE ONCOLOGY WHITE HOUSE
 PRIMARY SERVICE AREA**

Attachment 3N.BR
Service Area Demographic Table

**Table 3N-BR: Tennessee Oncology White House
Demographic Characteristics of Primary Service Area
2024-2028**

Revised on Supplemental Round 1

	Department of Health / Health Statistics							Bureau of the Census				TennCare	
Primary Service Area Counties	Current Total Population 2024	Projected Total Population 2028	Total Population % Change 2024-2028	Current Target* Population Age 18+ 2024	Projected Target* Population Age 18+ 2028	Projected Target* Population % Change 2024 - 2028	Projected Target* Population As % of Projected Total Population 2024	Median Age	Median Household Income	Persons Below Poverty Level	Persons Below Poverty Level as % of Total Population	Current TennCare Enrollees	TennCare Enrollees as % of Current Total County or Zip Code Population
Robertson	75,475	78,415	3.9%	58,292	60,696	4.1%	77.4%	39.4	\$74,440	6,868	9.1%	14,718	19.5%
Sumner	208,192	220,197	5.8%	161,094	170,778	6.0%	77.6%	39.7	\$81,883	15,614	7.5%	33,529	16.1%
Service Area Total	283,667	298,612	5.3%	219,386	231,474	5.5%	77.5%	39.6	\$78,162	22,483	7.9%	48,247	17.0%
Tennessee (TDH)	7,125,908	7,331,859	2.9%	5,565,604	5,736,895	3.1%	78.2%	38.0	\$64,035	947,746	13.3%	1,574,849	22.1%

Sources: UTCBER & TDH Population Projections, 2021; U.S. Census QuickFacts; TennCare Bureau.

Service area data is either total, or average, as appropriate.

Note: TDH does not publish population estimates for age 45+; age 18+ is provided in the table.

Attachment 9C
Charges of Similar Providers

**Table 9C: Tennessee Oncology White House
Proposed Most Frequent Gross Charges and Area Comparisons**

CPT	Descriptor	Current Medicare Allowable	Proposed Gross Charge			Similar Providers' Published Gross Charges					
			Current Average (NA)	Year 1 2026	Year 2 2027	CMC	Skyline	AST Midtown	AST West	Carpenter Cancer Center	Vanderbilt UMC
77300	Basic Rad Dosimetry Calcu Medical Radiation Physics Basic Radiation Dosimetry PC Only	\$59.74	\$105.00	\$105.00	\$105.00	\$1,253.63	\$1,242.79	\$585.70	\$585.60	\$122.86	\$1,117.00
77334	Treatment Devices Complex Medical Treatment Devices Design And Construction PC Only	\$113.83	\$245.00	\$245.00	\$245.00	\$3,232.15	\$2,950.73	\$1,027.05	\$1,027.31	\$2,098.12	\$2,486.00
77014	CT - Computed tomography Guidance For Placement Of Radiation Therapy Fields PC Only	\$107.65	\$218.00	\$218.00	\$218.00	\$4,114.49				\$2,289.94	\$1,298.00
G6002	Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy PC Only	\$67.29	\$115.00	\$115.00	\$115.00	\$734.50	\$670.55	\$366.15	\$366.15	\$812.27	\$73.00
G6012	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6-10 mev	\$201.91	\$344.00	\$344.00	\$344.00	\$2,087.78	\$1,525.99	\$882.45	\$882.45	\$1,127.72	\$1,632.00
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic mlc, per treatment session	\$312.65	\$532.00	\$532.00	\$532.00	\$4,429.53	\$4,043.85	\$2,178.50	\$2,178.50	\$2,963.07	\$4,613.00
77336	Continuing Medical Physics Consultation, Including Assessment Of Treatment Parameters, Quality Assurance Of Dose Delivery, And Review Of Patient Treatment Documentation In Support Of The Radiation Oncologist, Reported Per Week Of Therapy	\$77.41	\$132.00	\$132.00	\$132.00	\$1,674.51	\$1,525.99	\$926.10	\$926.10	\$1,222.86	\$1,221.00

Notes: 1. Years 1 & 2 gross charges assume no Medicare reimbursement changes. Applicant will adjust these charges if Medicare does change.
2. The applicant's gross charge data are technical gross charges only. It is not known if any of the other provider's published charges include professional fees.

Attachment
Medical Equipment
Supplemental Attachment Round 1

Attachment - MRI, PET, and/or Linear Accelerator

- 1a. For Magnetic Resonance Imaging (MRI) in a county with a population less than 175,000, describe the initiation of MRI services or addition of MRI scanners as part of the project, or
 - 1b. For Magnetic Resonance Imaging (MRI) in a county with a population greater than 175,000, describe the initiation of MRI services or addition of MRI scanners as part of the project if more than 5 patients per year under the age of 15 will be treated, and/or
 - 2. Describe the acquisition of any Positron Emission Tomography (PET) scanner that is adding a PET scanner in counties with population less than 175,000 and/or
 - 3. Describe the acquisition of any Linear Accelerator if initiating the service by responding to the following:
- A. Complete the chart below for acquired equipment.**

<input type="checkbox"/> Linear Accelerator	Mev <u>6,9,12,16,18</u> Types:	Hybrid	<input type="checkbox"/> SRS <input type="checkbox"/> IMRT <input type="checkbox"/> IGRT <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> By Purchase
	Total Cost*: <u>\$6,784,322</u> <input checked="" type="checkbox"/> New <input type="checkbox"/> Refurbished		<input type="checkbox"/> By Lease Expected Useful Life (yrs) _____ <input type="checkbox"/> If not new, how old? (yrs) _____
<input type="checkbox"/> MRI	Tesla: _____ Magnet:		<input type="checkbox"/> Breast <input type="checkbox"/> Extremity <input type="checkbox"/> Open <input type="checkbox"/> Short Bore <input type="checkbox"/> Other _____ <input type="checkbox"/> By Purchase
	Total Cost*: _____ <input type="checkbox"/> New <input type="checkbox"/> Refurbished		<input type="checkbox"/> By Lease Expected Useful Life (yrs) _____ <input type="checkbox"/> If not new, how old? (yrs) _____
<input type="checkbox"/> PET	<input type="checkbox"/> PET only <input type="checkbox"/> PET/CT <input type="checkbox"/> PET/MRI		<input type="checkbox"/> By Purchase
	Total Cost*: _____ <input type="checkbox"/> New <input type="checkbox"/> Refurbished		<input type="checkbox"/> By Lease Expected Useful Life (yrs) _____ <input type="checkbox"/> If not new, how old? (yrs) _____

* As defined by Agency Rule 0720-9-.01(4)(b). **The purchase price of the unit with sales tax will be \$5,559,349. The service contract with sales tax will be \$1,224,973. Together they total \$6,784,322.**

- B.** In the case of equipment purchase, include a quote and/or proposal from an equipment vendor. In the case of equipment lease, provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments along with the fair market value of the equipment. **Response: the vendor quotes are provided in supplemental Attachment Equipment Round 1.**
- C.** Compare lease cost of the equipment to its fair market value. Note: Per Agency Rule, the higher cost must be identified in the project cost chart. **Response: A comparison of lease outlay to the facility's fair market value is provided in supplemental Attachment Equipment Round 1.**
- D.** Schedule of Operations:

Location	Days of Operation (Sunday through Saturday)	Hours of Operation (example: 8 am – 3 pm)
Fixed Site (Applicant)	Monday through Friday	7:30 AM to 4 PM

**TENNESSEE ONCOLOGY WHITE HOUSE
COMPARISON OF LEASE OUTLAY VS. FMV OF LEASED SPACE**

SPACE LEASE OUTLAY--FIRST TERM						
First Term of Years	Rentable SF	Base Lease Rate-\$PSF	Annual Base Lease Outlay	Pass-through Expenses-\$PSF	Annual PassThrough Expenses	Total Costs for Leased Space
Year 1	10,631	\$40.80	\$433,744.80	12.00	127,572.00	\$561,316.80
Year 2	10,631	\$ 42.02	\$446,757.14	12.36	131,399.16	\$578,156.30
Year 3	10,631	\$ 43.28	\$460,159.86	12.73	135,341.13	\$595,500.99
Year 4	10,631	\$ 44.58	\$473,964.65	13.11	139,401.37	\$613,366.02
Year 5	10,631	\$ 45.92	\$488,183.59	13.51	143,583.41	\$631,767.00
Year 6	10,631	\$ 47.30	\$502,829.10	13.91	147,890.91	\$650,720.01
Year 7	10,631	\$ 48.72	\$517,913.97	14.33	152,327.64	\$670,241.61
Year 8	10,631	\$ 50.18	\$533,451.39	14.76	156,897.47	\$690,348.86
Year 9	10,631	\$ 51.68	\$549,454.94	15.20	161,604.39	\$711,059.33
Year 10	10,631	\$ 53.23	\$565,938.58	15.66	166,452.52	\$732,391.11
Year 11	10,631	\$ 54.83	\$582,916.74	16.13	171,446.10	\$754,362.84
Year 12	10,631	\$ 56.48	\$600,404.24	16.61	176,589.48	\$776,993.73
Year 13	10,631	\$ 58.17	\$618,416.37	17.11	181,887.17	\$800,303.54
Year 14	10,631	\$ 59.92	\$636,968.86	17.62	187,343.78	\$824,312.64
Year 15	10,631	\$ 61.71	\$656,077.93	18.15	192,964.10	\$849,042.02
1st Term Total			\$8,067,182.18		\$2,372,701	\$10,439,882.83

Note: Base lease rate and estimated pass through expenses projected to increase at 3.0% per year.

PROJECT SPACE--FAIR MARKET VALUE

Project Space	10,631	Lease
Building Area	31,165	Developer's Documents
Project % of Building	34.11%	
Bldg and Land Value	\$24,875,000	site cost + site imprlvmt+constr costs+relateds+interim int
Project Space FMV	\$8,485,356	Project Space % X Bldg and Land Cost

Tennessee Oncology White House -- Clinical Equipment Costs			
		Purchase Price	Service Contract
Equipment Item			
Major Equipment	Varian Trubeam Linear Accelerator	\$5,077,031	\$1,118,697
	Siemens CT Simulator	\$773,333	\$372,849
	Subtotal, Linac and Simulator	\$5,850,364	\$1,491,546
	Subtotal With 9.5% Tax	\$6,406,149	\$1,633,243
Minor Equipment		\$300,000	

Source: Tennessee Oncology Vendor Estimates

TENNESSEE ONCOLOGY PLLC ("Customer")

Al Lawson
2004 HAYES ST,STE 800
NASHVILLE Tennessee 37203-2646 United States
Tel : 615-329-0570
Fax : 615-320-7091
Email : alawson@tnonc.com

VMS Inc. Oncology Systems

Brandon Stotts
Director of Sales, Business Development
Work From Home
Atlanta , TN 99999 United States of America
Tel : 6155213493
Email : brandon.stotts@varian.com

*** Confidential - Proposal is intended for Recipient and Recipient's Site Representatives Only ***

Quote Information		
Quotation Number : 2024-448493-1	Quotation Date : February 08, 2024	Quotation Valid Until : June 05, 2024
Customer Requested Delivery Date : February 06, 2024		
Customer Procurement Contact Name : Needed		
Billing Plan	See Quote billing plan Summary on the following pages which is incorporated by reference	

Sales	
Incoterms : DPU Site Insured	Payment Terms : 30 days net
Sales PO Required : Yes	

Quotation Total
Quotation Total : US \$5,077,031.00

purchase

Terms and Conditions

Products and Services: Customer's access to and use of the Products, Support Services and Services (except Software-as-a-Service or Subscription Services) as indicated in this Quotation are subject to and governed by: (a) the Varian Terms and Conditions of Sale (Form RAD 1652) at: https://varian.com/RAD1652v_US_EN_OCT_2023 and (b) any Schedules, Exhibits and/or additional terms (including third party terms) contained, attached, referenced or otherwise indicated in this Quotation. All terms and conditions provided in the website link listed in item (a) above are incorporated by reference and form part of the contract between Varian and Customer.

If there is a separate written agreement (e.g. master agreement) in effect between the parties that expressly provides for and governs the purchase and sale of the specific Products, Support Services, Services, Software-as-a-Service and/or Subscription Service set forth in this Quotation, such written agreement shall govern. Hard copies of the referenced terms and conditions and any additional terms indicated will be provided to Customer upon request.

For and on behalf of Customer

Authorized Representative : Al Lawson
Title :
Date : February 08, 2024

Authorized Representative : Brandon Stotts
Title : Director of Sales, Business Development
Date : February 08, 2024



A Siemens Healthineers Company

Truebeam with ARIA RO & Eclipse Proposal

Quotation Number - 2024-448493-1

This quotation represents the proposed TrueBeam configuration to be referenced in the OneOncology Master Purchase Agreement.

All pricing and configurations contained within quotations supplied to OneOncology by Varian Medical Systems are confidential and only intended for OneOncology. Disclosure or release to others outside of the OneOncology network, either manually or electronically, without the prior written consent of Varian Medical Systems is strictly prohibited.

Pricing is reflective of a multi-system/multiyear OneOncology commitment.

0% down, 95% on shipment, 5% terms assume reasonable quote/order execution to Varian. Expedited shipments or credit review may require down payment.

Removal of existing and installation of new assumes standard rigging expenses. Nonstandard expenses to be quoted separately.

(Looking further)



*** Confidential - Proposal is intended for Recipient and Recipient's Site Representatives Only ***

Attachment 1

Service Price Table

Service Total
Quotation Total

→ US \$1,118,697.00
US \$1,118,697.00

Annually	Year 1	Year 2	Year 3
TrueBeam - Essentials	US\$ 290,619.00	US\$ 294,978.00	US\$ 299,403.00
IDENTIFY System - Essentials	US\$ 42,853.00	US\$ 43,497.00	US\$ 44,150.00
IDENTIFY System - Essentials	US\$ 24,136.00	US\$ 24,498.00	US\$ 24,866.00
RGSC - Essentials	US\$ 9,752.00	US\$ 9,898.00	US\$ 10,047.00
Total	US\$ 367,360.00	US\$ 372,871.00	US\$ 378,466.00

3 Year Point of Sale Service Agreement for Tennessee Oncology

Quotation Number - 2024-449421

This service quote is based off the configuration of the TrueBeam, Identify and RGSC on Capital Quote 2024-448493.

(Looking further)



Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Bradley Fox - +1 (615) 916-0136
brad.fox@siemens-healthineers.com

PRELIMINARY PROPOSAL

Customer Number: 0000342382

Date: 05-02-2024

TENNESSEE ONCOLOGY PLLC
2004 HAYES ST, STE 800
NASHVILLE, TN 37203

Siemens Medical Solutions USA, Inc. is pleased to submit the following quotation for the products and services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions on the face and back hereof, and on any attachment hereto.

<u>Table of Contents</u>	<u>Page</u>
SOMATOM go.Sim (Quote Nr. CPQ-1068778 Rev. 0)	2

Contract Total: 773,333 USD ← *Purchase*
(total does not include any Optional or Alternate components which may be selected)

Proposal valid until 21-03-2024



THIS QUOTATION REPRESENTS A PRELIMINARY PROPOSAL AND DOES NOT CONSTITUTE AN OFFER OR A CONTRACT. A BINDING CONTRACT THAT INCLUDES THE TERMS SET FORTH HEREIN SHALL ONLY BECOME EFFECTIVE UPON EXECUTION BY THE PARTIES OF A COMPLETE AGREEMENT.

DISTRICT / SALES OFFICE

SIEMENS MEDICAL SOLUTIONS USA, INC.

Attn: Brad Graef
 Phone: +1 (202) 860-8436
 Email: brad.graef@siemens-healthineers.com

SOLD TO	BILL TO	PAYER
TENNESSEE ONCOLOGY PLLC 2004 HAYES ST, STE 800, NASHVILLE, TN, 37203	TENNESSEE ONCOLOGY PLLC 2004 HAYES ST, STE 800, NASHVILLE, TN, 37203	TENNESSEE ONCOLOGY PLLC 2004 HAYES ST, STE 800, NASHVILLE, TN, 37203

Siemens Medical Solutions USA, Inc. is pleased to submit the following proposal for the service described herein at the stated prices and terms. Subject to your acceptance of the terms and conditions on the face and general terms and conditions Document hereof.

Item #	System Name	Functional Location	Service Agreement	Contract Duration	Warranty Period Price	Partial Year Price	Annual Price
1	SOMATOM go.Sim	N/A	Advance Plan Premium	Warranty +5 Years	0 USD	0 USD	94,371 USD

Terms of payment: Net 30 days from invoice date. Past due payment is subject to 1.5% interest charge per month

INCLUDES: Parts and/or Labor to the extent shown in Exhibit A. System Updates. Access to Siemens Customer Care Center for technical telephone support (remote diagnostics, if available to the site and the equipment).

EXCLUDES: Parts defective due to "acts of God", abuse, misuse, neglect, thermal and shock. Specialty components, including, but not limited to: Glassware, Flat Detectors, Consumables, Transducers, MRI coils, SPECT and PET sources (unless purchased as an option). Non-Siemens components and accessories (such as VCR, injector, laser printer, MR surface coils, tables/table tops, chiller, UPS, etc.) unless specifically identified in Exhibit A.

Additional Document 1

Miscellaneous Tables

#267, Question 5: 1E Overview, Linac Facilities & Map

#273, Question 11: 2N Service Area Map

#278, Question 16: 3C Effects of Competition

#283, Question 21: 6N Utilization (Text; Treatment Locations & Driving Distances; Patient Origin by Linac Facility)

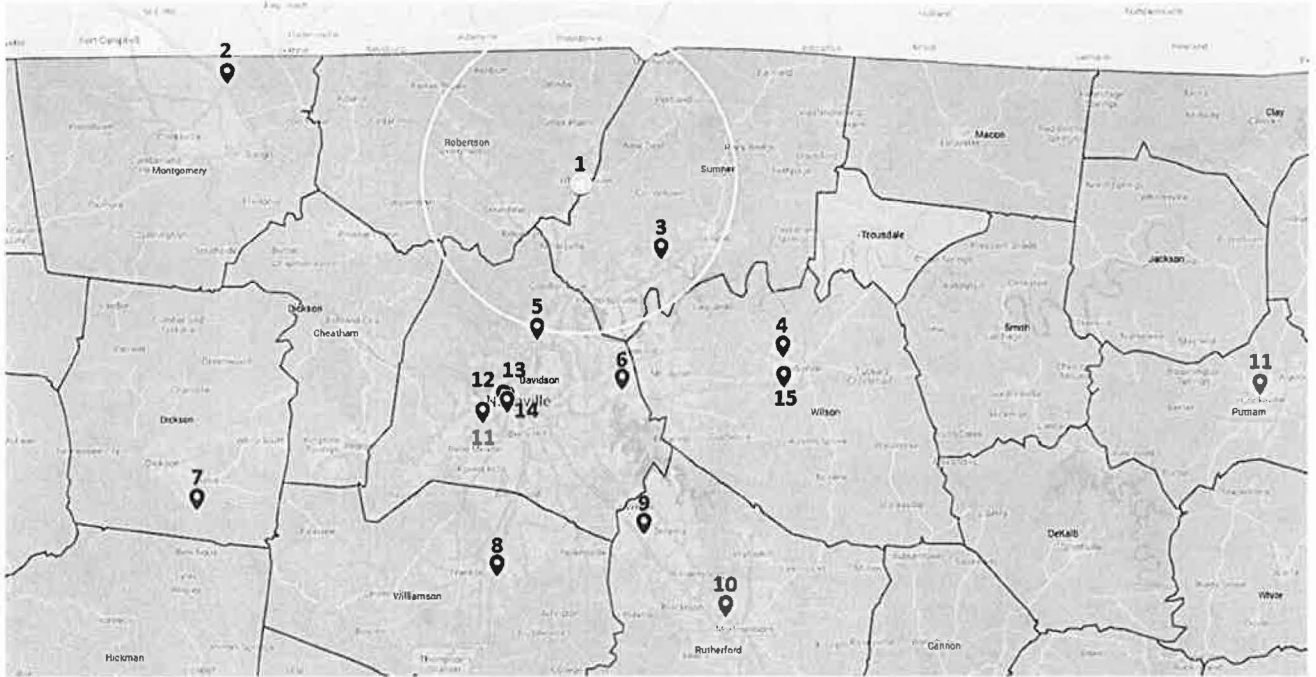
#284, Question 22: 6N Utilization (Referral Locations)

#288, Question 26: 1N MRT Criterion 3 (Linac Units by County; Cancer Cases, etc. by County)

#267

1E.Overview--Map of proposed and existing LINAC units in counties adjacent to Robertson County.

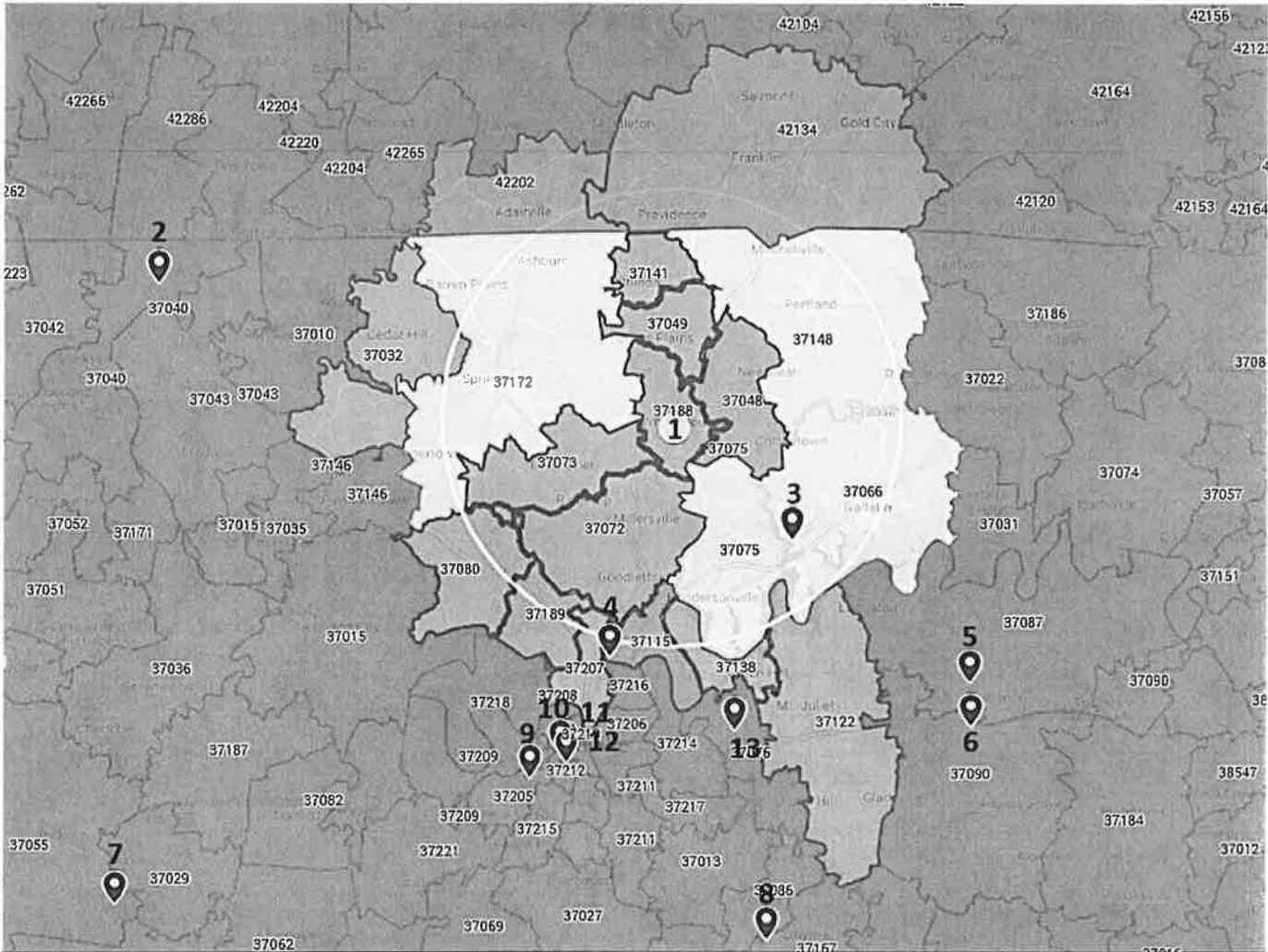
Response:



Number	County	Corresponding Center
1	Robertson	Proposed Tennessee Oncology White House
2	Montgomery	Vanderbilt-Ingram Cancer Center at Tennova Healthcare - Clarksville
3	Sumner	Carpenter Cancer Center
4	Wilson	Vanderbilt Wilson County Hospital
5	Davidson	TriStar Skyline Medical Center
6	Davidson	Sarah Cannon Cancer Institute at TriStar Summit
7	Dickson	TriStar Natchez Imaging Center
8	Williamson	Vanderbilt-Ingram Cancer Center Franklin
9	Rutherford	TriStar StoneCrest Medical Center
10	Rutherford	Ascension Saint Thomas Rutherford
11	Davidson	Ascension Saint Thomas Hospital West
12	Davidson	TriStar Centennial Medical Center
13	Davidson	Ascension Saint Thomas Midtown Hospital - Cancer Center
14	Davidson	Vanderbilt University Medical Center
15	Wilson	*UNDER CONSTRUCTION* Tennessee Oncology Lebanon Radiation Oncology Center

#273

Response 1: Service Area Map and Existing Linear Accelerators



Number	ZIP Code	Is this ZIP Code included in the 19 target ZIP Codes?	County	Corresponding Center
1	37188	Yes	Robertson	Proposed Tennessee Oncology White House
2	37040	No	Montgomery	Vanderbilt-Ingram Cancer Center at Tennova Healthcare - Clarksville
3	37066	Yes	Sumner	Carpenter Cancer Center
4	37207	Yes	Davidson	TriStar Skyline Medical Center
5	37087	No	Wilson	Vanderbilt Wilson County Hospital

6	37090	No	Wilson	*UNDER CONSTRUCTION* Tennessee Oncology Lebanon Radiation Oncology Center
7	37055	No	Dickson	TriStar Natchez Imaging Center
8	37167	No	Rutherford	TriStar StoneCrest Medical Center
9	37205	No	Davidson	Ascension Saint Thomas Hospital West
10	37203	No	Davidson	TriStar Centennial Medical Center
11	37203	No	Davidson	Ascension Saint Thomas Midtown Hospital - Cancer Center
12	37232	No	Davidson	Vanderbilt University Medical Center
13	37076	No	Davidson	Sarah Cannon Cancer Institute at TriStar Summit

Response 2: Total Service Area Population by Zip Code

ZIP Codes	2023	2028
37032 Cedar Hill	4787	4786
37048 Cottontown	6786	6802
37049 Cross Plains	3986	4073
37066 Gallatin	66591	73247
37072 Goodlettsville	33553	33468
37073 Greenbrier	15075	15077
37075 Hendersonville	74478	77521
37080 Joelton	7418	7349
37115 Madison	41190	42593
37122 Mount Juliet	67809	73409
37138 Old Hickory	25081	25100
37141 Orlinda	1033	1019
37148 Portland	26106	26598
37172 Springfield	32333	32930

37188 White House	18631	20229
37189 Whites Creek	3165	3302
37207 Nashville	41689	45809
42134 Franklin	19605	20145
42202 Adairville	2156	2153
Grand Total	491472	515610

Response 3: Based on Google Maps Driving Distances, the proposed White House facility will be the closest megavoltage radiation therapy (“MRT”) location for patients in the following ZIP Codes: 37049, 37073, 37141, 37188, 37148, 37172, 42134, and 42202.

Sites Referred To:		Proposed White House location	Carpenter Cancer Center Gallatin, TN	TriStar Skyline Medial Center Nashville, TN	Ascension Saint Thomas Hospital Midtown Nashville, TN	TriStar Centennial Medical Center Nashville, TN	Ascension Saint Thomas Hospital West Nashville, TN	TriStar Summit Medical Center Hermitage, TN	Tristar StoneCrest Medical Center Smyrna, TN
ZIP Code	White House Location's Proximity Ranking	Shortest Driving Distance (in miles)	Shortest Driving Distance (in miles)	Shortest Driving Distance (in miles)	Shortest Driving Distance (in miles)	Shortest Driving Distance (in miles)	Shortest Driving Distance (in miles)	Shortest Driving Distance (in miles)	Shortest Driving Distance (in miles)
37048	2nd Closest Facility	10.1	8.9	27.4	31	34.2	37.5	38.3	45.3
37049	Closest Facility	7.2	19.9	19	34.1	34.6	36.9	32.9	50.7
37072	2nd Closest Facility	12.2	13.2	6.8	14.9	15.4	17.3	13.7	31.5
37073	Closest Facility	10.4	18.3	16.1	24.6	25	26.5	23	41.2
37141	Closest Facility	13.9	26.5	34.3	40.8	41.3	43.6	39.6	57.4
37188	Closest Facility	2.7	16.9	21.4	27.8	28.3	30.4	26.8	44.5
37066	2nd Closest Facility	17.2	6.1	24	30.6	31.1	33.5	26.6	38.4
37075	2nd Closest Facility	14.5	6.1	14.5	21	21.4	24.4	19.5	37.6
37148	Closest Facility	15.4	19.1	34	45.8	41.1	49	39.4	54.2

37172	Closest Facility	13.1	27.3	23.6	29.4	27.8	32.6	38.1	46
37122	8th Closest Facility	33.8	13.2	25.4	22.6	23.7	26.6	8.9	21.6
37207	7th Closest Facility	20.1	18.7	1.8	6.7	9.4	12.1	15.3	25.4
37115	7th Closest Facility	15.9	14.3	4.3	11.6	12.1	15.2	11.2	28.3
37138	7th Closest Facility	22.2	20.6	11.6	15.9	17.6	19.8	4.2	22.4
37080	6th Closest Facility	22.5	30.3	15.4	16.1	16.6	20.3	26.6	37.8
37032	2nd Closest Facility	22	38.7	29.6	33.1	33.4	20.3	43.8	51.4
37189	7th Closest Facility	22.9	22.7	8	10.7	11	15.7	21.2	30.5
42134	Closest Facility	20.4	30.4	37.6	45.4	45.9	48.6	44.2	61.8
42202	Closest Facility	24	35.6	36.6	40	40.4	43.2	50.8	58.4

#278

3C. Effects of Competition and/or Duplication (2 Questions)

Response 1: The linear accelerator selected for White House is a Varian Truebeam, which is considered a hybrid linear accelerator, capable of 3D, IMRT, SRS, and SBRT treatment delivery. According to the most recent state equipment registry, 7 of the 8 centers located in Sumner, Davidson, and Wilson counties operate a Varian Truebeam unit. Machine capacity is comparable across all those locations.

TN HFC Registered Medical Equipment: Linear Accelerator Listings (As of 11/1/2023)					
County	Provider	Linac Data			
		Brand Name	MEV	Type	Photon/ Electron
Robertson	<i>*Proposed White House Location*</i>	<i>Varian Truebeam</i>	<i>6, 10, 6FFF, 6E, 9E, 12E, 16E, 18E</i>	<i>ERBT, IMRT, IGRT SRS, SBRT, RapidArc</i>	<i>Photon, Electron</i>
Davidson	St. Thomas Midtown Hospital	Halcyon	6	IMRT	Photon
Davidson	St. Thomas Midtown Hospital	Varian Truebeam	4, 6, 9, 10, 12, 15, 18	SRS, SBRT, IMRT, IGRT	Photon, Electron
Davidson	St. Thomas West Hospital	Varian Novalis Truebeam STx	4x, 6x, 10x, 15x, 6EEE, 10EEE, 6, 9, 12, 15, 18c	IMRT, SRS, SRT	Photon, Electron
Davidson	St. Thomas West Hospital	Varian Truebeam	6X, 6XFFF, 10X, 15X, 6E, 9E, 12E, 15E, 18E	IMRT, Conventional	Photon, Electron
Davidson	TriStar Centennial Medical Center	Varian Truebeam	6, 9, 12, 16, 20	VMAT; IMRT	Photon, Electron
Davidson	TriStar Centennial Medical Center	Varian Truebeam	6, 9, 12, 16, 20	VMAT; IMRT	Photon, Electron
Davidson	TriStar Skyline Medical Center	Varian Truebeam	6, 10, 18, 6FFF, 10FFF	IMRT, ERBT, SRS, SBRT, RapidArc	Photon, Electron
Davidson	TriStar Summit Medical Center - ODC	Varian Truebeam	10, 23	SRS, IMRT	Photon, Electron
Davidson	Vanderbilt University Medical Center	Varian Ethos	5	IMRT/Adaptive Radiotherapy	Photon
Davidson	Vanderbilt University Medical Center	Varian Novalis TX	6x		Photon
Davidson	Vanderbilt University Medical Center	Varian Truebeam		IMRT, IGRT	Photon, Electron
Davidson	Vanderbilt University Medical Center	Varian Truebeam			
Sumner	Carpenter Cancer Center	Varian Truebeam			
Wilson	Vanderbilt Wilson County Hospital	Varian Ethos	6	IMRT, IGRT, Adaptive	

Response 2: All prospective White House facility patients will benefit from the features available on the selected Truebeam unit. The unit will be equipped with Varian's IDENTIFY system, a surface-guided patient position monitoring system for radiotherapy with automatic beam hold functionality. If a patient shifts unexpectedly, the beam of radiation will turn off, eliminating the risk of radiating tissue outside the intended treatment target. The IDENTIFY positioning system will be used on every patient, improving treatment accuracy and promoting patient safety. The machine's technology also includes gated conebeam CT (CBCT) scanning, which provides the ability to acquire images synchronized with patient respiration. This unit will also have iterative CBCT imaging that improves the detectability of stationary soft tissue anatomy.

While other nearby linear accelerator facilities also utilize Truebeam units, it is not clear from the state equipment registry whether these machines are equipped with the same upgraded features.

1. 6N. Utilization and/or Occupancy Statistics

Response: In 2023, patients from the above ZIP Codes were referred to the following Tennessee Oncology radiotherapy facilities supervised by Tennessee Oncology radiation oncologists:

- Ascension Saint Thomas Midtown. Nashville, TN
- TriStar Centennial Medical Center. Nashville, TN
- Carpenter Cancer Center. Gallatin, TN
- Memorial Hospital. Chattanooga, TN
- Ascension Saint Thomas Rutherford. Murfreesboro, TN
- Tennessee Oncology Proton Center. Franklin, TN
- TriStar Skyline Medical Center. Nashville, TN
- TriStar StoneCrest Medical Center. Smyrna, TN
- Ascension Saint Thomas West. Nashville, TN
- TriStar Summit Medical Center. Hermitage, TN

Using Google Maps Driving Directions, the applicant determined the shortest driving distance (in miles) from the geographical center of each ZIP Code to each of the facilities above where Tennessee Oncology patients currently receive treatment. Then, the applicant calculated the percentage of patients from these ZIP codes that would save mileage by receiving treatment at the proposed White House facility. These percentages were as follows: 26.3% of patients from 37066; 43.5% of patients from 37072; 26.38% of patients from 37075; 7.4% of patients from 37122; 7.5% of patients from 37207; 12.1% of patients from 37115; 8.3% of patients from 37138; and 3.7% of patients from 37080. The results of these drive-time analyses are summarized in detail in the table below.

While the percentages may be small in some ZIP Codes, shorter driving distances can significantly impact a patient's willingness to seek treatment at a certain location. Thus, it is reasonable to conclude that patients in closer proximity to the proposed project may choose to pursue treatment in White House. Proximity to treatment, however, is only one factor contributing to a patient's decision to seek care at a specific facility. A patient's existing provider relationships, the location of a patient's job, and commute times, among other factors, impact patient choice. For example, some patients may want to avoid highway travel, driving through downtown Nashville traffic, or dealing with limited or difficult parking. While some patients in Minimal Patient Shift ZIP Codes may not save mileage by traveling to White House, they can save valuable time and reduce the burden of various treatment logistics. Patients from 37115 and 37138 would experience shorter commutes on average, while patients from 37122, 37207, and 37080 would experience commute times similar to what they experience seeking care at other facilities.

To determine commute times, Google Maps Driving Directions were utilized. Travel time was calculated by setting a 9:00am departure from the geographical center of the ZIP Code to each facility that received Tennessee Oncology referrals. The shortest and longest drivetimes were averaged to determine a general one-way commute time. The departure time of 9:00am was used for every search because it is near the end of morning rush hour and traffic is mild.

Tennessee Oncology Patient Treatment Locations and Driving Distances

Key for Column Headings:

% = Percentage of total Tennessee Oncology patients from that ZIP Code treated at relevant facility (calculated using Tennessee Oncology referral data from January 2023 to December 2023).

Distance = Using Google Maps Driving Directions, shortest one-way driving distance from the geographical center of the ZIP Code to that facility (miles). **Time** = Average one-way drive time from the geographical center of the ZIP Code, departing at 9:00am, to the relevant facility (minutes).

Facility	Moderate Shift ZIP Codes						Minimal Shift ZIP Codes														
	37066		37072		37075		37122			37207			37115			37138			37080		
	%	Distance	%	Distance	%	Distance	%	Distance	Time	%	Distance	Time	%	Distance	Time	%	Distance	Time	%	Distance	Time
Proposed White House Location	x	18	x	10.1	x	14.6	x	33.8	55.0	x	20.1	30.0	x	15.1	23	x	21.9	33	x	22.7	37.5
Ascension Saint Thomas Midtown Nashville, TN	5.4%	30.6	20.0%	14.9	5.7%	21	6.3%	22.6	40.0	26.9%	6.7	25.0	18.2%	11.6	32.5	5.6%	15.9	38	22.2%	16.1	34.5
TriStar Centennial Medical Center Nashville, TN	5.9%	31.1	5.9%	15.4	6.4%	21.4	7.4%	23.7	40.0	14.9%	9.4	27.0	10.6%	12.1	32.5	2.8%	17.6	41.5	7.4%	16.6	37
Carpenter Cancer Center Gallatin, TN	73.7%	6.1	8.2%	13.2	47.8%	6.1	N/A			3.0%	18.7	23.0	3.0%	14.3	21	1.4%	20.6	33	3.7%	30.3	42.5
Memorial Hospital Chattanooga, TN	N/A		N/A		2.5%	155	N/A			N/A			N/A			N/A			N/A		
Ascension Saint Thomas Rutherford Murfreesboro, TN	1.1%	41.5	N/A		N/A		0.6%	29.6	47.5	N/A			N/A			N/A			N/A		
Tennessee Oncology Proton Center Franklin, TN	3.8%	48.2	4.7%	32.1	8.3%	38.6	7.4%	36.4	50.0	7.5%	26.5	41.5	6.1%	29.9	47.5	8.3%	30.6	47.5	N/A		
TriStar Skyline Medical Center Nashville, TN	8.1%	24	56.5%	6.8	25.5%	14.5	2.3%	25.4	44.0	37.3%	1.8	10.0	53.0%	4.3	12.5	9.7%	11.6	26.5	55.6%	15.4	22
TriStar StoneCrest Medical Center Smyrna, TN	N/A		N/A		N/A		3.4%	21.6	45.0	N/A			N/A			N/A			N/A		
Ascension Saint Thomas West Nashville, TN	1.6%	33.5	3.5%	17.3	3.2%	24.4	4.6%	26.6	45.0	10.4%	12.1	25.5	6.1%	15.2	34.5	1.4%	19.8	41.5	11.1%	18.8	38
TriStar Summit Medical Center Hermitage, TN	0.5%	26.6	1.2%	13.7	0.6%	19.5	68.0%	8.9	19.0	N/A			3.0%	11.2	26.5	70.8%	4.2	12.5	N/A		
% patients saving mileage driving to proposed White House Location	26.3%		43.5%		26.8%		7.4%			7.5%			12.1%			8.3%			3.7%		
Average Drive Time to Other Facilities							41.3			25.3			29.6			34.4			34.8		
Average Drive Time White House Location							55			30			23			33			37.5		

#288

Attachment 1N, MRT Criterion #3:

The project’s primary service area consists of 19 ZIP Codes, stretching across 4 contiguous counties: Robertson, Davidson, Sumner, and Wilson. Currently, because there is no linear accelerator in Robertson County, 100% of patients requiring radiation therapy must travel outside their home county for treatment. Some 69% of patients in Wilson County are also seeking care outside their home county.

State Data: Number of Procedures/Treatments by Patient Destination - 2022 (As of 11/1/2023)						
2022 Linear Accelerator Procedures						
Patient's Home County	# of Registered Linear Accelerators in County	RT Procedures Completed by Providers <u>WITHIN</u> Resident's County	RT Procedures Completed by Providers <u>OUTSIDE</u> Resident's County	Total Procedures	Percent of Service Provided <u>WITHIN</u> County	Percent of Service Provided <u>OUTSIDE</u> County
Davidson	12	30275	1901	32176	94.1%	5.9%
Robertson	0	0	3751	3751	0.0%	100.0%
Sumner	1	5208	3558	8766	59.4%	40.6%
Wilson	1* (*LROC unit pending)	2656	5883	8539	31.1%	68.9%

Radiation Therapy Treatments Needed for New Cancer Patients in the Primary Service Area in 2028					
PSA County	2028 Population (in 100,000s) - 4 Years from Current Year	New Cancer Rate/100K Population (CDC Age Adjusted)	Projected New Cancer Patients/Year	Patients Needing Radiation Therapy Treatments (60%)	RT Treatments Needed at 17/Patient
Davidson	7.70119	434.1	3343.1	2005.9	34099.5
Robertson	0.78642	477.0	375.1	225.1	3826.2
Sumner	2.13896	464.6	993.8	596.3	10136.4
Wilson	1.62237	445.8	723.3	434.0	7377.2
Total PSA (Rounded)			5,435	3,261	55,439
Data Source:	Tennessee State Data Center, Population Projections 2016-2030	National Cancer Institute, State Cancer Profiles			

Additional Document 2
Applicant's Commitment of Resources

April 3, 2024

Mr. Phillip Earhart, Director of CON
Tennessee Health Facilities Commission
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re: Tennessee Oncology White House, LLC ("Applicant")
Linear Accelerator Certificate of Need Application

Dear Mr. Earhart,

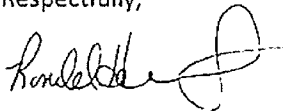
Tennessee Oncology White House, LLC ("Applicant") which is wholly owned by Tennessee Oncology, PLLC, is applying for a Certificate of Need to provide megavoltage radiation therapy services to the practice's patients, through initiating linear accelerator services at the premises located at an unaddressed site on North Sage Road, adjacent to 506 Hester Drive in the City of White House, in Robertson County.

Tennessee Oncology White House, LLC and its owner, Tennessee Oncology, PLLC, have the ability to effectively develop this service and operate it as a premier radiation center. We are committed to providing the best patient care and have the financial means and administrative resources to develop and maintain the facility resources, equipment and staffing cost to provide the appropriate services to our patients, as described more fully in our application.

As the Chief Executive Officer, please find this letter as confirmation that Tennessee Oncology has the financial means to maintain the resources necessary to support our patients and has the ability to sustain them for the long term, as we have done for our patients for many years.

If you should have any questions, please do not hesitate to contact me.

Respectfully,



Ronald Horowitz
Chief Executive Officer

Additional Document 3
FDA Approval Letters for Varian TruBeam



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

December 20, 2012

Ms. Vy Tran
Vice President, Regulatory Affairs and Quality Assurance
Varian Medical Systems, Inc.
3100 Hansen Way, m/s C-255
PALO ALTO, CA 94304-1038

Re: K123291

Trade/Device Name: TrueBeam Radiotherapy Treatment System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 19, 2012
Received: October 22, 2012

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Ms. Vy Tran

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

TrueBeam Radiotherapy Treatment System

Indications for Use

510(k) Number (if known): K123291

Device Name: TrueBeam Radiotherapy Treatment System

Indications for Use:

TrueBeam is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

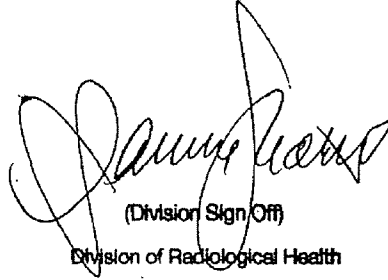
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123291

Page 1 of 1

K123291⁴⁹

DEC 20 2012

Premarket Notification [510(k)] Summary TrueBeam Radiotherapy Treatment System

The following information is provided following the format of 21 CFR 807.92.

Submitter's Name: Varian Medical Systems, Inc.
3100 Hansen Way E-110
Palo Alto, CA 94304

Contact Name: Vy Tran
Phone: 650.424.5731
Fax: 650.842.5040
Date: October 2012

Proprietary Name: TrueBeam™

Classification Name: Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: 90 IYE

Common/Usual Name: TrueBeam Radiotherapy Delivery System

Predicate Device: TrueBeam Radiotherapy System and Accessories: K111106

Device Description: The TrueBeam™ Radiotherapy Delivery System is a medical linear accelerator that integrates the previously cleared Trilogy Radiotherapy system and associated accessories into a single device.

The system consists of two major components, a photon, electron, and diagnostic kV X-ray radiation beam-producing component that is installed in a radiation-shielded vault and a control console area located outside the treatment room.

Intended Use Statement The TrueBeam™ system is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Indications for Use Statement The TrueBeam™ system is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Technological Characteristics: Significant changes to the predicate device are listed below.

Feature	Cleared device	Device with change
Energy used	4-25MV	2.5, 4-25MV
6 rotational Couch	No	Yes
2D/3D Matching	No	Yes
4D CBCT	No	Yes
Multi-scan CBCT Acquisition	No	Yes
Motion Management Interface (MMI)	No	Yes

Summary of performance testing: Results of verification and validation testing showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly.

Additional Document 4
International Journal of
Radiation Oncology, Biology, Physics

CLINICAL INVESTIGATION

Breast

BREAST CONSERVATION RATES—BARRIERS BETWEEN TERTIARY CARE AND COMMUNITY PRACTICE

CAROL A. HAHN, M.D.,* LAWRENCE B. MARKS, M.D.,* DAVID Y. CHEN,* PEHR A. LIND, M.D.,*[†]
HEIDI M. LIND, M.D.,* AND LEONARD R. PROSNITZ, M.D.*

*Duke University Medical Center, Durham, NC; [†]Karolinska Institute, Huddinge University Hospital, Stockholm, Sweden

Purpose: Low rates of breast conservation therapy (BCT) are reported in the southern United States. We evaluated the influence on BCT rates of opening a radiotherapy (RT) clinic at a community hospital in North Carolina. Before opening, RT was available 5 miles away at a tertiary care center.

Methods and Materials: A review of the pathology database of the community hospital identified patients who underwent definitive surgery for invasive breast malignancy or ductal carcinoma *in situ* between 1994 and 1995, and 1997 and 1998, before and after the opening of the RT clinic in 1996. From these data, the mode of therapy, mastectomy or BCT, was determined. The results were compared using logistic regression analysis. Surgical and RT physician staffing were unchanged throughout the study period.

Results: A total of 586 patients was evaluated. The BCT rate at the community hospital for 1994–1995 and 1997–1998 was 29% and 44%, respectively. On both univariate and multivariate logistic regression analysis, the era of treatment was statistically significant in its impact on the procedure performed ($p < 0.001$).

Conclusion: The use of BCT increased at a community hospital after the opening of an on-site RT facility, even though RT was available 5 miles away previously. © 2003 Elsevier Science Inc.

Breast cancer, Radiotherapy, Breast conservation therapy.

INTRODUCTION

Multiple randomized studies have demonstrated that modified radical mastectomy and breast-conserving therapy (BCT) provide equivalent overall survival rates in patients with early-stage breast cancer (1–9). Approximately 85% of patients receiving BCT have a good to excellent cosmetic result (8, 10–13), and studies examining the impact of treatment on quality of life have revealed that BCT provides better preservation of body image with less chance of sexual dysfunction (14–16). Thus, BCT is the National Cancer Institute's recommended standard of care for patients who are candidates for the procedure. Morrow *et al.* (17) estimated that 75% of early-stage breast tumors can be appropriately managed with BCT, with the balance having, for example, multicentric disease or incomplete histologic margins. Other patients may not be acceptable candidates for BCT because of pregnancy, diffuse indeterminate or malignant-appearing microcalcifications on mammography, large tumor/breast ratio, or collagen vascular disease (18).

Because of the excellent cosmetic and survival outcomes achieved with BCT, one would expect BCT to be used more

frequently than modified radical mastectomy. However, BCT is used less frequently than modified radical mastectomy. Furthermore, BCT rates vary dramatically by geography, by travel distance to radiotherapy (RT) facilities, between surgeons, and between tertiary vs. nontertiary care settings (19–24). Morrow *et al.* (25) reported that the BCT rates in the U.S. Northeast and Pacific regions are approximately 50% vs. 32% in the South (25). Kotwall *et al.* (22) estimated a BCT rate of 10–28% in North Carolina.

This study assessed the influence of an on-site RT facility and radiation oncology staffing on the rate of BCT at a community hospital in Durham, North Carolina, located 5 miles from Duke University Medical Center, a tertiary care referral center. Before 1996, RT was provided for the community hospital patients at Duke. In 1996, a center was opened at the community hospital staffed by the same Duke radiation oncologists. Aside from the opening of the on-site practice, no known changes occurred in surgical staffing or the demographics of patients between 1994 and 1998. Neither was a breast clinic or a breast tumor board established during this period. The BCT rates at this hospital before and after opening the RT facility were compared.

Reprint requests to: Carol A. Hahn, M.D., Department of Radiation Oncology, Duke University Medical Center, Box 3085, Durham, NC 27710. Tel: 919 668 7336; Fax: 919 668 7345; E-mail: hahn@radonc.duke.edu

Presented at the 43rd Annual Meeting of the American Society

for Therapeutic Radiology and Oncology, November 2001, San Francisco, CA.

Received May 31, 2002, and in revised form Oct 30, 2002. Accepted for publication Nov 4, 2002.

METHODS AND MATERIALS

Patients with breast cancer were identified from the community hospital department of pathology database. The report of all breast specimens signed out from the years 1994–1995 and 1997–1998 were retrospectively reviewed. Information beyond 1998 was not included because of changes in the pathology computer system that prohibited extraction of comparable data beyond 1998. From these reports, cases of invasive breast cancer and ductal carcinoma *in situ* (DCIS) were identified. Each was reviewed to determine whether the patient was definitively surgically treated at the community hospital, and, if so, whether the surgery was mastectomy or BCT. For consistency, specimens were considered a mastectomy if the surgical resection contained a nipple areolar complex and was not otherwise specified as a breast-conserving procedure.

Correlation was attempted with patient RT records, but, because of missing data, particularly from the earlier period, was not possible. Before the on-site clinic, although Duke was the closest site providing RT, patients may have been referred to other, more distant, RT facilities or not have been referred at all. Because these referrals were not formally tracked, or perhaps provided, by the community hospital, no comparative data on RT rates between the periods could be extracted. The analysis, therefore, was restricted to the pathologic information that was consistently available between the two periods.

A review of the database and pathology reports revealed the patient's age, but not race. Tumor size information was variably reported in the older pathology reports and, because it was not uniformly available for the entire group, was not considered. Most cases, however, were Stage 0, I, or II (Tis, T1, or T2).

Univariate and multivariate logistic regression analysis was performed using the Statistical Package for Social Sciences software to assess the impact of patient age, era of treatment, and DCIS vs. invasive cancer on the BCT rate.

RESULTS

A total of 677 reports diagnostic of breast malignancy were identified. Of these, 91 patients appeared to have undergone only a diagnostic biopsy at the community hospital, with definitive therapy performed elsewhere. A total of 586 patients had initial and definitive surgical therapy performed at the community hospital and formed the basis of our analysis.

Between 1994 and 1995, before on-site RT was available, 282 breast cancers were diagnosed and treated at the community hospital. Mastectomy was performed on 201 patients (71.3%), and BCT was performed on 81 (28.7%). Between 1997 and 1998, after on-site RT was available, 304 breast cancers were diagnosed and treated at the community hospital; 171 had mastectomy (56.3%) and 133 BCT (43.7%). On both univariate and multivariate logistic regression analyses, the treatment era (1994–1995 vs. 1997–

Table 1. Treatment by era*

Treatment	1994–1995 (n = 282)	1997–1998 (n = 304)
MRM (%)	71.3	56.3
BCT (%)	28.7	43.7

Abbreviations: MRM = modified radical mastectomy; BCT = breast-conserving therapy.

* *p* value <0.001 according to univariate and multivariate logistic regression analyses.

1998) was significant for its impact on the procedure performed ($p < 0.001$; Table 1). The vast majority of this difference was seen for patients who underwent BCT with invasive cancer, rather than DCIS (Table 2).

The BCT rates in 1994 and 1995 were essentially the same, as were the rates in 1997 and 1998 (Fig. 1). The differences, therefore, between the two study periods were due to an abrupt change in 1996, rather than a gradually increased use.

On multivariate analysis, DCIS (vs. invasive cancer) had a significant impact on the breast procedure performed ($p = 0.03$). Patients with DCIS were more likely to undergo BCT than those with invasive cancer during both intervals.

The mean patient age for 1994–1995 and 1997–1998 was 59.2 years and 60.7 years, respectively. The difference in age for patients treated with mastectomy or BCT was not statistically significant ($p = 0.7$).

DISCUSSION

We have demonstrated increased use of BCT in a community hospital in North Carolina after the opening of a RT center on site. The change in the BCT rate after the opening of the on-site facility may have been due to several factors.

The first factor is distance. Studies have suggested that travel distances on the order of 75 miles do have a dramatic impact on the use of BCT and breast RT (19). However, none to our knowledge have demonstrated any impact with the short distance in our study. Why, then, did there seem to be such an effect?

The second factor is the use of a different facility vs. on-site consultation. It seems probable that the need to travel for care (26), in this case to a different facility, was an important factor. During this same period, the BCT rate at

Table 2. BCT rates by histologic type

Period	Invasive cancer (%)	DCIS (%)
1994–1995	21.7	42.9
1997–1998	44.1	46.8
<i>p</i> *	<0.001	0.7

Abbreviations: BCT = breast-conserving therapy; DCIS = ductal carcinoma *in situ*.

* Univariate logistic regression analysis.

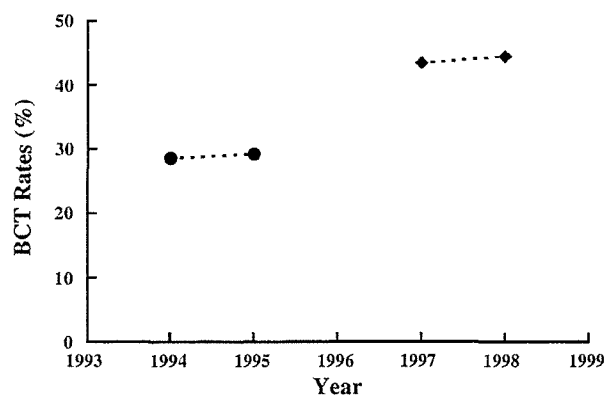


Fig. 1. Plot of BCT rates by year at the community hospital.

Duke University Medical Center, at which all breast cancer care could be delivered at one site, was approximately 45%. No statistically significant difference was found in the BCT rates at Duke for invasive cancer or DCIS between the 1994–1995 and 1997–1998 periods (data not shown).

The associated anxiety of moving to a different facility, as well as a lack of accurate and complete information about RT, was also probably important. Being able to receive care in a familiar environment, particularly during a time of great stress, is a dominant factor. As Nugent (27) pointed out, location and habit determine to a large extent where patients seek medical care. Thus, if BCT is available at a site at which patients comfortably receive their care, it will be used. Having RT physicians on-site to discuss the details of RT, again in a relatively familiar environment, likely reduces anxiety and increases patients' willingness to consider treatment options.

A third factor is the accessibility of tertiary care centers. Although the radiation oncology physicians at Duke believe they were providing courteous and timely care to patients referred from the community hospital, this clearly is not always the case. Duke, like many large medical centers, often can present logistical barriers to patient care. Incoming phone calls might be routed through complex voice mail systems. Parking is often somewhat distant from the clinic and can be expensive. Patients often wait to see their doctors longer at tertiary care hospitals than in community settings (28). There is a perception that tertiary care centers "steal" patients from community hospitals. These factors, probably all in concert, play a part in community care physicians recommending treatment to their patients that does not require referral to another institution. Langley *et al.* (29) pointed to the access of facilities and relations between consultants as influencing referral decisions. It is more likely that physicians will refer patients to other physicians they know personally. By moving to the community hospitals, radiation oncology physicians became that much more familiar to patients and community hospital physicians alike.

It is interesting that patients with DCIS were undergoing BCT more frequently than were patients with invasive can-

cer in the era before on-site RT was available. Correlation was not undertaken with RT records, but we suspect that many patients with DCIS were receiving BCT without RT. The addition of postlumpectomy RT was widely accepted as an important component of BCT in patients with invasive cancer throughout the 1990s. The role of postlumpectomy RT for patients with DCIS, despite data supporting it from two randomized prospective trials, continues to be questioned by some (30). The use of BCT in the DCIS subset in 1994–1995 demonstrates that the surgeons were technically familiar with BCT surgical procedures at that time. Therefore, the relatively low rate of BCT in the patients with invasive disease in 1994–1995 (vs. DCIS) suggests that the referral for breast RT at the tertiary care institution was a hindrance to BCT. This is further substantiated by the increase in the use of BCT for invasive cancer after the on-site RT facility was opened.

There were, of course, limitations to this retrospective study. Tumor size may have had an impact on decisions regarding patient surgical treatment. With no information on patient race, we may not be accounting for differences due to ethnicity. Minor changes in physician staffing of which we were unaware or the influence of nonphysician medical professionals may have contributed to the differences we observed in BCT rates.

The "Certificate of Need" legislation in North Carolina permits accelerator installation on the basis of geographic catchment areas. Our data suggest that the situation may be more complex. The proximity of the unit (5 miles distant) by no means ensures access. This may indicate that perhaps all breast cancer patients are best served by treatment in tertiary care facilities to ensure equitable consideration of all care options or that RT facilities should be more liberally distributed throughout the catchment area. The former is not practical, because travel distance is a factor for extended treatment courses and insurance coverage often provides for care only at certain facilities but not others. What is the solution? Better systems to integrate the community hospital centers with the tertiary care centers in a user-friendly way would be a good starting point.

What are the implications of this study for the future? Tertiary care facilities should work to improve their systems so as to be more accessible to physicians in the community and facilitate referrals of appropriate patients when the tertiary service in question is not available at the community hospital. On the other hand, the need for a particular service at a community hospital should be evaluated with the thought that the demand for such a service may increase if it is more readily accessible. Finally, community physicians should increase their efforts as well to ensure that the care of their patients is not compromised by the logistic difficulties of dealing with a tertiary care medical center.

Future studies, as well future legislation, should consider the influence of localization of RT treatment facilities, whether access is equal, and factors that prevent patients from seeking care at tertiary care centers to ensure that care is not separate and unequal.

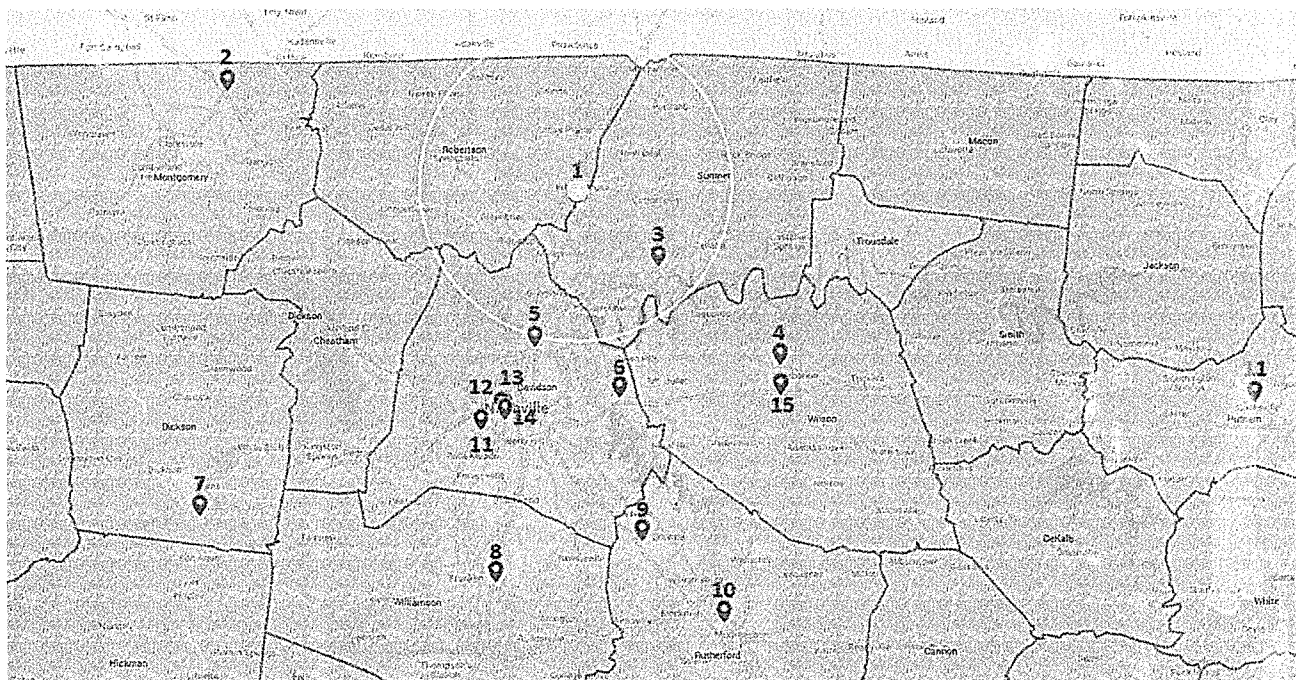
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Additional Document 5
Location of Linacs

1E.Overview--Map of proposed and existing LINAC units in counties adjacent to Robertson County.

Response:



Number	County	Corresponding Center
1	Robertson	Proposed Tennessee Oncology White House
2	Montgomery	Vanderbilt-Ingram Cancer Center at Tennova Healthcare - Clarksville
3	Sumner	Carpenter Cancer Center
4	Wilson	Vanderbilt Wilson County Hospital
5	Davidson	TriStar Skyline Medical Center
6	Davidson	Sarah Cannon Cancer Institute at TriStar Summit
7	Dickson	TriStar Natchez Imaging Center
8	Williamson	Vanderbilt-Ingram Cancer Center Franklin
9	Rutherford	TriStar StoneCrest Medical Center
10	Rutherford	Ascension Saint Thomas Rutherford
11	Davidson	Ascension Saint Thomas Hospital West
12	Davidson	TriStar Centennial Medical Center
13	Davidson	Ascension Saint Thomas Midtown Hospital - Cancer Center
14	Davidson	Vanderbilt University Medical Center
15	Wilson	*UNDER CONSTRUCTION* Tennessee Oncology Lebanon Radiation Oncology Center

Project Name : Tennessee Oncology White House

Supplemental Round Name : 1

Certificate No. : CN2403-006

Due Date : 4/10/2024

Submitted Date : 4/1/2024

1. 4A. Purpose of Review

Please select Initiation of Health Care Service as Defined in §TCA 68-11-1607(3) and initiation of megavoltage radiation therapy in response to Item 4A.

Response : Please see the change in the portal. Consistent with TCA § 68-11-1607(3)(F), the applicant indicates the initiation of linear accelerator services to provide megavoltage radiation therapy.

2. 3Q. Accreditation/Certification/Licensure Plans

Please confirm which accrediting body(s) the applicant intends to pursue accreditation through, the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO), National Cancer Institute (NCI), or a similar accrediting authority in response the table for Item 3.Q.

Response : Tennessee Oncology White House will pursue APEx Accreditation through the American Society for Radiation Oncology (ASTRO) or Radiation Oncology Practice Accreditation through the American College of Radiology (ACR), based on the preference of our physician leaders.

3. 12A. Plot Plan

Please include a wider view of the plot plan identifying nearby roadways and interstates. Please resubmit Attachment 12A. (labeled as Attachment 12AR.)

Response : The plot plan map showing a wider area is provided in supplemental Attachment 12AR.

4. 1E. Overview

Please complete and attach a copy of the HFC Medical Equipment Form with the application. The form can be located at the following link:

https://www.tn.gov/content/dam/tn/hfc/documents/HFC_CON_Attachment-MedEquip.pdf

Response : The form is attached in supplemental Attachment Equipment Round 1. The attachment contains the HFC Medical Equipment Form, vendor quotations on the purchase and service of the linear accelerator and simulator, a table listing the project's major clinical equipment costs, and a table comparing the fair market value of the facility to the lease outlay for the facility.

5. 1E. Overview

Please include a map of the proposed LINAC unit as well as the other LINAC units in adjacent counties to Robertson County.

Response : The requested map is included in supplemental Additional Document 5.

6. 1E. Overview

Regarding the Service Area statement on page 6 of the application that "This area north of Nashville annually refers more to Tennessee Oncology more than 1,000 patients", please clarify whether the 1,000 patients include the entirety of the residents of the 19 ZIP Codes in Robertson, Sumner, Davidson and Wilson Counties or only the population of patients who reside within the 15-mile radius from the proposed site?

Response : In 2023, 1,053 Tennessee Oncology patients came from the 19 ZIP Codes surrounding the proposed White House location. This total reflects the entirety of patients coming from each of the 19 ZIP Codes, not just patient populations who reside within a 15-mile radius of the proposed location.

7. 1E. Overview

Does TN Oncology have any ownership or management affiliation with the Carpenter Cancer Center in Gallatin or any other LINAC units in Robertson, Sumner, Davidson or Wilson County?

Response : Tennessee Oncology has no ownership or management affiliation with Carpenter Cancer Center or any other operating linear accelerator provider in those counties. Tennessee Oncology PLLC wholly owns Lebanon Radiation Oncology Center LLC, which wholly owns the Lebanon Radiation Oncology Center ("LROC") facility under construction in Wilson County, implementing CN2210-041A. LROC will not be operational until October 15, 2024.

8. 2E. Rationale for Approval

When is the Lebanon MRT facility expected to begin serving patients?

Response : The projected date for LROC's first patient treatment is October 15, 2024.

9. 2E. Rationale for Approval

Please confirm whether the applicant will pursue licensure as an ASTC if it is confirmed by the HFC licensure division as unnecessary to support the operation of this linear accelerator.

Response : If the HFC deems ASTC licensure for the project unnecessary for operation, the applicant may or may not pursue ASTC licensure. At this time, and consistent with LROC (CN2210-041A), the applicant would like to maintain both options.

10. 4E. Project Cost Chart

Please include a list of all equipment over \$50,000 as a separate attachment.

Please include a comparison of facility lease costs vs fair market value in response to Item 4E.

Response : The equipment list and a table comparing the fair market value of the facility to the lease outlay for the facility are attached in supplemental Attachment Equipment Round 1.

11. 2N. Service Area

Please include a map of the 19 ZIP Codes in the service area with a map of the existing and pending linear accelerators in Robertson, Sumner, Davidson, and Wilson Counties.

Please include a list of the total population for each of the service area ZIP Codes?

Please identify which ZIP Codes / portions or ZIP Codes included in the service area represent a lesser driving distance to the proposed facility than to other existing or pending linear accelerator facilities?

Response : Please see supplemental Attachment Additional Document 1.

12. 6N. Utilization and/or Occupancy Statistics

There appears to be a typo at the end of the applicant's response to Item 6N. on page 16 of the application that needs to be corrected.

Response : The applicant has made two corrections to Item 6N in the portal. First, the footnote has been removed. In addition, the second line in the first paragraph on page 16 has been amended to read: *Ten of them are wholly or substantially (50+%) within...* This same change has been made in the Executive Summary's Service Area response, in the bulleted explanations of the projection methodology in the portal, and in the revised Attachment N-1R for the State Plan Criteria for RT.

13. 7N. Outstanding CoN

Please list any outstanding CON projects that the applicant is affiliated with in response to Item 7N.

Response : Tennessee Oncology, PLLC, the group practice that owns the applicant, is the owner of the linear accelerator being established with the LROC project (CN2210-041A). The applicant has no other outstanding CON projects.

14. 1C. Transfer Agreements

Which facilities does the applicant intend to pursue transfer agreements with if the project is approved?

Response : The applicant intends to pursue transfer agreements with Carpenter Cancer Center and TriStar Skyline Medical Center. Both locations are currently staffed with Tennessee Oncology Radiation Oncologists. In addition to those locations, patients may be referred to alternate locations where Tennessee Oncology Radiation Oncologists practice.

15. 3C. Effects of Competition and/or Duplication

Please respond to Item 3C. of the application.

Response : The following response has been added to Item 3C of the application:

The project improves consumer choice significantly by offering patients a closer-to-home option for their cancer treatment. Patients receiving treatment through the proposed project will have reduced total round-trip hours of travel time compared to what they would incur if using most existing providers closer to Nashville. Patients choosing the White House facility will avoid crowded highways and will have accessible parking and entry. Continuity of care will be enhanced as patients will continue to utilize Tennessee Oncology's unified medical records system during their treatment phase, rather than being set up under separate hospital medical records systems. In terms of charges, the White House project will not adversely impact any existing provider's charge structure, and the project's gross charge structure will compare favorably to other regional providers' gross charges. By committing 2% of technical charges to charity care, the project further improves community access to radiation therapy treatments. Finally, the project will not decrease existing providers' utilization below the State Health Plan capacity threshold.

16. 3C. Effects of Competition and/or Duplication

What are the differences in capacity between this hybrid linear accelerator and the other units in Robertson, Sumner, Davidson and Wilson Counties?

How many of the patients projected to be served at this proposed facility are expected to require the capacity of the hybrid unit as opposed to the other units in the area?

Response : See supplemental Attachment Additional Documents 1.

17. 6C. Historical/Projected Data Chart

The Projected Data Chart can be submitted for the Total Facility and removed for the Project only.

Response : In the portal, the Projected Data Chart has the same data entered in both the Total Facility and Project Only sections. The application software appears to have done this on its own because the project is the same as the total service. The applicant was unable to delete the data in the Project Only section.

18. 7A. Type of Ownership of Control

Please include the referenced organizational chart in response to Item 7A. Please submit Attachment 7A. (labeled as Attachment 7AR.)

Response : The organization chart has been added to 7A in supplemental Attachment 7AR.

19. 3N. Demographics

The following rows appear to contain errors in Attachment 3NB.:

Tennessee Total - TennCare Enrollees and TennCare Enrollees as a % of County Population.

Please revise and resubmit Attachment 3NB (labeled as Attachment 3NBR.)

Response : The Tennessee statewide TennCare Enrollment has been corrected in Attachment 3NBR to 1,574,859. This changed the state percent of enrollment from 23.4% to 22.1%.

20. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #1.b., Determination of Need

Please explain whether there is any difference between the treatment codes utilized to report to the HFC Equipment Registry and the "actual treatment codes" referenced by the applicant in response to Criterion #1.b.

Response : There is no difference. The treatment codes utilized in this application came from the HSDA Medical Equipment Utilization Survey list: 77372, 77373, 77385, 77386, 77402, 77407, 77412, G6004, G6005, G6008, G6012, G6015.

21. 6N. Utilization and/or Occupancy Statistics

Please discuss the inclusion patients from the following ZIP Codes being referred to Tennessee Oncology in the utilization projections for the White House facility, which appear to be closer to other existing or pending linear accelerator units:

Moderate Patient Shift: 30%-40%

37066 - Gallatin

37075 - Hendersonville

37072 - Goodlettsville

Minimal Patient Shift: 10%

37122 - Mt Juliet

37115 - Madison

37207 - Nashville

37138 - Old Hickory

37080 - Joelton

Response : See supplemental Attachment Additional Documents 1.

22. 6N. Utilization and/or Occupancy Statistics

What linear accelerator facilities are TN Oncology patients currently being referred to from the 19 ZIP Codes identified in the project service area?

Response : See supplemental Attachment Additional Documents 1.

23. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #1.b., Determination of Need

Please confirm whether TN Oncology patients from the identified service area ZIP Codes are referred to any non-hospital based linear accelerator facilities?

Response : With the exception of Carpenter Cancer Center in Gallatin, all operational linear accelerators are located on hospital campuses. Carpenter is located at Sumner Station, an outpatient building owned by LifePoint's Sumner Regional Hospital in nearby Gallatin. The Sumner Station outpatient building is 14.9 miles and 22 minutes southeast from White House via highway 258. If a patient is coming from Sumner Regional Hospital, Sumner Station is 7.1 miles and 16 minutes southwest of the hospital via Vietnam Veterans Boulevard (Highway 386) and Camp Station Road.

24. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #1.c., Determination of Need

Please provide the required Tennessee Cancer Registry data in response to Criterion #1.c and d. utilizing the linked template.

Response The table below uses the latest available CDC age-adjusted cancer incidence rates and the 60% state health plan to project a need in 2028 for 55,439 treatments in this area – assuming at least 17 treatments per patient. A total of 3,261 patients requiring radiation therapy treatments will reside in the area, far above the minimum threshold of 360 patients.

Radiation Therapy Treatments Needed for New Cancer Patients in the Primary Service Area 2028					
PSA County	2028 Population (in 100,000s) - 4 Years from Current Year	New Cancer Rate/100K Population (CDC Age Adjusted)	Projected New Cancer Patients/Year	Patients Needing RT Treatments (60%)	Treatments
Davidson	7.70119	434.1	3343.1	2005.9	
Robertson	0.78642	477.0	375.1	225.1	
Sumner	2.13896	464.6	993.8	596.3	
Wilson	1.62237	445.8	723.3	434.0	
Total PSA (Rounded)			5,435	3,261	
Data Source:	Tennessee State Data Center, Population Projections 2016-2030	National Cancer Institute, State Cancer Profiles			

25. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #2 Relationship with Existing Service Providers

What type of linear accelerator unit is located at Carpenter Cancer Center in Gallatin?

Are all projected patients expected to shift from Carpenter Cancer Center in Gallatin or are residents of the 19 ZIP Code service area also expected to shift from other providers in the service area counties? If other shifts are expected, please identify where those patients are being referred to currently.

Response Response 1: According to the most recent state equipment registry (11/01/23), the Carpenter Cancer Center is currently utilizing a Varian Truebeam to delivery radiation therapy treatments.

Response 2: In 2023, Tennessee Oncology radiation oncologists treated 1,053 patients from the 19 target ZIP Codes. Of these patients, 327 were treated at Carpenter Cancer Center in Gallatin and 304 were treated at TriStar Skyline. The other 422 patients received treatment at the following facilities:

- Ascension Saint Thomas Midtown. Nashville, TN
- TriStar Centennial Medical Center. Nashville, TN
- Memorial Hospital. Chattanooga, TN
- Ascension Saint Thomas Rutherford. Murfreesboro, TN
- Tennessee Oncology Proton Center. Franklin, TN
- TriStar StoneCrest Medical Center. Smyrna, TN
- Ascension Saint Thomas West. Nashville, TN
- TriStar Summit Medical Center. Hermitage, TN

Based on Tennessee Oncology 2023 patient data, 125 patients outside the target 19 ZIP Codes selected for this application received treatment at Carpenter Cancer Center; TriStar Skyline treated an additional 88 patients from ZIP codes outside the 19 selected for this application.

Due to proximity, the applicant anticipates the majority of projected patients will likely shift from Carpenter Cancer Center and TriStar Skyline, though patients receiving treatment at other facilities may also transition to the proposed White House location. But, the proposed project will minimally impact treatment at other facilities. In fact, assuming each patient receives 17 fractions, it is possible for Carpenter Cancer Center and TriStar Skyline to lose 65% of their patients from the 19 target ZIP Codes only and still **remain above the 3,162 minimum treatment volume threshold**. Carpenter Cancer Center would have to lose 82% of their patients from the target 19 ZIP Codes before it drops below the minimum treatment threshold.

Tennessee Oncology Patients Treated at Carpenter Cancer Center & TriStar Skyline (January 2023 to December 2023)		Assuming 65% Shift of from 19 Target ZIP Codes	
	TriStar Skyline		TriStar Skyline

	Carpenter Cancer Center		Carpenter Cancer Center	
# Pts from Non-Target ZIP Codes	125	88	125 (unchanged)	(unc
<i>Estimated # of treatments, assuming 17 fractions per patient</i>	2125	1496	2125 (unchanged)	(unc
# Pts from 19 Target ZIP Codes	327	304	Decreased to 114	Decr
<i>Estimated # of treatments, assuming 17 fractions per patient</i>	5559	5168	1946	
# Pts from ALL ZIP Codes	452	392	239	
<i>Estimated # of treatments, assuming 17 fractions per patient</i>	7684	6664	4071	:

26. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #3 Establishment of Service Area

Please include the required Tennessee Cancer Registry data in the response to this Criterion.

Response : The data are included in supplemental Attachment Additional Documents 1 and in the revised responses to Criterion #3 in 1NR, MRT Criteria.

27. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #4 Access to MRT Units

Please respond to Criterion #4 by completing the template included with the following link:
https://www.tn.gov/content/dam/tn/hfc/documents/HFC-1N-Megavoltage_Radiation_Therapy.xlsx

Criteria #4. Access to MRT Units			
Service Area County	Distance to Proposed MRT Facility	Projected Number of Cases Year 1	% of Projected Cases Year 1
<i>Add Rows as Necessary</i>			
TOTAL			

Are there any MRT units located in KY that are located within a shorter drive time distance than the proposed facility?

Response 1. 1N. Criteria and Standards

:

Attachment 1N, MRT Criterion #4 Access to MRT Units

Please respond to Criterion #4 by completing the template included with the following link:

https://www.tn.gov/content/dam/tn/hfc/documents/HFC-1N-Megavoltage_Radiation_Therapy.xlsx

Response:

Access to MRT Units					
Service Area County	Driving Distance from the Center of the County to Proposed MRT Facility	Projected Number of Cases Year 1 <i>(2028 RT patient metrics from section 1d)</i>	% of Projected Cases Year 1	Percent of Service Provided OUTSIDE County	P P Cas Tr OU Hon
Davidson	24.2 miles	2005.9	62%	5.9%	
Robertson	13.2 miles	225.1	7%	100.0%	
Sumner	12.7 miles	596.3	18%	40.6%	
Wilson	39.7 miles	434.0	13%	68.9%	
TOTAL		3261			

Are there any MRT units located in KY that are located within a shorter drive time distance than the facility?

Response: No, the closest facilities with MRT units in Kentucky are in Bowling Green, which is 31 miles from White House.

28. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #5 Economic Efficiencies

Which facilities in Robertson, Sumner, Davidson and Wilson Counties operate hybrid MRT units?

Response : According to the most recent state equipment registry (11/01/23), the following facilities operate hybrid MRT units:

Robertson County	<i>No current Linac facilities exist in Robertson County</i>
Davidson County	St. Thomas Midtown Hospital St. Thomas West Hospital TriStar Centennial Medical Center TriStar Skyline Medical Center Vanderbilt University Medical Center
Sumner County	Carpenter Cancer Center
Wilson County	Vanderbilt Wilson County Hospital

29. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #6 Separate Inventories

Please confirm that the applicant will maintain separate inventories for the types of MRT units referenced in this criterion.

Response : It is the applicant's understanding that the state equipment registry maintains separate inventories of types of MRT units. State equipment registry data has been used in this CON application.

30. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #7 Patient Safety and Quality of Care

- a. Please attach documentation that the proposed MRT unit has been certified by the FDA for clinical use.
- b. Please provide a brief description of the physical facility environment's conformity with all applicable federal standards, manufacturer's specifications and licensing agencies requirements.
- c. Please identify the nearest medical facilities which the applicant will consider establishing a transfer agreement with.
- g. Which facilities are included in the 9 of 13 linear accelerators referenced in the applicant's response?
- h. Who will serve as the Medical Director for the proposed facility?

Response : Please attach documentation that the proposed MRT unit has been certified by the FDA for clinical use.

Response: Please see supplemental Attachment Additional Document 3, for the FDA letters.

Please provide a brief description of the physical facility environment's conformity with all applicable federal standards, manufacturer's specifications and licensing agencies requirements.

Response: Upon approval of the CON application, the applicant will engage architectural and engineering consultants who will commit to conform this facility's environment with all applicable federal standards, manufacturer's specifications, and, if needed, licensing requirements.

Please identify the nearest medical facilities which the applicant will consider establishing a transfer agreement with.

Response: The applicant intends to pursue transfer agreements with Sumner Regional Medical Center (in Gallatin) and TriStar Skyline Medical Center. According to Google Maps Driving Directions, Sumner Regional is 17 miles away from White House. TriStar Skyline is approximately 19 miles away. Both locations are currently staffed with Tennessee Oncology radiation oncologists. In addition to these locations, patients may be referred to alternate locations where Tennessee Oncology radiation oncologists practice.

Which facilities are included in the 9 of 13 linear accelerators referenced in the applicant's response?

Response: Of the 12 linear accelerators (linacs) registered in Davidson County and 1 registered in Sumner County, as of 11/1/2023, Tennessee Oncology radiation oncologists supervise treatments on the following 9 linacs:

- Davidson County:
 - o Ascension Saint Thomas Midtown Hospital (2 linacs)
 - o Ascension Saint Thomas West Hospital (2 linacs)
 - o TriStar Centennial Medical Center (2 linacs)
 - o TriStar Skyline Medical Center (1 linac)
 - o TriStar Summit Medical Center (1 linac)
- Sumner County:
 - o Carpenter Cancer Center (1 linac)

Who will serve as the Medical Director for the proposed facility?

Response: Dr. Ryan Jones. Tennessee Oncology's Radiation Oncology Medical Director, will serve as the site's Medical Director.

31. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #9 Adequate Staffing

Please restate the staffing plan for the project and address the availability of the staffing resources required for the project.

Response : As set forth in the application, the applicant intends to employ the staff listed in the table below.

The applicant recognizes that recruitment of some of these clinical employees, though few in number, will be challenging. However, Tennessee Oncology has well-established internal resources to recruit and retain qualified personnel for its numerous offices. Recruitment resources will include human resource administrators and talent acquisition specialists. Tennessee Oncology will provide competitive financial incentives to attract qualified candidates.

Medical Physicist	1
Dosimetrist	1
Radiation Therapists (1 Lead)	3
Radiation Therapist, PRN	0.25
Nurse	1
Dietician	0.2
Clinical Services Assistant	1
TOTAL	7.45

32. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #12 Assurance of Resources

Please submit the referenced attachment.

Response : This assurance letter from the applicant's management is provided in supplemental Attachment Additional Document 2.

33. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #14 Licensure and Quality Considerations

This Criterion applies to any of the applicant's affiliated facilities providing linear accelerator services in TN. Please respond accordingly.

Response : Please see the response to Criterion #14 in supplemental Attachment 1NR. The applicant is not an existing facility, and does not own an interest in any operational facility of this type. It owns LROC, a linear accelerator facility under

construction in Lebanon (Wilson County), scheduled to open in October of 2024. As committed in its approved CON application, LROC's accreditation will be pursued at the earliest possible time.

34. 1N. Criteria and Standards

Attachment 1N, ASTC Criterion #1 Need

Please explain why the applicant is applying as an ASTC facility?

Response : Please see revised Attachment 1NR. As explained elsewhere in these responses, the applicant wishes to preserve the option of pursuing that licensure, depending on conditions at the time it is established and further direction from licensure officials.

35. 1N. Criteria and Standards

Attachment 1N, ASTC Criterion #9 Access and Economic Efficiencies

Please respond to this Criterion.

Response : Please see supplemental Attachment 1NR, containing a response to this ASTC criterion.

36. 1N. Criteria and Standards

Attachment 1N, ASTC Criterion #10 Patient Safety and Quality of Care

b. How many radiation oncologists are projected to utilize the proposed facility?

Response : The White House location will staff one Tennessee Oncology Radiation Oncologist.

37. 9C. Other Facilities Charges

Please provide a source citation for the charge comparison data provided in response to Item 9C.

Response The applicant utilized publicly available pricing transparency data available on each facility’s website :

Entity:	2024 Medicare Allowable	Tennessee Oncology White House	
Data Source:	https://www.cms.gov/medicare/physician-fee-schedule/search	Internal Data	https://www.tristarh

Project Name : Tennessee Oncology White House

Supplemental Round Name : 2

Certificate No. : CN2403-006

Due Date : 4/12/2024

Submitted Date : 4/9/2024

1. 7N. Outstanding CoN

Please include the information on CN2210-041A within the e-application Item 7N table.

Response : **Response:** This change has been made in the portal.

2. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #1.c., Determination of Need

Please include the table provided within the supplemental responses as a part of Attachment 1N. Also, please ensure that the table fits within the page of the Attachment as the table is not completely visible in the supplemental responses.

Response : **Response:** This has been provided in supplemental Attachment 1NR.

3. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #2 Relationship with Existing Service Providers

Please include the information that is provided in the supplemental response within the revised Attachment 1N an ensure that the table fits within the page of the Attachment as the table is not completely visible in the supplemental responses.

Response : **Response:** This has been provided in supplemental Attachment 1NR.

4. 1N. Criteria and Standards

Please confirm that Attachment 1N as included with the responses to Supplemental #1 are the revised version as they do not appear to be updated for either if the required sets of standards and criteria.

Response : **Response:** The required version of both sets of standards and criteria is provided in supplemental Attachment 1NR.

5. 1N. Criteria and Standards

Attachment 1N, MRT Criterion #4 Access to MRT Units

Please include the information that is provided in the supplemental response within the revised Attachment 1N an ensure that the table fits within the page of the Attachment as the table is not completely visible in the supplemental responses.

Response : **Response:** This has been provided in supplemental Attachment 1NR.

Project Name : Tennessee Oncology White House

Supplemental Round Name : 3

Certificate No. : CN2403-006

Due Date : 4/12/2024

Submitted Date : 4/11/2024

1. 7N. Outstanding CoN

Please include the information on CN2210-041A within the e-application Item 7N table.

Response : The information for Item 7N has been added to the application. This includes the completed table.

2. 1N. Criteria and Standards

Attachment 1N, ASTC Criterion #10 Patient Safety and Quality of Care

Please confirm whether the applicant will commit to becoming accredited by any accrediting organization approved by the Centers for Medicare and Medicaid Services, such as the Joint Commission, the Accreditation Association of Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgical Facilities, or other nationally recognized accrediting organization in the event that it decides to pursue licensure as an ASTC facility.

Response : If licensure as an ASTC facility is pursued, the applicant will become accredited by an organization approved by the Center for Medicare and Medicaid Services. Currently the applicant prefers that ASAAHC (the American Association for Accreditation of Ambulatory Surgical Facilities) will be that organization. This commitment will be added to the application record.