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HEALTH FACILITIES COMMISSION
OCTOBER 22, 2025
APPLICATION REVIEW

NAME OF PROJECT: American Health Imaging of Knoxville

PROJECT NUMBER: CN2508-028

ADDRESS: 326 Lovell Road
Knoxville (Knox County), TN 37934

LEGAL OWNER: American Health Imaging of Tennessee, LLC
2200 Centrury Parkway NE, Suite 600
Atlanta, GA 30345

OPERATING ENTITY: N/A

CONTACT PERSON: Rebecca Thornhill
(865) 686-5630

DATE FILED: August 29, 2025

PROJECT COST: \$5,913,239

PURPOSE FOR FILING: Establishment of an Outpatient Diagnostic Center that includes the initiation of MRI services

PROJECT DESCRIPTION:

This application is for the establishment of an Outpatient Diagnostic Center (ODC) and the initiation of MRI (3.0T) services located at 326 Lovell Road, Knoxville (Knox County), TN 37934.

Executive Summary

- If approved, the applicant projects the proposed project will open for service in April 2026.
- The applicant will offer MRI (3.0T) and CT (64-Slice) imaging services. The project will not involve X-ray services. Ultrasound equipment will be added later according to patient demand.
- The proposed service area consists of Knox, Blount, and Loudon Counties.

- Please see application Item 1E. on pages 6-7 for the applicant's executive summary overview that includes project description, ownership, service area, existing similar service providers, project cost, and staffing.

Consent Calendar: ☐ Yes ☒ No

- Executive Director's Consent Memo Attached: ☐ Yes ☒ Not applicable

Facility Information

- The proposed freestanding ODC will occupy a one-story 4,704 SF building.
- The applicant, American Health Imaging of Tennessee has signed an Option to Lease Agreement with Lovell Pointe, LLC for an initial 60-month term with a target rent commencement date of December 1, 2025.

Ownership

The applicant is owned by American Health Imaging, Inc., which is ultimately owned by Luxema Imaging Equity Holdco, LLC.

Project Cost Chart

- The total project cost is \$5,913,239. Of this amount, the highest line-item costs of the project are Fixed Equipment Costs (\$2,238,279), Facility Lease Costs (\$2,170,703), and Total Construction Costs (\$1,157,256).
- For additional information, please see Project Costs Chart on page 10 of the original application.

NEED

The applicant provided the following supporting the need for the proposed project:

- This project is needed due to the high utilization of existing MRIs in the 3-County proposed service area. The 3-County proposed service area MRI utilization per MRI unit of 3,771 in 2023 was above the 2,880 per unit need CON threshold required to add additional units.
- There is a lack of freestanding ODCs in the proposed service area. There are only two (2) 3.0T MRI ODC units in Knox County with both located at the ODC, East Tennessee Community Open MRI. The ODC is located approximately 20 minutes in the Bearden area of Knoxville from the proposed project's location.
- Enhanced technology offering, including a 3.0T MRI unit. The 3.0T MRI scanner can produce clearer, more detailed images that may not be visible with a 1.5T MRI. The applicant provided an overview of the differences between a 3.0T MRI and 1.5T MRI in Attachment 1N-Outpatient Diagnostic Center.

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- Please see Section 2E. of the original application for the applicant's complete description of how the proposed project meets the need criteria.

(For applicant discussion, see the Original Application, Item 2.E., Page 7R and 8)

SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW

This project involved the review of the following two (2) project types:

1. Outpatient Diagnostic Centers

All applicable criteria and standards appear to be met.

2. Magnetic Resonance Imaging (MRI)

All applicable criteria and standards appear to be met.

Please see attached for a full listing of the criteria and standards and the applicant's responses.

Service Area Demographics

- The proposed primary service area consists of Blount, Knox and Loudon Counties (see Attachment 2N for a county level map).
- The target population is individuals aged 18 and older. (See page 14 in the original application for more demographic detail.)

	2025 Population		2029 Population		% Change		TennCare %
	Total	18+	Total	18+	Total	18+	
Service Area	697,673	553,979	721,965	573,445	3.5%	3.5%	15.3%
Tennessee Total	7,176,847	5,607,941	7,384,270	5,780,535	2.9%	3.1%	19.6%

Source: The University of Tennessee Center for Business and Economic Research Population Projection Data Files, Reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.

- The total population of the services area is projected to increase by 3.5% from 2025 to 2029. The target population (18+) is also projected to increase by 3.5%.
- The service area has a lower rate of TennCare enrollment (15.3%) than the statewide rate (19.6%).

Service Area- Historical Utilization

Combined, the MRI providers in the proposed service area reported an increase of 18.7% in MRI utilization from 2021 to 2023, from 104,828 procedures on 34 MRI units in 2021, to 124,454 MRI procedures on 32 units in 2023. Please refer to Item 5N in the application

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Need Section for a complete listing of each provider's specific three-year utilization in the proposed service area.

Note to Commission Members: University Diagnostics, CN2207-031A, approved in September 2022, located at 7326 Maynardsville Pike, Knoxville TN, was originally licensed in 2/10/2023. The provider reported 2,868 procedures for one MRI machine to the HFC Equipment Registry representing approximately 11 months of utilization in 2023.

Covenant Health Diagnostic Center-South, CN2010-031A was approved February 24, 2021, located at 7625 Chapman Highway, Knoxville, was originally licensed on May 11, 2023. The provider reported 288 MRI procedures for one MRI machine to the HFC Medical Registry representing approximately 7 months of utilization.

CN2010-031A has a CON limitation on their license that no pediatric MRIs will be provided.

The following are CT and MRI Utilization trends for ODCs in the primary service from 2022-2024:

	2022	2023	2024	% Change 22-24
# of ODCs in Service Area	4	7	7	+75%
MRI Units	5	7	7	+40%
MRI Procedures	16,005	17,552	20,464	+28%
CT Units	3	6	6	+100%
CT Procedures	10,073	17,171	24,125	+140%

Source: CN2508-028, Supplemental #1, Page 3, Joint Annual Report Data.

- Combined, the ODC facilities in the service area reported an increase of 28% in MRI utilization from 2022 to 2024, from 16,005 procedures on 5 MRI units in 2022, to 20,464 MRI procedures on 7 units in 2024.
- Combined, the ODC facilities in the service area reported an increase of 140% in CT utilization from 2022 to 2024, from 10,073 procedures on 3 MRI units in 2022, to 24,125 CT procedures on 6 units in 2024.
- East Tennessee Community Open MRI operates two (2) 3.0 Tesla MRIs in the proposed service area. According to the ODC Joint Annual Report, in 2023 the combined utilization of the two MRIs was 3,417 which calculates to 1,708.5 procedures per MRI unit.

- See Supplemental #1 page 3 for a full listing of ODC MRI and CT utilization from 2022-2024 for the proposed service area.

The following chart displays the type of imaging services available at ODCs in the proposed 3-county service area.

Service Area ODC Imaging Services Available

Facility	County	MRI	CT	Ultrasound	X-Ray
University Diagnostics Northshore	Knox	No	Yes	Yes	Yes
University Diagnostics Hall of Fame	Knox	Yes	Yes	Yes	Yes
Covenant Health Diagnostic Center	Knox	Yes	Yes	Yes	Yes
East Tennessee Community Open MRI	Knox	Yes	No	Yes	Yes
East Tennessee Diagnostic Center	Knox	No	Yes	No	No
University Diagnostics-Halls	Knox	Yes	Yes	Yes	Yes
Covenant Health Diagnostics, LLC	Knox	Yes	Yes	Yes	Yes

Source: CN2508-028, Supplemental #1, Page 10

Applicant's Historical and Projected Utilization

The following table indicates the applicant's historical and projected utilization.

Projected Utilization (Patients and Procedures) by Procedure Type Year 1 (2026) and Year 2 (2027)

Equipment Type	Procedure Volumes		% Change
	Year 1 (2025)	Year 2 (2026)	
MRI	2,340	2,600	+11 %
CT	975	1,560	+60 %
TOTAL	3,315	4,160	25.5%

Source: CN2508-028, Supplemental #1, Page 4

- Projected procedure volumes for all procedure types are expected to increase by 25.5% from 3,315 in Year 1 (2025) to 4,160 in Year 2 (2026) of the project.

CONSUMER ADVANTAGE ATTRIBUTED TO COMPETITION

Charges

- The applicant's projected charges for both CT and MRI services combined for Year 1 and Year 2 are provided in the following table:

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	Projected Data Chart	
	Year 1 (2026)	Year 2 (2027)
Gross Charges	\$1,673	\$1,625
Deduction from Revenue	\$1,513	\$1,313
Average Net Charges	\$161	\$312

Source: CN2508-028, Page 10

The applicant's projected charges for MRI services only for Year 1 and Year 2 are provided below:

	Projected Data Chart	
	Year 1 (2026)	Year 2 (2027)
Gross Charges	\$1,850	\$1,850
Deduction from Revenue	\$1,667	\$1,484
Average Net Charges	\$182	\$366

Source: CN2508-028, Supplemental #1, Page 5.

A comparison of the proposed charge per MRI procedure with other ODCs in the proposed service area is provided below.

2023-Average MRI Charge per Procedure – ODCs in the Service Area	
Facility	Average Gross Charge
East Tennessee Community Open MRI (3.0T)	\$634
Covenant Health DX Center South (1.5T)	\$625
University Diagnostics Hall of Fame (1.5T)	\$1,021
University Diagnostics Halls (1.5T)	\$876
Applicant-American Health Imaging of TN (3.0T)	\$1,850

Source: CN2207-031, Supplemental #1, Page 10

- The applicant's proposed gross charge per procedure is higher than the other ODC facilities in the service area (\$1,850 per procedure) in 2023.
- East Tennessee Community Open MRI is the only ODC in the proposed service with two (2) 3.0T MRIs.

The average gross MRI charge per procedure for all provider types in the proposed service in 2023 was \$2,495. Please see page 25 in the original application for a full listing of MRI utilization across all provider types for 2023.

Project Payor Mix

	Percentage of Gross Operating Revenue				
	Medicare	Medicaid	Commercial	Self-Pay	Charity Care
Year 1	27%	3%	66%	4.0%	3.7%
Year 2	41.1%	13.8%	40.4%	4.7%	0.8%

Source: CN2508-028, Original Application, Page 27

- Please refer to Item 10C. in the Consumer Advantage section of the application for specific Payor Mix information.

Agreements

- The applicant will not seek transfer agreements with hospitals, rather a patient will be transferred to the nearest emergency room if needed.
- The applicant states that it will contract with all service area TennCare Managed Care Organizations (MCOs) including Amerigroup Community Care, BlueCare, UnitedHealthcare Community Plan, and TennCare Select.
- A full list of in-network payors is included as Item 2.C. in the application.

Staffing

The applicant's Year One proposed direct patient care staffing includes the following:

	Year One
Direct Patient Care Positions	2.0
Non-Patient Care Positions	3.0
Contractual Staff	0
Total	5.0

Source: CN2207-031, Original Application, Page 23

- Direct Care positions include the following: MRI Tech (1.0 FTE); and CT Tech (1.0 FTE).
- Non-Patient Care positions include the following: Manager (1.0 FTE); Sales Representative (1.0 FTE); and Patient Services Representative (1.0 FTE).
- Please refer to Item 8Q. on Page 6 of Supplemental #1 for additional details regarding project staffing.

QUALITY STANDARDS

The applicant commits to obtaining and/or maintaining the following:

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Licensure	Certification	Accreditation
TN Health Facilities Commission	Medicare and TennCare	Intersocietal Accreditation Commission (IAC)

Source: CN2508-028, Original Application, Page 22, and Supplemental #1, Page 12

Application Comments

Application Comments may be filed by the Department of Health, Department of Mental Health, and Substance Abuse Services, and the Department of Intellectual and Developmental Disabilities. The following department(s) filed comments with the Commission and are attached:

- ☐ Department of Health
- ☐ Department of Mental Health and Substance Abuse Services
- ☐ Department of Intellectual and Developmental Disabilities
- ☒ **No comments were filed**

Should the Agency vote to approve this project, the CON would expire in two years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT:

There are no other Letters of Intent, denied applications, pending applications, or Outstanding Certificates of Need on file for this applicant.

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent, denied applications, or pending applications, or Outstanding Certificates of Need for other entities proposing this type of service.

PME (10/15/2025)

CRITERIA AND **STANDARDS**

ATTACHMENT 1N

OUTPATIENT DIAGNOSTIC CENTERS

OUTPATIENT DIAGNOSTIC CENTERS

1. **The need for outpatient diagnostic services shall be determined on a county by county basis (with data presented for contiguous counties for comparative purposes) and should be projected four years into the future using available population figures.**

Response: AHI of Knoxville will be located in Knox County and will serve patients from a three-county area including Knox, as well as Blount and Loudon counties, which are contiguous to Knox. The need for the proposed ODC, as well as the current market utilization and projected utilization, is provided in response to the Magnetic Resonance Imaging Rules found in **Attachment 1N**. Population and utilization were both projected four years into the future based on current population (2025/2029) and most recent utilization (2023).

The proposed ODC will increase access to freestanding imaging services in a particularly fast-growing area of Knoxville, Farragut. Currently, Knox County is the 3rd largest county in Tennessee, with nearly half a million residents. At the current time, area MRI units are highly utilized. Additionally, there is a lack of freestanding ODCs in the area, as most units are either located inside hospitals, inside outpatient departments of hospitals, or physician offices. Finally, the proposed project will offer access to enhanced MRI technology, as AHI of Knoxville plans to install a 3.0T MRI unit. Typically, 3.0T MRI units are operated within the hospital setting, so the availability of this advanced technology in a lower cost, freestanding setting will benefit patients in the proposed service area.

2. **Approval of additional outpatient diagnostic services will be made only when it is demonstrated that existing services in the applicant's geographical service area are not adequate and/or there are special circumstances that require additional services.**

Response: As discussed in response to the Magnetic Resonance Imaging Rules found in **Attachment 1N**, ODC services are not adequate to meet demand in the proposed service area. Specifically:

- Knox County has a mix of hospital, physician office and ODC imaging centers, but none located in Farragut, which is the fastest growing area of Knoxville.
- Neither Loudon, nor Blount have any freestanding ODC MRI units. In Loudon, the only MRI unit is hospital-based and in Blount, there is one hospital-based unit and one physician office practice-based unit.

Additionally, the aggregate utilization standard set forth in the Certificate of Need Standards and Criteria for Magnetic Resonance Imaging services is met in Knox and Blount Counties, while Loudon's sole unit was very close to the required volume threshold in 2023, reporting

2,498 scans. These high levels of utilization indicate a need for access to additional MRI services in the area.

AHI TN intends to install Siemens MAGNETOM Lumina MRI system. This unit is particularly notable with its unique, high performance 3.0T clinical technology. This particular technology embraces the unique set of challenges each patient brings to the exam and overcomes patient variability, resulting in fewer rescans, predictable scheduling, and personalized exams as well as cost efficient energy management. This proposed innovative imaging technology will promote high quality clinical care and outcomes, foster patient safety and satisfaction, and encourage optimal operational efficiencies. Moreover, the 3T technology has become the preferred modality for diagnosing and monitoring the progression of numerous neurological disorders, including Alzheimer's, Multiple Sclerosis, Epilepsy, and Parkinsonism. 3T imaging is also uniquely suited to the early detection of prostate cancer, advanced breast imaging, and the evaluation of small orthopedic joints.

The proposed ODC in Knox County will increase access to freestanding MRI and other imaging services for residents of the area.

3. Any special needs and circumstances:

- a. The needs of both medical and outpatient diagnostic facilities and services must be analyzed.**

Response: The applicant has provided a summary of utilization for MRI, CT and ultrasound in Attachment 5N to the application. The figures show the most recent three years of publicly available data for all providers in the proposed three-county service area, including area hospitals, ODCs and physician offices. Between 2021 and 2023:

- MRI volume has increased in the post-COVID era (2021-2023);
- Knox County has experienced the highest MRI growth, with nearly 111,000 MRI scans generated by the area population in 2023;
- Blount and Loudon have also experienced high levels of growth in the past three years; and
- Just 16% of Knox County MRI scans were performed in an ODC environment, with the vast majority occurring in a hospital or physician office.

In an environment of increasingly higher patient co-pays and deductibles, the applicant complements existing hospital-based and HOPD imaging services such as MRI and CT. The average cost of imaging services at a freestanding imaging center is significantly less than the cost of an imaging service at a HOPD imaging service. Shifting clinically appropriate imaging

services from the hospital setting to the freestanding imaging setting will enhance scheduling and operational efficiencies while achieving cost containment, as freestanding imaging centers do not carry the costly overhead required for 24/7 care at hospitals. Furthermore, Medicare has long incentivized its patients to use freestanding imaging centers such as the applicant through lower patient co-pays and deductibles.

Recently, major commercial payors have instituted site of care medical necessity requirements, which direct beneficiaries to freestanding imaging centers instead of hospital-based centers. For example, some payors will no longer reimburse for advanced radiology imaging procedures like CT and MRI at HOPDs unless patients are at higher risk such as pediatric or obstetrical patients or those with a known contrast allergy. Anthem was amongst the first major payors to adopt coverage policies for non-emergency outpatient MRI and CT scans, reportedly based on studies showing that average prices for MRI and CT scans ranged from 70 percent to 149 percent higher at hospitals than at freestanding centers. The other payors, including Cigna, Aetna, and United Healthcare began following Anthem's lead. While these policies are designed to reduce costs, they also lead to delays in obtaining care at hospital-based centers because providers are required to identify the clinical condition that warrants the need for the service to be performed in an outpatient hospital setting. If a service is performed at a hospital-based center and the insurer determines that the setting is not medically necessary, the patient may receive a denial of coverage, and the claim will not be paid.

There is clearly a need for additional true freestanding ODC imaging capacity in the three-county area. A discussion of need for the project is provided in detail in response to the specific Magnetic Resonance Imaging Rules.

b. Other special needs and circumstances, which might be pertinent, must be analyzed.

Response: The proposed MRI scanner, a Siemens MAGNETOM Lumina MRI system, is particularly notable with its unique, high performance 3.0T clinical technology. This technology is particularly unique at freestanding imaging centers; market research shows that the vast majority of 3.0T MRIs are located in the hospital or hospital outpatient department settings. Increasing access to this type of advanced imaging technology in the freestanding imaging setting such as American Health Imaging of Knoxville will offer numerous benefits, including enhanced convenience such as 24-hour scheduling, a strong emphasis on personalized care in a smaller environment, ease of navigation with readily available parking, improved patient satisfaction, and contained costs.

The 3.0T technology embraces the unique set of challenges each patient brings to the exam and overcomes patient variability, resulting in the following:

- ✓ Fewer rescans;
- ✓ Predictable scheduling; and
- ✓ Consistent, high quality, personalized exams for high end clinical routine.

The higher magnetic field strength of a 3.0T MRI scanner can produce clearer, more detailed images with a better signal-to-noise ratio (SNR) and contrast. This can help identify smaller structures and lesions that might not be visible with a 1.5T MRI, which can lead to more accurate diagnoses. With lower image noise it decreases the risk of image distortion and the need to rescan a patient which can lead to lower overall healthcare costs.

3.0T MRI technology can be particularly helpful for specific sites and studies, including the following:

- ✓ A 3.0T MRI is a powerful tool in cancer detection. For early prostate cancer detection, a urologist will order a non-invasive Prostate Imaging Reporting and Data System (PI-RADS) exam to categorize lesions, which can reduce unnecessary biopsies and treatment for benign and subclinical diseases. This exam is typically only able to be performed on a 3.0T MRI.
- ✓ New and novel monoclonal antibody (MAB) immunotherapies are now available for treatment of Alzheimer disease. These new therapies require up to five brain MRIs for each patient to monitor for ARIA-E and ARIA-H lesion side effects. These brain MRIs for side effect monitoring inform the physician whether the patient can continue the Alzheimer's therapy for the treatment of the disease.
- ✓ For body exams, the 3.0T scan enables free-breathing high-resolution magnetic resonance cholangiopancreatography (MRCP) to pancreatic and pelvic studies to diagnose pancreatic cancer, pancreatitis, gallstones, and bile duct problems.
- ✓ Orthopedic physicians prefer the 3.0T for smaller structures to exam ligament tears to cartilage degeneration.

The distinct capabilities of the 3T have become even more necessary in recent years, as Alzheimer's and prostate cancer diagnoses continue to rise. For instance, according to the Alzheimer's Association, 10.9 percent of individuals age 65 and older have been diagnosed with Alzheimer's. Similarly, one in eight men will be diagnosed with prostate cancer during his lifetime.

Differences in 1.5T and 3.0T MRI Technology

While 3.0T MRI technology has become more widespread in recent years, the majority of MRI units currently in use are 1.5T units. When comparing 1.5T with 3.0T MRI technology, field strength is the biggest difference. According to Radiology Today, a 1.5T MRI system is approximately 30,000 times stronger than the Earth's magnetic field,

whereas a 3.0T MRI system is double that. 3.0T systems allow for higher signal to noise ratio as well as increased image resolution capabilities, which is crucial for MRI imaging.

Benefits of a 3.0T MRI scanner over a 1.5T MRI scanner are particularly distinct for clinical areas such as neuroradiology and musculoskeletal studies. In these cases, 3.0T MRI technology gives higher resolution images and more possibilities to do advanced work like looking at degenerative diseases, brain connectivity, or sports medicine. As a result, 3.0T MRI technology is quickly becoming the standard of care for neurological diseases and disorders.

Finally, the proposed 3.0T scanner promotes cost efficient energy management with a power management system that disables power-consuming components during scan breaks, resulting in up to 30 percent energy savings compared to the industry average. This proposed innovative imaging technology will promote high quality clinical care and outcomes, foster patient safety and satisfaction, and encourage optimal operational efficiencies.

- c. **The applicant must provide evidence that the proposed diagnostic outpatient services will meet the needs of the potential clientele to be served.**
 - 1. **The applicant must demonstrate how emergencies within the outpatient diagnostic facility will be managed in conformity with accepted medical practice.**
 - 2. **The applicant must establish protocols that will assure that all clinical procedures performed are medically necessary and will not unnecessarily duplicate other services.**

Response: AHI staff members are trained to perform emergency response procedures. For patients experiencing an emergency that exceeds staff expertise, local EMS will be called to transport the patient to a hospital emergency department. AHI of Knoxville staff will attempt to stabilize the patient until EMS arrival.

Consistent with other AHI imaging centers, AHI of Knoxville will implement guidelines and protocols for ensuring that MRI procedures are medically necessary. Additionally, most insurance companies require prior authorization for imaging procedures such as MRI. Insurance company approval for an MRI scan indicates medical necessity or clinically appropriate treatment.

A copy of AHI's policy for Ordering Exams is provided in **Attachment 1N7d**. The policy's purpose is: To establish written guidelines for the order of diagnostic tests by treating physicians and practitioners. The policy also states: orders must be provided in writing by the

physician treating the beneficiary, i.e., the physician furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in managing the beneficiary's specific medical problem. AHI of Knoxville will implement the AHI policy and will ensure that all MRI tests are medically necessary and will not unnecessarily duplicate other services.

ATTACHMENT 1N

MAGNETIC RESONANCE IMAGING

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR
MAGNETIC RESONANCE IMAGING SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Magnetic Resonance Imaging (MRI) services. Existing providers of MRI services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for MRI services.

These standards and criteria are effective immediately as of December 21, 2011, the date of approval and adoption by the Governor of the State Health Plan changes for 2011. Applications to provide MRI services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Capacity: The measure of the maximum number of MRI procedures per MRI unit per year based upon the type of MRI equipment.

Dedicated Breast MRI Unit: An MRI unit that is configured to perform only breast MRI procedures and is not capable of performing other types of non-breast MRI procedures.

Dedicated Extremity MRI Unit: An MRI unit that is utilized for the imaging of extremities only and is of open design with a field of view no greater than 25 centimeters.

Magnetic Resonance Imaging (MRI): A noninvasive diagnostic modality in which electronic equipment is used to create tomographic images of body structure. The MRI scanner exposes the target area to non ionizing magnetic energy and radio frequency fields, focusing on the nuclei of atoms such as hydrogen in the body tissue. Response of selected nuclei to this stimulus is translated into images for evaluation by the physician.

MRI Procedure: A single, discrete MRI study performed on a single patient during a single visit. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition, including the development of a selected set of CPT codes, which shall not include research-only CPT codes for purposes of determining capacity and need.

MRI Study: An MRI scan defined by a CPT procedure code.

MRI Unit: Medical imaging equipment (often referred to as a "scanner") that uses nuclear magnetic resonance to create tomographic images of body structure. MRI units may be differentiated by magnetic field strength ("tesla" or "T"), and also by construction or orientation. A "closed" scanner typically uses a higher strength magnet and an "open" scanner typically uses a lower strength magnet. There are also "multi-position" or "stand-up" scanners (often used for spine and joint evaluation, where weight-bearing is required) and limited-use scanners, such as those designed only to scan the breast or extremities (e.g., elbows, wrists, toes, etc.).

Mobile MRI Unit: An MRI unit and transporting equipment that is moved or able to be moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the United States.

Mobile MRI Unit Capacity: Total capacity of a mobile MRI unit is 600 annual procedures per day of operation per week and is based upon a daily operating efficiency of 12 procedures per day x 50 weeks per year, multiplied by the number of days per week that the equipment is used. The optimal efficiency of a mobile MRI unit is based upon the number of days per week that it is in operation. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of total capacity.

Dedicated Multi-position MRI Unit: An MRI unit that permits the patient to be scanned in various positions, such as sitting, standing, bending, or leaning, as well as lying down, for the purpose of providing weight-bearing scans.

Service Area: The contiguous counties or portions thereof representing a reasonable area in which an applicant intends to provide MRI unit services and in which at least 75% of its service recipients reside. An MRI unit should be located at a site that allows reasonable access for residents of the service area.

Service Area Capacity: The estimate of the number of MRI units needed in a given service area. The estimate is based upon an optimal efficiency of 2,880 procedures per year for a stationary MRI unit and an optimal efficiency of 480 annual procedures per day of operation per week for a mobile MRI unit.

Specialty MRI Unit: A Dedicated Breast, Extremity, or Multi-position MRI unit.

Stationary MRI Unit: A non-moveable MRI unit housed at a single permanent

location.

Stationary MRI Unit Capacity: Total capacity of a stationary MRI unit is 3600 procedures per year and is based upon a daily operating efficiency of 1.20 procedures per hour, 12 hours per day x 5 days a week x 50 weeks of operation per year. The optimal efficiency for a stationary MRI unit is 80 percent of total capacity, or 2,880 procedures per year.

Project Overview and Introduction to the Applicant

American Health Imaging of Tennessee, LLC proposes to develop an Outpatient Diagnostic Center in Knoxville (Knox County), including the initiation of outpatient MRI service. The proposed ODC will offer a 3.0T MRI unit, CT, and ultrasound. The proposed ODC will be located at 326 Lovell Road in Knoxville, TN, 37934.

AHI is a developer and operator of freestanding imaging centers. Headquartered in Atlanta, GA, American Health Imaging (AHI) invests in the most up-to-date imaging equipment to enhance the patient experience and provide the highest quality diagnostic images since 1998. In 2019, AHI partnered with US Radiology Specialists. Today, AHI owns and operates over 45 best-in-class diagnostic imaging facilities in Alabama, Georgia, Florida, South Carolina and Texas.

American Health Imaging of Tennessee, LLC (AHI TN), a Tennessee Limited Liability Corporation, is a wholly owned subsidiary of American Health Imaging, Inc. (AHI). AHI is wholly owned by US Outpatient Imaging Specialists, Inc. and US Outpatient Imaging Specialists, Inc. is wholly owned by US Radiology Specialists, Inc.

The proposed service area for the project includes three counties: Knox County (the project location), as well as Blount and Loudon Counties, which are contiguous. Knox County has a mix of hospital, physician office and ODC imaging centers, but none of the ODC units are located in Turkey Creek, which is the fastest growing area of Knoxville. Additionally, the aggregate utilization standard set forth in the Certificate of Need Standards and Criteria for Magnetic Resonance Imaging services is met in Knox County, indicating a need for access to additional MRI services. Neither Loudon, nor Blount have any freestanding ODC MRI units. In Loudon, the only MRI unit is hospital-based and in Blount, there is one hospital-based unit and one physician office practice-based unit. Blount County units' utilization exceeds the aggregate minimum volume standard. The proposed ODC in Knox County will increase access to freestanding MRI and other imaging services for residents of the area.

The proposed project is needed for a variety of reasons, including:

1. High utilization of existing MRI units in the area;
2. Lack of freestanding ODCs in the area; and
3. Enhanced technology offering, including a 3.0T MRI unit.

The total cost of the project is estimated to be \$5,913,239.

Standards and Criteria

1. Utilization Standards for non-Specialty MRI Units.

- a. An applicant proposing a new non-Specialty stationary MRI service should project a minimum of at least 2160 MRI procedures in the first year of service, building to a minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2880 procedures per year by the third year of service and for every year thereafter.

Response: The proposed project includes a new non-specialty MRI unit. However, the proposed MRI unit will be a Siemens MAGNETOM Lumina MRI system, which includes a 3.0T magnet. This unit is particularly notable with its unique, high performance 3.0T clinical technology. This technology is particularly unique at freestanding imaging centers; market research shows that the vast majority of 3.0T MRIs are located in the hospital or hospital outpatient department settings. Increasing access to this type of advanced imaging technology in the freestanding imaging setting such as American Health Imaging of Knoxville will offer numerous benefits, including enhanced convenience such as 24-hour scheduling, a strong emphasis on personalized care in a smaller environment, ease of navigation with readily available parking, improved patient satisfaction, and contained costs.

The 3.0T technology embraces the unique set of challenges each patient brings to the exam and overcomes patient variability, resulting in the following:

- ✓ Fewer rescans;
- ✓ Predictable scheduling; and
- ✓ Consistent, high quality, personalized exams for high end clinical routine.

The higher magnetic field strength of a 3.0T MRI scanner can produce clearer, more detailed images with a better signal-to-noise ratio (SNR) and contrast. This can help identify smaller structures and lesions that might not be visible with a 1.5T MRI, which can lead to more accurate diagnoses. With lower image noise it decreases the risk of image distortion and the need to rescan a patient which can lead to lower overall healthcare cost.

3.0T MRI technology can be particularly helpful for specific sites and studies, including the following:

- ✓ A 3.0T MRI is a powerful tool in cancer detection. For early prostate cancer detection, a urologist will order a non-invasive Prostate Imaging Reporting and Data

System (PI-RADS) exam to categorize lesions, which can reduce unnecessary biopsies and treatment for benign and subclinical diseases. This exam is typically only able to be performed on a 3.0T MRI.

- ✓ New and novel monoclonal antibody (MAB) immunotherapies are now available for treatment of Alzheimer disease. These new therapies require up to five brain MRIs for each patient to monitor for ARIA-E and ARIA-H lesion side effects. These brain MRIs for side effect monitoring inform the physician whether the patient can continue the Alzheimer's therapy for the treatment of the disease.
- ✓ For body exams, the 3.0T scan enables free-breathing high-resolution magnetic resonance cholangiopancreatography (MRCP) to pancreatic and pelvic studies to diagnose pancreatic cancer, pancreatitis, gallstones, and bile duct problems.
- ✓ Orthopedic physicians prefer the 3.0T for smaller structures to exam ligament tears to cartilage degeneration.

The distinct capabilities of the 3T have become even more necessary in recent years, as Alzheimer's and prostate cancer diagnoses continue to rise. For instance, according to the Alzheimer's Association, 10.9 percent of individuals age 65 and older have been diagnosed with Alzheimer's. Similarly, one in eight men will be diagnosed with prostate cancer during his lifetime.

Differences in 1.5T and 3.0T MRI Technology

While 3.0T MRI technology has become more widespread in recent years, the majority of MRI units currently in use are 1.5T units. When comparing 1.5T with 3.0T MRI technology, field strength is the biggest difference. According to Radiology Today, a 1.5T MRI system is approximately 30,000 times stronger than the Earth's magnetic field, whereas a 3.0T MRI system is double that. 3.0T systems allow for higher signal to noise ratio as well as increased image resolution capabilities, which is crucial for MRI imaging.

Benefits of a 3.0T MRI scanner over a 1.5T MRI scanner are particularly distinct for clinical areas such as neuroradiology and musculoskeletal studies. In these cases, 3.0T MRI technology gives higher resolution images and more possibilities to do advanced work like looking at degenerative diseases, brain connectivity, or sports medicine. As a result, 3.0T MRI technology is quickly becoming the standard of care for neurological diseases and disorders.

Finally, the proposed 3.0T scanner promotes cost efficient energy management with a power management system that disables power-consuming components during scan breaks, resulting in up to 30 percent energy savings compared to the industry average. This

proposed innovative imaging technology will promote high quality clinical care and outcomes, foster patient safety and satisfaction, and encourage optimal operational efficiencies.

Overview of Three-County Area

The proposed service area for AHI of Knoxville will be Knox, Blount and Loudon Counties. The service area is currently home to nearly 700,000 total residents in 2025 and is projected to grow to more than 720,000 residents by 2029. The three-county area currently accounts for approximately 9.7 percent of the total population of Tennessee. **Figure 1N-1** shows the 2025-2029 population in the proposed service area.

Figure 1N-1
2025-2029 AHI of Knoxville Service Area Population

County	2025	2029	Actual Growth	CAGR
Knox	497,744	514,586	16,842	0.8%
Blount	141,393	146,200	4,807	0.8%
Loudon	58,536	61,179	2,643	1.1%
Three County Total	697,673	721,965	24,292	0.9%

Source: Boyd Center for Business and Economic Research, University of Tennessee, Knoxville.

The proposed ODC will serve all patients, but will primarily adult patients. In 2025, the service area is home to more than 553,000 adult residents (ages 18 and over) and is projected to increase to more than 573,000 in the next four years. The growth in the adult population in the proposed service area is projected to outpace statewide growth between 2025 and 2029, with the service area increasing by 3.5% while Tennessee's adult population is only projected to increase by just 3.1% during the same period.

It is important to note that high school sports are very active and important, particularly in Knox County. As a result, AHI of Knoxville expects that it will receive referrals of high school athletes in need of imaging studies resulting from sports injuries. According to the state demographer, there are more than 33,000 residents of Knox County who fall into ages 15-19.

The service area population's median age differs by county, with Knox County's population being notably younger than both Blount and Loudon's populations. The median age of the Knox County population is 37.3 years, with Blount's median age at 43.9 years and Loudon's at 48.7

years. Knox County is more in line with the overall median average of the state of Tennessee, which is 38.9 years.

The proposed three-county service area has a strong economy, as well as strong socio-economic indicators. Currently, the median household income of Knox County (\$71,662) is consistent with the statewide average (\$67,097). Blount and Loudon have higher median household income than Knox at \$74,607 and \$80,296, respectively. Knox County's poverty rate (13.8%) is consistent with the state of Tennessee (14.0%), while Blount and Loudon have slightly lower rates of poverty. Finally, the service area's rate of TennCare enrollees is lower than the state average.

Overall, the proposed three-county service area has a large and growing population that will continue to drive the need for outpatient imaging services, including MRI.

Historical Utilization of Existing Service Area MRI Units

There are currently 34 MRI units in the three-county area. The units are located primarily in hospitals or hospital-based outpatient centers, with some units located in private physician offices. There are very few ODCs in the area and the ODCs that exist are affiliated with area hospitals. **Figure 1N-2** provides a current inventory of MRI units throughout the three-county area.

Figure 1N-2
Inventory of Three-County Service Area MRI Units

Provider	County	Provider Type	2023 No of Units
Abercrombie Radiology	Knox	RPO	1
Summit Medical Group	Knox	PO	2
Summit Medical Group - Midlake	Knox	PO	1
Covenant Health Dx Center West	Knox	HODC	1
Covenant Health Dx Center South	Knox	ODC	1
East TN Children's Hospital	Knox	HOSP	1
East TN Community Open MRI	Knox	ODC	2
Fort Sanders Regional Med Ctr	Knox	HOSP	2
Knoxville Comprehensive Breast Ctr	Knox	PO	2
North Knoxville Medical Center	Knox	HOSP	1
OrthoTN - Knox County	Knox	PO	2
OrthoTN - Knox Accelerator Way	Knox	PO	1
OrthoTN - Knox Dannaher Lane	Knox	PO	1
Parkwest Medical Center	Knox	HOSP	2
TN Orthopaedic Clinics - Parkwest MRI	Knox	PO	1
TN Orthopaedic Clinics - Regional MRI	Knox	PO	1
Turkey Creek Medical Center	Knox	HOSP	1
University Dx Hall of Fame	Knox	ODC	2
University Dx Halls	Knox	ODC	1
University of TN Medical Center	Knox	HOSP	5
Knox County Subtotal			31
Fort Loudon Medical Center	Loudon	HOSP	1
Loudon County Subtotal			1
Blount Memorial Hospital	Blount	HOSP	1
East TN Medical Group	Blount	PO	1
Blount County Subtotal			2
Total, All Units in Three-County Area			34

Sources: TN HFC Medical Equipment Utilization Reports 10/2/2024; Joint Annual Reports.

The 34 existing MRI units are highly utilized, with increasing utilization over the past three years for which data is available (2021-2023). **Figure 1N-3** shows the annual number of MRI scans performed by area MRI units in 2021, 2022 and 2023, as well as the compound annual growth rate for the period.

Figure 1N-3
2021-2023 Three-County Service Area MRI Utilization

	MRI Scans			
	2021	2022	2023	CAGR
Knox	93,060	86,816	110,883	9.2%
Blount	9,625	10,114	11,073	7.3%
Loudon	2,143	2,434	2,498	8.0%
Three-County Total	104,828	99,364	124,454	9.0%

Sources: TN HFC Equipment Utilization Report.

Utilization is high and increasing, with associated use rates increasing, as well. In 2021, the number of MRI scans per 1,000 population in Knox County (which accounts of the majority of scans in the service area) was 193.3 scans per 1,000. By 2023, the use rate had increased by approximately 17% to 226.5 scans per 1,000 population. Overall, the three-county use rate is increasing, which is indicative of the continued demand for MRI services in the area. **Figure 1N-4** details the three-year use rates per 1,000 population by county for the proposed AHI of Knoxville service area.

Figure 1N-4
2021-2023 MRI Scans per 1,000 Population
AHI of Knoxville Proposed Three-County Service Area

	MRI Scans					Total Population					Use Rate per 1,000 Pop		
	2021	2022	2023	CAGR		2021	2022	2023	CAGR		2021	2022	2023
Knox	93,060	86,816	110,883	9.2%		481,352	485,407	489,496	0.8%		193.3	178.9	226.5
Blount	9,625	10,114	11,073	7.3%		136,715	137,872	139,039	0.8%		70.4	73.4	79.6
Loudon	2,143	2,434	2,498	8.0%		55,986	56,615	57,250	1.1%		38.3	43.0	43.6
Three-County Total	104,828	99,364	124,454	9.0%		674,053	679,894	685,785	0.9%		155.5	146.1	181.5

Sources: TN HFC Equipment Utilization Report; Boyd Center for Business and Economic Research, University of Tennessee, Knoxville.

Overall, area MRI units are very highly utilized and there is a need for additional capacity in the area. Additionally, there is a lack of freestanding ODCs in the area. The proposed AHI of Knoxville ODC will increase access to MRI and other imaging services in a lower cost setting with often quicker access for patients.

Projected Utilization

In order to project utilization, three-county area MRI scans were forecasted to increase conservatively at the projected compound annual growth rate of the area population by

county from 2025-2029. Additionally, AHI of Knoxville assumed utilization levels (MRI scans per day) consistent with other comparable markets served by the applicant's related entities. **Figure 1N-5** shows the projected market MRI scans projected into the future, including the first three years of operation of the proposed MRI unit (2026-2028).

Figure 1N-5
Projected Market MRI Scans
AHI of Knoxville Three-County Service Area

					<i>Year 1</i>	<i>Year 2</i>	<i>Year 3</i>
County	2023 MRI Scans	2025-2029 Pop CAGR	2024	2025	2026	2027	2028
Knox	110,883	0.8%	111,809	112,743	113,685	114,635	115,593
Blount	11,073	0.8%	11,166	11,260	11,354	11,449	11,546
Loudon	2,498	1.1%	2,526	2,554	2,582	2,611	2,640
Three-County Total	124,454		125,501	126,557	127,621	128,695	129,779

AHI of Knoxville utilized both internal data regarding ramp up and utilization of MRI units in similar markets, including average scans per day in order to project its annual volume of MRI scans. **Figure 1N-6** below shows the projected utilization for AHI of Knoxville's proposed 3.0T MRI unit.

Figure 1N-6
Projected MRI Utilization, Years 1-3
AHI of Knoxville

	Year 1	Year 2	Year 3
MRI Scans	1,820	2,340	2,990

The projected utilization of AHI of Knoxville's proposed 3.0T MRI unit results in very conservative market share of the three-county area's projected MRI scans. **Figure 1N-7** shows the resulting market share based on AHI of Knoxville's internal ramp up and utilization projections.

Figure 1N-7
Projected MRI Market Share, Years 1-3
AHI of Knoxville

	Year 1	Year 2	Year 3
Market MRI Scans	127,621	128,695	129,779
AHI of Knoxville Scans	1,820	2,340	2,990
Market Share	1.4%	1.8%	2.3%

The projected ODC will bring much needed MRI capacity to the market and will provide a truly freestanding setting for patients, which will increase access to affordable MRI scans for residents of the three-county area. The need for additional capacity is evident based on the exceedingly high utilization of existing units in each of the three counties, as well as the lack of truly freestanding ODCs in the market.

- b. Providers proposing a new non-Specialty mobile MRI service should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.

Response: Not applicable. The proposed project is not a mobile MRI service.

- c. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.

Response: Not applicable. The applicant projects that it will meet the standard number of procedures required under Criterion 1a, above.

- d. Mobile MRI units shall not be subject to the need standard in paragraph 1 b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's Service Area are not adequate and/or that there are special circumstances that require these additional services.

Response: Not applicable. The proposed project is not a mobile MRI service.

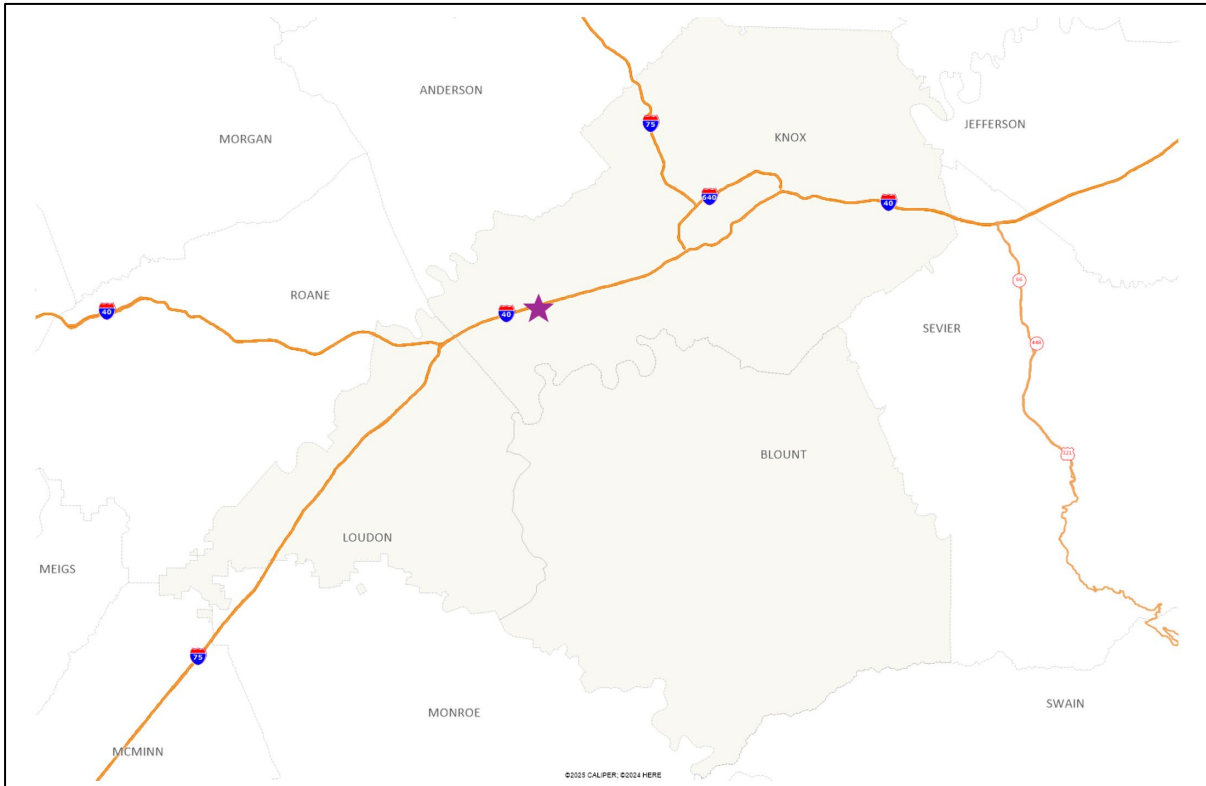
- e. Hybrid MRI Units. The HSDA may evaluate a CON application for an MRI "hybrid" Unit (an MRI Unit that is combined/utilized with another medical equipment such as a megavoltage radiation therapy unit or a positron emission tomography unit) based on the primary purposes of the Unit.

Response: Not applicable. The proposed project is not a hybrid MRI unit.

2. Access to MRI Units. All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the Service Area's population. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRI units that service the non-Tennessee counties and the impact on MRI 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 that data are available).

Response: The proposed MRI unit will be easily accessible to residents of the proposed three-county service area. AHI of Knoxville will be located at 326 Lovell Road, which is located just off I-40 at TN 131 near the Parkside Greenway in the Turkey Creek area of western Knoxville/Knox County. **Figure 1N-8** shows the proposed location of AHI of Knoxville within the proposed service area.

Figure 1N-8
Proposed AHI of Knoxville Location
Within Three-County Service Area



Knox County is currently home to nearly half a million residents. In total, the three-county service area is home to approximately 700,000 residents in 2025. By 2029, the population is expected to increase to more than 721,000. The rate of population growth in the service area is projected to outpace statewide population growth during the same period.

Knox County is the proposed location for AHI of Knoxville. Knox County accounts for more than 70% of the service area population in 2025. It is approximately 27 miles from the proposed AHI of Knoxville location to the extreme eastern edge of Knox County, meaning that the majority of Knox County population is located less than 27 miles away from the proposed center. Additionally, Blount and Loudon are located to the south of central and western Knox County, proximate to the proposed center.

The proposed location is widely accessible to service area ZIP Codes. In fact, the average drive time from the geographic center of service area ZIP Codes to 326 Lovell Road is

slightly less than 25 minutes, with many ZIP Codes within a 15-20 minute drive time. **Figure 1N-9** shows the weekday midday driving distances and times from service area ZIP Codes to the proposed AHI of Knoxville ODC.

Figure 1N-9
Driving Distances and Times from Service Area ZIP Codes
To AHI of Knoxville

ZIP Code	County	To: 326 Lovell Road	
		Miles	Minutes
37721	Knox	27.8	34
37754	Knox	26.1	30
37806	Knox	28.7	34
37849	Knox	21.4	26
37902	Knox	14.4	18
37909	Knox	8.3	15
37912	Knox	15.8	19
37914	Knox	25.6	29
37915	Knox	16.1	22
37916	Knox	15.3	21
37917	Knox	16.8	22
37918	Knox	19.8	27
37919	Knox	11.8	20
37920	Knox	19.6	30
37921	Knox	11.5	20
37922	Knox	6.4	13
37923	Knox	4.5	10
37924	Knox	23	26
37929	Knox	14.7	21
37930	Knox	5.2	12
37931	Knox	6.9	15
37932	Knox	7.1	13
37934	Knox	3.5	9
37938	Knox	26	37
37995	Knox	9.3	15
37996	Knox	13.9	17
37997	Knox	15.6	18
37998	Knox	28.1	38
37701	Blount	18.4	24
37737	Blount	23.5	31
37777	Blount	19.4	25
37801	Blount	30.6	44
37803	Blount	28.3	39
37804	Blount	19.4	26
37853	Blount	17	21
37882	Blount	42	59
37742	Loudon	25.6	36
37771	Loudon	12.3	14
37772	Loudon	10.7	20
37774	Loudon	23.9	27
37846	Loudon	30.3	37
Average Minutes		24.7	

Source: GoogleMaps; weekday midday; fastest route.

The proposed imaging center will be easily accessible for the service area population.

3. Economic Efficiencies. All applicants for any proposed new MRI Unit should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

Response: In an environment of increasingly higher patient co-pays and deductibles, the applicant complements existing hospital-based and HOPD imaging services such as MRI and CT. Shifting clinically appropriate imaging services from the hospital setting to the freestanding imaging setting will enhance scheduling and operational efficiencies while achieving cost containment, as freestanding imaging centers do not carry the costly overhead required for 24/7 care at hospitals. Furthermore, Medicare has long incentivized its patients to use freestanding imaging centers such as the applicant through lower patient co-pays and deductibles.

Recently, major commercial payors have instituted site of care medical necessity requirements. For example, some payors will no longer reimburse for advanced radiology imaging procedures like CT and MRI at HOPDs unless patients are at higher risk such as pediatric or obstetrical patients or those with a known contrast allergy. Thus, there is a demand for the MRI and CT services that will be offered at American Health Imaging of Knoxville, and for a wide range of procedures that are more appropriate for the proposed state-of-the-art equipment in the outpatient setting.

Additionally, the project will bring a 3.0T MRI unit to the service area, in an independent, non-hospital-affiliated ODC. 3.0T MRI services provide faster scan time, increased accuracy/fewer rescans, and enhanced capabilities for a wide range of conditions.

4. Need Standard for non-Specialty MRI Units.

A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelvemonth period reflected in the provider medical equipment report maintained by the HSDA. The total capacity **per MRI unit is based upon the following formula:**

Stationary MRI Units: 1.20 procedures per hour x twelve hours per day x 5 days per week x 50 weeks per year = 3,600 procedures per year

Mobile MRI Units: **Twelve (12) procedures per day** x days per week in operation x 50 weeks per year. For each **day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.**

Response: Knox County has a mix of hospital, physician office and ODC imaging centers, but no ODC located in Turkey Creek, which is the fastest growing area of Knoxville. Additionally, all of the ODC's affiliated with hospitals and are not truly freestanding facilities. Neither Loudon, nor Blount have any freestanding ODC MRI units. In Loudon, the only MRI unit is hospital-based and in Blount, there is one hospital-based unit and one physician office practice-based unit. The MRI units are highly utilized and accommodated more than 124,000 scans in 2023. **Figure 1N-10** shows the most recent three years' utilization for all MRI units in the proposed three-county service area.

Figure 1N-10
2021-2023 MRI Unit Utilization Summary
All MRI Units in Knox, Blount and Loudon Counties

Provider	County	Provider Type	2023 No of Units	MRI Procedures			2021-2023 Growth
				2021	2022	2023	
Abercrombie Radiology	Knox	RPO	1	2,857	2,240	2,700	(157)
Summit Medical Group	Knox	PO	2	3,207	3,220	4,653	1,446
Summit Medical Group - Midlake	Knox	PO	1	3,069	3,201	3,176	107
Covenant Health Dx Center West	Knox	HODC	1	486	625	740	254
Covenant Health Dx Center South	Knox	ODC	1	NA	NA	288	NA
East TN Children's Hospital	Knox	HOSP	1	3,762	4,061	4,995	1,233
East TN Community Open MRI	Knox	ODC	2	4,118	3,637	3,433	(685)
Fort Sanders Regional Med Ctr	Knox	HOSP	2	9,215	9,839	10,136	921
Knoxville Comprehensive Breast Ctr	Knox	PO	2	2,676	2,576	2,110	(566)
North Knoxville Medical Center	Knox	HOSP	1	4,141	3,517	3,541	(600)
OrthoTN - Knox County	Knox	PO	2	9,252	8,247	7,806	(1,446)
OrthoTN - Knox Accelerator Way	Knox	PO	1	NA	1,538	4,364	NA
OrthoTN - Knox Dannaher Lane	Knox	PO	1	NA	4,398	4,756	NA
Parkwest Medical Center	Knox	HOSP	2	9,863	9,784	10,507	644
TN Orthopaedic Clinics - Parkwest MRI	Knox	PO	1	4,696	5,305	4,552	(144)
TN Orthopaedic Clinics - Regional MRI	Knox	PO	1	1,022	429	1,861	839
Turkey Creek Medical Center	Knox	HOSP	1	3,100	3,097	3,401	301
University Dx Hall of Fame	Knox	ODC	2	11,254	NA	11,573	319
University Dx Halls	Knox	ODC	1	NA	NA	2,868	NA
University of TN Medical Center	Knox	HOSP	5	20,342	21,102	23,423	3,081
Fort Loudon Medical Center	Loudon	HOSP	1	2,143	2,434	2,498	355
Blount Memorial Hospital	Blount	HOSP	1	5,382	5,950	6,396	1,014
East TN Medical Group	Blount	PO	1	4,243	4,164	4,677	434
Total, All Units in Three-County Area			34	104,828	99,364	124,454	19,626

Sources: TN HFC Medical Equipment Utilization Reports 10/2/2024; Joint Annual Reports.

As shown in the Figure, MRI utilization increased significantly from 2021 to 2023. It is reasonable to assume that it will continue to increase into the future.

The Certificate of Need Standards and Criteria for MRI units set forth a minimum aggregate volume threshold of 2,880 MRI scans per unit per year. In 2023, the most recent twelve-month period reflected in the medical equipment report, the combined average utilization of Knox County units was 3,577 and the combined average utilization of Blount County units was 5,537, meaning that the minimum volume was met in both counties. Further, in Loudon County, the combined average utilization was 2,498 scans, which is very close the minimum volume threshold. **Figure 1N-11** shows the 2023 utilization per unit for all MRI units in the proposed three-county service area and the county-level aggregate utilization for Knox, Blount and Loudon Counties.

Figure 1N-11
2023 MRI Scans per Unit
All MRI Units in Knox, Blount and Loudon Counties

Provider	County	Provider Type	2023 No of Units	MRI Procedures	
				2023 Scans	2023 Per Unit
Abercrombie Radiology	Knox	RPO	1	2,700	2,700
Summit Medical Group	Knox	PO	2	4,653	2,327
Summit Medical Group - Midlake	Knox	PO	1	3,176	3,176
Covenant Health Dx Center West	Knox	HODC	1	740	740
Covenant Health Dx Center South	Knox	ODC	1	288	288
East TN Children's Hospital	Knox	HOSP	1	4,995	4,995
East TN Community Open MRI	Knox	ODC	2	3,433	1,717
Fort Sanders Regional Med Ctr	Knox	HOSP	2	10,136	5,068
Knoxville Comprehensive Breast Ctr	Knox	PO	2	2,110	1,055
North Knoxville Medical Center	Knox	HOSP	1	3,541	3,541
OrthoTN - Knox County	Knox	PO	2	7,806	3,903
OrthoTN - Knox Accelerator Way	Knox	PO	1	4,364	4,364
OrthoTN - Knox Dannaher Lane	Knox	PO	1	4,756	4,756
Parkwest Medical Center	Knox	HOSP	2	10,507	5,254
TN Orthopaedic Clinics - Parkwest MRI	Knox	PO	1	4,552	4,552
TN Orthopaedic Clinics - Regional MRI	Knox	PO	1	1,861	1,861
Turkey Creek Medical Center	Knox	HOSP	1	3,401	3,401
University Dx Hall of Fame	Knox	ODC	2	11,573	5,787
University Dx Halls	Knox	ODC	1	2,868	2,868
University of TN Medical Center	Knox	HOSP	5	23,423	4,685
Knox County Subtotal			31	110,883	3,577
Fort Loudon Medical Center	Loudon	HOSP	1	2,498	2,498
Loudon County Subtotal			1	2,498	2,498
Blount Memorial Hospital	Blount	HOSP	1	6,396	6,396
East TN Medical Group	Blount	PO	1	4,677	4,677
Blount County Subtotal			2	11,073	5,537
Total, All Units in Three-County Area			34	124,454	3,660

Sources: TN HFC Medical Equipment Utilization Reports 10/2/2024; Joint Annual Reports.

As shown in the Figure, MRI units in the three-county area are highly utilized. In 2023, the three-county units' aggregate utilization was 3,660 per unit, which exceeds both the total utilization standard (3,600) and the optimal utilization standard (2,880). There is clearly a need for increased access to MRI services in the three-county area. The proposed ODC in Knox County will increase access to freestanding MRI and other imaging services for residents of the area.

5. Need Standards for Specialty MRI Units.

- a. Dedicated fixed or mobile Breast MRI Unit. An applicant proposing to **acquire a dedicated fixed or mobile breast MRI unit shall not receive a CON to use the MRI unit for non-dedicated purposes and shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:**
 1. It has an **existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound, and MM unit equipment, and** that is trained to interpret images produced by an MRI unit configured exclusively for mammographic studies;
 2. Its existing **mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit are in compliance with the federal Mammography Quality Standards Act;**
 3. It is part of or has a formal affiliation with an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is **based in the proposed service area.**
 4. It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, **and primary care providers.**

Response: Not applicable. The proposed project does not include a specialty MRI unit.

- b. Dedicated fixed or mobile Extremity MR1 Unit. An applicant proposing to institute a Dedicated fixed or mobile Extremity MR1 Unit shall provide

documentation of the total capacity of the proposed MR1 Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MR1 procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Extremity MRI Unit and a CON granted for this use should so state on its face.

Response: Not applicable. The proposed project does not include a dedicated fixed or mobile extremity MRI unit.

- c. Dedicated fixed or mobile Multi-position MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Multi-position MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Multi-position MRI Unit and a CON granted for this use should so state on its face.

Response: Not applicable. The proposed project does not include a dedicated fixed or mobile multi-position MRI unit.

6. Separate Inventories for Specialty MRI Units and non-Specialty MRI Units. If data availability permits, Breast, Extremity, and Multi-position MRI Units shall not be counted in the inventory of non-Specialty fixed or mobile MRI Units, and an inventory for each category of Specialty MRI Unit shall be counted and maintained separately. None of the Specialty MRI Units may be replaced with non-Specialty MRI fixed or mobile MRI Units and a Certificate of Need granted for any of these Specialty MRI Units shall have included on its face a statement to that effect. A non-Specialty fixed or mobile MRI Unit for which a CON is granted for Specialty MRI Unit purpose use-only shall be counted in the specific Specialty MRI Unit inventory and shall also have stated on the face of its Certificate of Need that it may not be

used for non-Specialty MRI purposes.

Response: The proposed project is for a non-specialty MRI unit. Currently, there are 34 such units in the proposed service area, the majority of which (31) are located in Knox County. The non-specialty MRI units in the proposed service area are highly utilized, with the aggregate utilization in both Knox and Blount exceeding the optimal utilization standard for the most recent year (2023). Additionally, the one hospital-based unit in Loudon County is very highly utilized at 2,498 scans in 2023, which is close to the minimum volume threshold.

7. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRI Unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed MRI Unit for clinical use.

Response: A letter showing FDA approval for the proposed MRI unit is provided in **Attachment 1N1**.

- b. The applicant should demonstrate that the proposed MRI Procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

Response: The proposed MRI unit will be installed in an existing office building at 326 Lovell Road, Knoxville, Tennessee, 37934. The applicant proposes to lease 4,704 square feet of space to establish the center. Proposed renovation of the rentable square footage will conform to all applicable federal standards, manufacturer's specifications and licensing agencies' requirements.

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

Response: AHI staff members are trained to perform emergency response procedures. For patients experiencing an emergency that exceeds staff expertise, local EMS will be called to transport the patient to a hospital emergency department. AHI of Knoxville staff will attempt to stabilize the patient until EMS arrival.

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

other services.

Response: Consistent with other AHI imaging centers, AHI of Knoxville will implement guidelines and protocols for ensuring that MRI procedures are medically necessary. Additionally, most insurance companies require prior authorization for imaging procedures such as MRI. Insurance company approval for an MRI scan indicates medical necessity or clinically appropriate treatment. A copy of AHI's policy for Ordering Exams is provided in **Attachment 1N7d**. The policy's purpose is: To establish written guidelines for the order of diagnostic tests by treating physicians and practitioners. The policy also states: orders must be provided in writing by the physician treating the beneficiary, i.e., the physician furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in managing the beneficiary's specific medical problem. AHI of Knoxville will implement the AHI policy and will ensure that all MRI tests are medically necessary and will not unnecessarily duplicate other services.

- e. An applicant proposing to acquire any MRI Unit or institute any MRI service, including Dedicated Breast and Extremity MRI Units, shall demonstrate that it meets or is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, including staff education and training programs.

Response: AHI is a large, multi-state imaging company with a long history of quality of care. Additionally, AHI has numerous programs in place to ensure that it recruits and retains highly qualified staff to provide care within its numerous imaging centers. AHI centers maintain accreditation by the American College of Radiology and the proposed center will follow the same staffing guidelines as other AHI facilities.

The applicant will offer competitive salaries and benefits and will be committed to minimizing turnover through educational opportunities and other benefits. Staff members will be recruited through a variety of channels, including in-house listings of available positions, local and regional newspaper listings, advertisements in professional publications and recruitment through local training programs as well as colleges.

- f. All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.

Response: American Health Imaging has a history of the provision of high-quality

imaging. The organization's imaging center's existing CT and MRI programs are accredited by the Intersocietal Accreditation Commission (IAC), which is a nonprofit organization in operation to evaluate and accredit facilities that provide diagnostic imaging and procedure-based modalities, thus improving the quality of patient care provided in private offices, clinics, and hospitals where such services are performed. The proposed imaging center will also participate in this accreditation process.

- g. 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 transfer agreement hospital medical staff.

Response: In the unlikely event of an emergency, AHI staff will use 911 emergency services to initiate a transfer of patients who need care in a hospital emergency room. AHI staff members are trained to perform emergency response procedures. For patients experiencing an emergency that exceeds staff expertise, local EMS will be called to transport the patient to a hospital emergency department. AHI of Knoxville staff will attempt to stabilize the patient until EMS arrival.

- 8. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

Response: AHI of Knoxville will submit all data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

- 9. 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: According to the Health Resources and Services Administration, Knox County is a medically underserved area, as are Blount and Loudon Counties. Specifically:

- Knox is a medically underserved area

- Blount is a medically underserved area for low-income population; and
- Loudon is a non-rural medically underserved area.

American Health Imaging of Knoxville will provide services to all patients, regardless of their ability pay, and does not discriminate based upon race, gender, creed, nationality, or disability.

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

Response: Not applicable. The applicant proposes to develop an ODC and is not a safety net hospital or children's hospital.

- 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: AHI contracts with Medicaid Managed Care Organizations in the states in which it operates imaging centers. Additionally, AHI participates in the Medicare program. The proposed AHI of Knoxville ODC commits that it will contract with at least one TennCare MCO and will participate in the Medicare program.

- d. Who is proposing to use the MR1 unit for patients that typically require longer preparation and scanning times (e.g., pediatric, special needs, sedated, and contrast agent use patients). The applicant shall provide in its application information supporting the additional time required per scan and the impact on the need standard.

Response: Not applicable. The applicant does not propose to use the MRI unit for patients that typically require longer preparation and scanning times.

Rationale for Revised and Updated Standards and Criteria for Magnetic Resonance Imaging Services

Definitions

Specialty MRI Units. The Office of Health Planning recognizes that certain MR1 Units dedicated for breast, extremity, and multi-position purposes do not reach the level of utilization that standard MRI Units do. Consequently, definitions for these Specialty Units have been created and specific standards for each have been developed.

MRI Procedure. To provide for uniform procedure reporting, the Health Services and Development Agency is responsible for setting CPT code reporting requirements consistent with the definition of MRI Procedure. Research CPT codes are excluded from capacity and need calculations.

Capacity. The Office solicited operating schedule information from owners/operators of MRI Units. From this information, while total capacity of a non-Specialty MRI Unit could conceivably be based on an operating schedule of 24 hours per day, 7 days per week, usual practice does not cover such extended hours of operation. It appears that physician offices and outpatient diagnostic centers more usually operate their MRI Units Monday-Friday; inpatient facilities typically operate Monday-Friday, with the potential to operate on Saturdays as needed. There are exceptions, however, with both outpatient and inpatient MRI Units operating more than five days a week. Hours of operation vary and seem to not be dependent upon outpatient or inpatient use, usually from 12 to 16 hours per day. Utilization and operating practices can and do vary widely.

Additionally, from the information received, the length of time per scan varies depending on a variety of circumstances, including protocols in place, whether a patient is sedated or needs longer time to be placed in the unit, whether the scan is with or without contrast, etc. A scan may take as little as 30 minutes or as long as 80 (or more) minutes. Typically, due to sedation and/or contrast requirements, an inpatient facility will take longer to perform its scans. However, Tennessee does not collect sufficient data on these scans in order to develop a total capacity formula based on them.

We are basing a total non-Specialty MR1 unit capacity number on the performance of 1.20 scans per hour, Monday through Friday utilization, 12 hours a day, 50 weeks a year, for a total capacity number of 3,600. Using an 80% optimal efficiency number, we arrive at 2,880 as the number of scans a year that a typical stationary non-Specialty MRI Unit should be able to perform.

Standards and Criteria Regarding Certificate of Need Applications for Magnetic Resonance Imaging Services

- . Exceptions to Utilization Standards: Exceptions to the standard number of procedures has been retained for new or improved technology and diagnostic applications, and for mobile MRI Units in operation fewer than 150 days of service per year. Applications for hybrid MRI Units (e.g., MRI Units combined with PET Units or MRT Units) may be assessed under the primary use of the hybrid unit.
2. Other Access Issues: The provision of health care doesn't recognize state boundaries. Accordingly, applicants may include non-Tennessee counties in proposed service areas if that data are available.
3. Economic Efficiencies: To support the goal of reducing health care costs, applicants should document that other options have been investigated and found less advantageous.
4. Specialty **MRI** Units Standards: Dedicated Breast MRI Units have a proposed total capacity estimate of 2,000 procedures per year. Dedicated Extremity and Dedicated Multi-position MRI Units do not have a defined estimate; an applicant must demonstrate total capacity as well as its estimated annual utilization that, by the third year, will be at least 80% of total capacity.
5. Inventories: Given that there are proposed different standards for Specialty and non-Specialty MRI Units, separate inventories should be maintained. Additionally, a CON granted for the institution of a Specialty MRI Unit should not be permitted to be used for non-Specialty MRI purposes; it is recommended that any CON granted for Specialty MRI purposes so state on its face.
6. Quality of Care: Specific staffing, training, and education standards are included to help ensure patient safety and quality of care provided.

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

hsda.staff@tn.gov

LETTER OF INTENT

The Publication of Intent is to be published in The Knoxville News Sentinel which is a newspaper of general circulation in Knox, Loudon, and Blount Counties, Tennessee, Tennessee, on or before 08/14/2025 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 American Health Imaging of Knoxville, a/an Outpatient Diagnostic Center owned by American Health Imaging of Tennessee, 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 an outpatient diagnostic center to serve Knox, Loudon, and Blount counties, and it will provide MRI, CT, and ultrasound services. The address of the project will be 326 Lovell Road, Knoxville, Knox County, Tennessee, 37934. The estimated project cost will be \$5,913,239.

The anticipated date of filing the application is 08/29/2025

The contact person for this project is Attorney Rebecca Thornhill who may be reached at Maynard Nexsen PC - 4800 Old Kingston Pike, Knoxville Tennessee 37919 – Contact No. 865-686-5630.

Rebecca Thornhill

08/13/2025

rthornhill@maynardnexsen.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 .



**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

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 American Health Imaging of Knoxville, a/an Outpatient Diagnostic Center owned by American Health Imaging of Tennessee, 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 an outpatient diagnostic center to serve Knox, Loudon, and Blount counties, and it will provide MRI, CT, and ultrasound services. The address of the project will be 326 Lovell Road, Knoxville, Knox County, Tennessee, 37934. The estimated project cost will be \$5,913,239.

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The contact person for this project is Attorney Rebecca Thornhill who may be reached at Maynard Nexsen PC - 4800 Old Kingston Pike, Knoxville Tennessee 37919 – Contact No. 865-686-5630.

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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

American Health Imaging of Knoxville

Name

326 Lovell Road

Knox County

Street or Route

County

Knoxville

Tennessee

37934

City

State

Zip

americanhealthimaging.com

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

Rebecca Thornhill

Attorney

Name

Title

Maynard Nexsen

RThornhill@maynardnexsen.com

Company Name

Email Address

4800 Old Kingston Pike, Suite 120

Street or Route

Knoxville

Tennessee

37919

City

State

Zip

Legal Counsel

865-686-5630

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: 08/13/25

Date LOI was Published: 08/13/25

RESPONSE: Attachment 3A provides a copy of the publication as proof of the publication of the letter of intent.

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)

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 -

Hospital -

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

American Health Imaging of Tennessee, LLC

Name

2200 Century Parkway NE, Suite 600

404-297-5202

Street or Route**Phone Number**

Atlanta

Georgia

30345

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: American Health Imaging of Tennessee, LLC (AHI TN), a Tennessee Limited Liability Corporation, is a wholly owned subsidiary of American Health Imaging, Inc. (AHI). AHI is wholly owned by Lumexa Imaging Outpatient, Inc. which is wholly owned by Lumexa Imaging Outpatient Intermediate Holdings, Inc. which is wholly owned by Lumexa Imaging Equity Holdco, LLC. Attachment 7A includes organizational documents, including articles of organization, organizational chart and operating agreement. The proposed center, AHI TN d/b/a American Health Imaging of Knoxville (AHI of Knoxville), will be one of over 45 imaging centers owned and/or operated by AHI. These centers are in Georgia, Alabama, Texas, South Carolina and Florida.

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
-

RESPONSE: The proposed Outpatient Diagnostic Center (“ODC”) will be located at 326 Lovell Road, Knoxville, TN 37934. The applicant has obtained an option to lease the proposed site. The option to lease includes the terms of the lease, including permitted use by the tenant, square footage, base rent, and lease term. The lessor will be Lovell Pointe, LLC, and American Health Imaging of Tennessee will be the lessee and the licensee of the ODC. Attachment 9A contains the Option to enter into the lease, conditioned on CON approval. It states the terms and anticipated expenses of the intended lease.

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: The proposed ODC will consist of 4,704 square feet of space on one level in a freestanding center. A copy of the floor plan is provided in Attachment 10A.

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: Response: The proposed ODC will be located at 326 Lovell Road, Knoxville, TN, 37934. The site is easily accessible via Lovell Road and I-40/75. The proposed location is just 1,000 feet from the intersection of I-40/75 and Lovell Road in the Turkey Creek commercial district of Knoxville. From a public transportation standpoint, the area is served by Knoxville Area Transit (“KAT”). KAT operates fixed route buses and paratransit service across the City of Knoxville and carries around 3 million passengers each year. While KAT fixed route buses do not currently travel to Lovell Road, KAT is introducing a new on-demand transportation service called katConnect. The on-demand transportation service operates similarly to ride-sharing services and will connect passengers to fixed-route services. Finally, the proposed location is near the Parkside Greenway, which is a two-mile pedestrian greenway that begins at Lovell Road (connecting to the road's sidewalk system that links to a multitude of restaurants), runs behind the Turkey Creek commercial district (with several connections to access the stores and restaurants along the way), and ends at the sidewalk system along Campbell Station Rd. Additionally, the

area around the proposed site experiences a significant volume of individual traveling past the site. In 2024 and 2025 the site, 326 Lovell Rd, experienced an average daily vehicle volume of over 40,000 per day.

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: Response: A site plan for the proposed ODC is provided in Attachment 12A

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:

Description: American Health Imaging of Tennessee, LLC proposes to develop an Outpatient Diagnostic Center in Knoxville (Knox County), under the facility name American Health Imaging of Knoxville, including the initiation of outpatient MRI service. The proposed ODC will offer a 3.0T MRI unit, CT, and ultrasound. The proposed ODC will be located at 326 Lovell Road in Knoxville, TN, 37934.

The proposed project is needed for a variety of reasons, including:

1. High utilization of existing MRI units in the area;
2. Lack of freestanding ODCs in the area; and
3. Enhanced technology offering, including a 3.0T MRI unit.

- Ownership structure

RESPONSE: Ownership Structure: American Health Imaging of Tennessee, LLC (AHI TN), a Tennessee Limited Liability Corporation, is a wholly owned subsidiary of American Health Imaging, Inc. (AHI). AHI is wholly owned by Lumexa Imaging Outpatient, Inc. which is wholly owned by Lumexa Imaging Outpatient Intermediate Holdings, Inc. which is wholly owned by Lumexa Imaging Equity Holdco, LLC.

- Service Area

RESPONSE: Service Area: The proposed service area for the project includes three counties: Knox County (the project location), as well as Blount and Loudon Counties, which are contiguous.

- Existing similar service providers

RESPONSE: Existing Similar Service Providers: Knox County has a mix of hospital, physician office and ODC imaging centers, but none located in Farragut which is the fastest growing area of Knoxville. Additionally, the aggregate utilization standard set forth in the Certificate of Need Standards and Criteria for Magnetic Resonance Imaging services is met in Knox County, indicating a need for access to additional MRI services. Neither Loudon, nor Blount have any freestanding ODC MRI units. In Loudon, the only MRI unit is hospital-based and in Blount, there is one hospital-based unit and one physician office practice-based unit. The proposed ODC in Knox County will increase access to freestanding MRI and other imaging services for residents of the area

- Project Cost

RESPONSE: Project Cost: \$5,913,239

- Staffing

RESPONSE: Staffing: The ODC will have five full-time employees, including an MRI tech, a CT tech, a center manager, a sales representative, and one patient service representative.

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: Response: American Health Imaging of Tennessee, LLC proposes to develop an Outpatient Diagnostic Center in Knoxville (Knox County), under the facility name American Health Imaging of Knoxville, to include the initiation of outpatient MRI service. The proposed ODC will offer a 3.0T MRI unit, CT, and ultrasound. The proposed ODC will be located at 326 Lovell Road in Knoxville, TN, 37934. Need: The proposed service area for the project includes three counties: Knox County (the project location), as well as Blount and Loudon Counties, which are contiguous. The proposed project is needed for a variety of reasons, including: 1. High utilization of existing MRI units in the area: a. The Certificate of Need Standards and Criteria for MRI units set forth an minimum aggregate volume threshold of 2,880 MRI scans per unit per year. b. In 2023, the most recent twelve-month period reflected in the medical equipment report, the combined average utilization of Knox County units was 3,696 and the combined average utilization of Blount County units was 5,537, meaning that the minimum volume was met in both counties. c. Further, in Loudon County, the combined average utilization was 2,498 scans, which is approaching the minimum volume threshold. 2. Lack of freestanding ODCs in the area: a. Knox County has a mix of hospital, physician office and ODC imaging centers, but no ODC located in Farragut, which is the fastest growing area of Knoxville. Additionally, all but one of the ODC's are affiliated with hospitals and are not truly freestanding facilities. b. Neither Loudon nor Blount have any freestanding ODC MRI units. In Loudon, the only MRI unit is hospital-based and in Blount, there is one hospital-based unit and one physician office practice-based unit. c. The proposed ODC in Knox County will increase access to freestanding MRI and other imaging services for residents of the area. 3. Enhanced technology offering, including a 3.0T MRI unit: AHI TN intends to install Siemens MAGNETOM Lumina MRI system. This unit is particularly notable with its unique, high performance 3.0T clinical technology. This particular technology embraces the unique set of challenges each patient brings to the exam and overcomes patient variability, resulting in fewer rescans, predictable scheduling, and personalized exams as well as cost efficient energy management. This proposed innovative imaging technology will promote high quality clinical care and outcomes, foster patient safety and satisfaction, and encourage optimal operational efficiencies. The 3.0T technology has become the standard of care for diagnosing and monitoring the progression of numerous neurological disorders, including Alzheimer's, Multiple Sclerosis, Epilepsy, and Parkinsonism. 3T imaging is also uniquely suited to the early detection of prostate cancer, advanced breast imaging, and the evaluation of small orthopedic joints.

- Quality Standards

RESPONSE: Quality Standards: AHI has a history of the provision of high-quality imaging care, and this same level of care will be offered at American Health Imaging of Knoxville. The imaging center's MRI and CT programs will be accredited by the Intersocietal Accreditation Commission, which is a nonprofit organization in operation to evaluate and accredit facilities that provide diagnostic imaging and procedure-based modalities, thus improving the quality of patient care provided in private offices, clinics, and hospitals where such services are performed.

- Consumer Advantage

- Choice

RESPONSE: 1. Choice: The proposed freestanding ODC will provide increased access to outpatient imaging services and in a lower cost environment than hospital-based outpatient imaging centers. Additionally, physician practice-based MRI units are typically inaccessible to patients outside of the practice.

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

RESPONSE: 2. Improved Access/Availability to Health Care Services: The proposed ODC will offer a 3.0T MRI scanner in a low cost, freestanding setting. The proposed ODC would make imaging services more readily available for patients who due to payor mandates or limited financial resources, are faced with quality vs. cost decisions when selecting their imaging provider. Hospital based sites, which dominate the service area, are not alternatives for patients with site of service insurance coverage limitations that require non-emergent imaging services to be performed in a non-hospital, freestanding imaging center.

- Affordability

RESPONSE: 3. Affordability: The freestanding imaging setting promotes cost containment, as freestanding imaging centers do not carry the costly overhead required for 24/7 care at hospitals and hospital-based outpatient departments. The average cost of imaging services at a freestanding imaging center is up to 70% less than the cost of an imaging service at a hospital-based imaging service.

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	\$68,000
2. Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	\$50,000
3. Acquisition of Site	
4. Preparation of Site	
5. Total Construction Costs	\$1,157,256
6. Contingency Fund	\$115,726
7. Fixed Equipment (Not included in Construction Contract)	\$2,238,279
8. Moveable Equipment (List all equipment over \$50,000 as separate attachments)	\$100,000
9. Other (Specify): _____	

B. Acquisition by gift, donation, or lease:

1. Facility (inclusive of building and land)	\$2,170,703
2. Building only	
3. Land only	
4. Equipment (Specify): _____	
5. Other (Specify): _____	

C. Financing Costs and Fees:

1. Interim Financing	
2. Underwriting Costs	
3. Reserve for One Year's Debt Service	
4. Other (Specify): _____	

D. Estimated Project Cost (A+B+C)	\$5,899,964
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E. CON Filing Fee	\$13,275
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F. Total Estimated Project Cost (D+E)	\$5,913,239
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TOTAL

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:

Response: The applicant’s responses to the Certificate of Need Standards and Criteria for MRI Services and Outpatient Diagnostic Services are provided in **Attachment 1N**.

- 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:

Response: American Health Imaging of Tennessee, LLC proposes to develop an ODC, American Health Imaging of Knoxville, that will include MRI, CT and ultrasound services. The ODC will serve Knox County, as well as two contiguous counties: Blount and Loudon. **Figure 1** shows the proposed location of the AHI TN ODC within the proposed service area.

Figure 1

Service Area Map and Proposed Location of AHI of Knoxville ODC



The proposed service area is reasonable and there is a demonstrated need for additional MRI services in the area. There is currently a lack of freestanding ODCs in the proposed service area. Specifically, Knox County has a mix of hospital, physician office and ODC imaging centers, but none located in Farragut, which is the fastest growing area of Knoxville. Neither Loudon, nor Blount have any freestanding ODC MRI units. In Loudon, the only MRI unit is hospital-based and in Blount, there is one hospital-based unit and one physician office practice-based unit.

The Certificate of Need Standards and Criteria for MRI units set forth a minimum aggregate volume threshold of 2,880 MRI scans per unit per year. In 2023, the most recent twelve-month period reflected in the medical equipment report, the combined average utilization of Knox County units was 3,696 and the combined average utilization of Blount County units was 5,537, meaning that the minimum volume was met in both counties. Further, in Loudon County, the combined average utilization was 2,498 scans, which is approaching minimum volume threshold, even with a much smaller population than Knox and Blount counties. The proposed ODC in Knox County will increase access to freestanding MRI and other imaging services for residents of the area.

In 2023, there were 124,424 MRI scans in the proposed three-county service area, up from 104,738 in 2021 and 99,364 in 2022. The vast majority of service area MRI scans were performed on residents of Knox County.

Please see Attachment 2N for a county service area map

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

PROJECTED UTILIZATION

Unit Type:

- ☒ Procedures
☐ Cases
☐ Patients
☐ Other

Service Area Counties	Projected Utilization Recent Year 1 (Year =)	% of Total
Loudon	67	2.02%
Blount	295	8.90%
Knox	2,953	89.08%
Total	3,315	100%

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

RESPONSE:

Response: The proposed service area for AHI of Knoxville will be Knox, Blount and Loudon Counties. The service area is currently home to nearly 700,000 total residents in 2025 and is projected to grow to more than 720,000 residents by 2029. The three-county area currently accounts for approximately 9.7 percent of the total population of Tennessee. The proposed ODC will serve all patients, but will primarily adult patients, ages 18 and older. In 2025, the service area is home to more than 553,000 adult residents (ages 18 and over) and is projected to increase to more than 573,000 in the next four years. The growth in the adult population in the proposed service area is projected to outpace statewide growth between 2025 and 2029, with the service area increasing by 3.5% while Tennessee's adult population is only projected to increase by just 3.1% during the same period. Additionally, high school sports are an important part of the culture of Knoxville. As a result, AHI of Knoxville expects to provide imaging services to high school aged patients who have experienced a sports injury. There are currently more than 33,000 residents ages 15-19 who reside in Knox County.

Since 2020, the three-county area has experienced growth at a much higher rate than the state average. For 2020 to 2023, the compound annual growth rate (CAGR) ranged from 1.6 to 3.3 percent, with an average of 1.8 percent. During that same time period, the state experienced only a 1.1 CAGR.

The service area population's median age differs by county, with Knox County's population being notably younger than both Blount and Loudon's populations. The median age of the Knox County population is 37.3 years, with Blount's median age at 43.9 years and Loudon's at 48.7 years. Knox County is more in line with the overall median average of the state of Tennessee, which is 38.9 years.

The proposed three-county service area has a strong economy, as well as strong socio-economic indicators. Currently, the median household income of Knox County (\$71,662) is consistent with the statewide average (\$67,097). Blount and Loudon have higher median household income than Knox at \$74,607 and \$80,296, respectively. Knox County's poverty rate (13.8%) is consistent with the state of Tennessee (14.0%), while Blount and Loudon have slightly lower rates of poverty. Finally, the service area's rate of TennCare enrollees is lower than the state average.

Overall, the proposed three-county service area has a large and growing population that will continue to drive the need for outpatient imaging services, including MRI.

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:

Response: Specific demographic data for the service area, compared to the state of Tennessee, is provided in **Attachment 3N**.

- 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:

Response: According to data collected by the US Census Bureau, there are an estimated 88,550 persons living in poverty. Additionally, 9.8% of Knox County residents, 11.3% of Blount County residents and 11.2% of Loudon County residents under the age of 65 do not have health insurance. Based on current Census data, this means that nearly 60,000 service area residents under the age of 65 are uninsured.

American Health Imaging of Knoxville will provide services to all patients, regardless of their ability to pay, and will not discriminate based upon race, gender, creed, nationality, or disability. American Health Imaging of Knoxville will operate in the same manner as other AHI facilities and will provide financial counseling, payment plans and other opportunities for financial assistance for patients. The proposed ODC's administrative staff will describe prospective charges to each patient when the patient arrives at the facility. The staff will explain the billing process to each patient and answer any questions the patient may have either regarding billing or the procedure itself. If a patient is uninsured and financially indigent, the patient will be offered consideration pursuant to the facility's financial policies. The patient's insurance or ability to pay status is usually documented during the pre-appointment process with the referring physician's office so the patient avoids repeating the registration process upon arrival at the imaging center.

- 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:

Response: There are no approved and unimplemented MRI units or ODCs located in the proposed service area. It appears that the last approval was University Diagnostics – Halls, which was approved in 2022 and became operational in 2023.

There are 33 operational MRI units located in the proposed three-county service area, 30 of which are located in Knox County. **Attachment 5N** provides a three-year summary of utilization for all existing MRI units in the proposed service area.

- 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:

Response: The applicant is a new entity with no utilization history in Tennessee. However, AHI has a long history of the provision of high quality imaging services for residents of neighboring states. Overall, area MRI units are very highly utilized and there is a need for additional capacity in the area. Additionally, there is a lack of freestanding ODCs in the area. The proposed AHI of Knoxville ODC will increase access to MRI and other imaging services in a lower cost setting with often quicker access for patients.

Projected Utilization

In order to project utilization, three-county area MRI scans were forecasted to increase conservatively at the projected compound annual growth rate of the area population by county from 2025-2029. Additionally, AHI of Knoxville assumed utilization levels (MRI scans per day) consistent with other comparable markets served by the applicant's related entities. The figure below shows the projected market MRI scans projected into the future, including the first three years of operation of the proposed MRI unit (2026-2028).

Projected Market MRI Scans

AHI of Knoxville Three-County Service Area

					<i>Year 1</i>	<i>Year 2</i>	<i>Year 3</i>
County	2023 MRI Scans	2025-2029 Pop CAGR	2024	2025	2026	2027	2028
Knox	110,883	0.8%	111,809	112,743	113,685	114,635	115,593
Blount	11,073	0.8%	11,166	11,260	11,354	11,449	11,546
Loudon	2,498	1.1%	2,526	2,554	2,582	2,611	2,640
Three-County Total	124,454		125,501	126,557	127,621	128,695	129,779

AHI of Knoxville utilized both internal data regarding ramp up and utilization of MRI units in similar markets, including average scans per day in order to project its annual volume of MRI scans. The following figure shows the projected utilization for AHI of Knoxville's proposed 3.0T MRI unit.

Projected MRI Utilization, Years 1-3

AHI of Knoxville

	Year 1	Year 2	Year 3
MRI Scans	2,340	2,600	2,990

The projected utilization of AHI of Knoxville's proposed 3.0T MRI unit results in very conservative market share of the three-county area's projected MRI scans. The following figure shows the resulting market share based on AHI of Knoxville's internal ramp up and utilization projections.

Projected MRI Market Share, Years 1-3**AHI of Knoxville**

	Year 1	Year 2	Year 3
Market MRI Scans	127,621	128,695	129,779
AHI of Knoxville Scans	2,340	2,600	2,990
Market Share	1.8%	2.0%	2.3%

The projected ODC will bring much needed MRI capacity to the market and will provide a truly freestanding setting for patients, which will increase access to affordable MRI scans for residents of the three-county area. The need for additional capacity is evident based on the exceedingly high utilization of existing units in each of the three counties, as well as the lack of a choice of freestanding ODCs in the market.

- 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:

Response: Not applicable. The applicant entity, American Health Imaging of Tennessee does not have any outstanding CON applications in Tennessee.

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: Response: In the unlikely event of an emergency, AHI staff will use 911 emergency services to initiate a transfer of patients who need care in a hospital emergency room. AHI staff members are trained to perform emergency response procedures. For patients experiencing an emergency that exceeds staff expertise, local EMS will be called to transport the patient to a hospital emergency department. AHI of Knoxville staff will attempt to stabilize the patient until EMS arrival.

- 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

- 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:

Response: There is no alternative to the proposed ODC. The existing service area MRI units are highly utilized and will benefit from the additional capacity resulting from the proposed AHI of Knoxville. Knox and Blount County MRI units exceed the minimum volume per unit threshold (2,880) set forth in the Criteria and Standards for Magnetic Resonance Imaging.

The freestanding imaging setting promotes cost containment, as freestanding imaging centers do not carry the costly overhead required for 24/7 care at hospitals. Knox County is dominated by hospital-based providers and data shows that hospital-based imaging centers provide the same imaging services at a much higher cost. Additionally, Medicare has long incentivized its patients to use freestanding imaging centers such as the proposed one through lower patient co-pays and deductibles, and there is a trend among commercial payors that encourages the setting of the freestanding imaging center. In fact, most major commercial payors have adopted site of care coverage policies for imaging, which direct beneficiaries to freestanding imaging centers instead of hospital-based centers. Anthem was amongst the first major payors to adopt coverage policies for non-emergency outpatient MRI and CT scans, reportedly based on studies showing that “average prices for MRI and CT scans ranged from 70 percent to 149 percent higher at hospitals [than at freestanding centers]. The other payors began following Anthem’s lead, including Cigna, United Health Care, and Aetna. While these policies are designed to reduce costs, they also lead to delays in obtaining care at hospital-based centers because providers are required to identify the clinical condition that warrants the need for the service to be performed in an outpatient hospital setting. If a service is performed at a hospital-based center and the insurer determines that the setting is not medically necessary, the patient may receive a denial of coverage, and the claim will not be paid.

It's also important to note that this setting enhances scheduling and operational efficiencies and increases patient comfort and convenience. The project will enhance access to imaging services for three-county residents, particularly to the unique, high performance 3.0T MRI technology which results in fewer re-scans, enhances scheduling, and personalized exams while promoting cost efficient energy management. Additionally, the proposed innovative imaging technology will promote improved clinical care and outcomes, patient safety and satisfaction, and optimal operational efficiencies. The 3.0T technology is particularly unique at freestanding imaging centers; market research shows that the vast majority of 3.0T MRIs are located in hospital or HOPD settings. Increasing access to this type of advanced imaging technology in the freestanding imaging setting such as the proposed center offers numerous benefits, including enhanced convenience, emphasis on personalized care in a smaller environment, ease of navigation, improved patient satisfaction, and contained costs. The 3T MRI unit, which has become the standard of care for diagnosing and monitoring the progression of numerous neurological disorders, including Alzheimer's, Multiple Sclerosis, Epilepsy, and Parkinsonism. 3T imaging is also uniquely suited to the early detection of prostate cancer, advanced breast imaging, and the evaluation of small orthopedic joints.

- 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:

Response: The applicant's affiliated entities in other states have a long history of successfully recruiting professional and administrative staff. Not only does AHI offer competitive salaries and benefits, but it is committed to minimizing turnover through educational opportunities and other benefits. If necessary, staff members are recruited through a variety of channels, including in-house listings of available positions, local and regional newspaper listings, advertisements in professional publications and recruitment through local training programs as well as colleges.

AHI utilizes a contractual relationship with Connexia, LLC, which is a teleradiology group affiliated with Lumexa Imaging Outpatient, Inc.. Connexia includes a network of over 1,000 subspecialized radiologists who deliver precise, high-quality results that drive accurate diagnosis and treatment decisions. Additionally, the Connexia teleradiology platform ensures reliable capacity and physician coverage and ensures accelerated turnaround times, even amid national radiologist shortages. Connexia combines national scale with local expertise, delivering consistent, high-quality care through strategic partnerships and cutting edge technology.

- 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:

Response: The proposed facility will be licensed by the State of Tennessee as an Outpatient Diagnostic Center ("ODC"). The applicant will comply with applicable State licensure requirements and applicable regulations.

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>3315</u>	<u>4160</u>
B. Revenue from Services to Patients		
1. Inpatient Services	<u>\$0.00</u>	<u>\$0.00</u>
2. Outpatient Services	<u>\$5,547,750.00</u>	<u>\$6,760,000.00</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>\$5,547,750.00</u>	<u>\$6,760,000.00</u>
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	<u>\$4,876,100.00</u>	<u>\$5,294,242.00</u>
2. Provision for Charity Care	<u>\$55,478.00</u>	<u>\$67,600.00</u>
3. Provisions for Bad Debt	<u>\$83,216.00</u>	<u>\$101,400.00</u>
Total Deductions	<u>\$5,014,794.00</u>	<u>\$5,463,242.00</u>
NET OPERATING REVENUE	<u>\$532,956.00</u>	<u>\$1,296,758.00</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>3315</u>	<u>4160</u>
B. Revenue from Services to Patients		
1. Inpatient Services	<u>\$0.00</u>	<u>\$0.00</u>
2. Outpatient Services	<u>\$5,547,750.00</u>	<u>\$6,760,000.00</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>\$5,547,750.00</u>	<u>\$6,760,000.00</u>
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	<u>\$4,876,100.00</u>	<u>\$5,294,242.00</u>
2. Provision for Charity Care	<u>\$55,478.00</u>	<u>\$67,600.00</u>
3. Provisions for Bad Debt	<u>\$83,216.00</u>	<u>\$101,400.00</u>
Total Deductions	<u>\$5,014,794.00</u>	<u>\$5,463,242.00</u>

	72		
NET OPERATING REVENUE		<u>\$532,956.00</u>	<u>\$1,296,758.00</u>

- 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	\$1,673.53	\$1,625.00	0.00
Deduction from Revenue (<i>Total Deductions/Utilization Data</i>)	\$0.00	\$0.00	\$1,512.76	\$1,313.28	0.00
Average Net Charge (<i>Net Operating Revenue/Utilization Data</i>)	\$0.00	\$0.00	\$160.77	\$311.72	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:

Response: The projected charges associated with the proposed project will be based on the applicant's historical experience in other markets, adjusted for local factors. As a new provider, there are no existing patient charges.

- 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:

Response: The projected average charge per MRI scan is consistent with other area providers. AHI of Knoxville projects \$1,850 per scan in Year 1 and Year 2. The three-county area average charge per MRI scan was \$2,495 in 2023, according to data reported on the HFC Medical Equipment Utilization Reports. The following figure details the average charge per MRI scan for facilities that reported charge information on the October 2024 report.

2023 Average Charge per MRI Scan

AHI of Knoxville Service Area Existing Providers

Provider	County	Provider Type	MRI Procedures		
			2023 Scans	Gross Charges	Average Charge Per MRI Scan
Abercrombie Radiology	Knox	RPO	2,700	NA	NA
Summit Medical Group	Knox	PO	4,653	NA	NA
Summit Medical Group - Midlake	Knox	PO	3,176	NA	NA
Covenant Health Dx Center West	Knox	HODC	740	\$469,188	\$634
Covenant Health Dx Center South	Knox	ODC	288	\$179,899	\$625
East TN Children's Hospital	Knox	HOSP	4,995	\$23,546,124	\$4,714
East TN Community Open MRI	Knox	ODC	3,433	\$2,176,449	\$634
Fort Sanders Regional Med Ctr	Knox	HOSP	10,136	\$22,007,811	\$2,171
Knoxville Comprehensive Breast Ctr	Knox	PO	2,110	NA	NA
North Knoxville Medical Center	Knox	HOSP	3,541	NA	NA
OrthoTN - Knox County	Knox	PO	7,806	\$7,583,343	\$971
OrthoTN - Knox Accelerator Way	Knox	PO	4,364	\$4,449,372	\$1,020
OrthoTN - Knox Dannaher Lane	Knox	PO	4,756	\$4,457,783	\$937
Parkwest Medical Center	Knox	HOSP	10,507	\$23,230,632	\$2,211
TN Orthopaedic Clinics - Parkwest MRI	Knox	PO	4,552	\$5,721,229	\$1,257
TN Orthopaedic Clinics - Regional MRI	Knox	PO	1,861	\$2,318,291	\$1,246
Turkey Creek Medical Center	Knox	HOSP	3,401	NA	NA
University Dx Hall of Fame	Knox	ODC	11,573	\$11,817,517	\$1,021
University Dx Halls	Knox	ODC	2,868	\$2,511,566	\$876
University of TN Medical Center	Knox	HOSP	23,423	\$86,347,914	\$3,686
Knox County Subtotal*			110,883	\$196,817,118	\$2,156
Fort Loudon Medical Center	Loudon	HOSP	2,498	\$5,418,812	\$2,169
Loudon County Subtotal			2,498	\$5,418,812	\$2,169
Blount Memorial Hospital	Blount	HOSP	6,396	\$41,884,227	\$6,549
East TN Medical Group	Blount	PO	4,677	\$17,561,362	\$3,755
Blount County Subtotal			11,073	\$59,445,589	\$5,369
Total, All Units in Three-County Area			124,454	\$261,681,519	\$2,495

Sources: TN HFC Medical Equipment Utilization Reports 10/2/2024; Joint Annual Reports.

Note: Knox County subtotal average charge per MRI scan excludes procedures for facilities that did not report charge information.



- 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	\$1,497,892.00	27.00	\$1,825,200.00	27.00
TennCare/Medicaid	\$166,433.00	3.00	\$202,800.00	3.00
Commercial/Other Managed Care	\$3,661,515.00	66.00	\$4,461,600.00	66.00
Self-Pay	\$221,910.00	4.00	\$270,400.00	4.00
Other(Specify)				
Total	\$5,547,750.00	100%	\$6,760,000.00	100%
Charity Care	\$55,478.00		\$67,600.00	

**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: Response: American Health Imaging provides services to all patients, regardless of their ability pay, and does not discriminate based upon race, gender, creed, nationality, or disability. The proposed imaging center will operate in the same manner. American Health Imaging of Knoxville's administrative staff will describe to each patient the prospective charges for the physician-ordered diagnostic procedure when the patient arrives at the facility. The staff will explain the billing process to each patient and will answer any questions the patient may have either regarding billing or the procedure itself. If a patient is uninsured and financially indigent, the patient will be offered consideration pursuant to the facility's financial policies. The patient's insurance or ability to pay status is usually documented during the pre-appointment process with the referring physician's office so the patient avoids repeating the registration process upon arrival at the imaging center.

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 standing?

☒ 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	☒ Health Facilities Commission/Licensure Division ☐ Intellectual & Developmental Disabilities ☐ Mental Health & Substance Abuse Services	Will Apply	
Certification	☒ Medicare ☒ TennCare/Medicaid ☐ Other _____	Will Apply Will Apply	
Accreditation(s)	Other - Specify	Will Apply	

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

Please Explain

RESPONSE: Please see Additional Attachment 3 which provides information on this topic.

- 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		
MRI Tech	0.00	1.00
CT Tech	0.00	1.00
Total Direct Patient Care Positions	N/A	2

B. Non-Patient Care Positions		
Manager	0.00	1.00
Sales Representative	0.00	1.00
Patient Services Representative	0.00	1.00
Total Non-Patient Care Positions	N/A	3
Total Employees (A+B)	0	5

C. Contractual Staff		
Contractual Staff Position	0.00	0.00
Total Staff (A+B+C)	0	5

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.

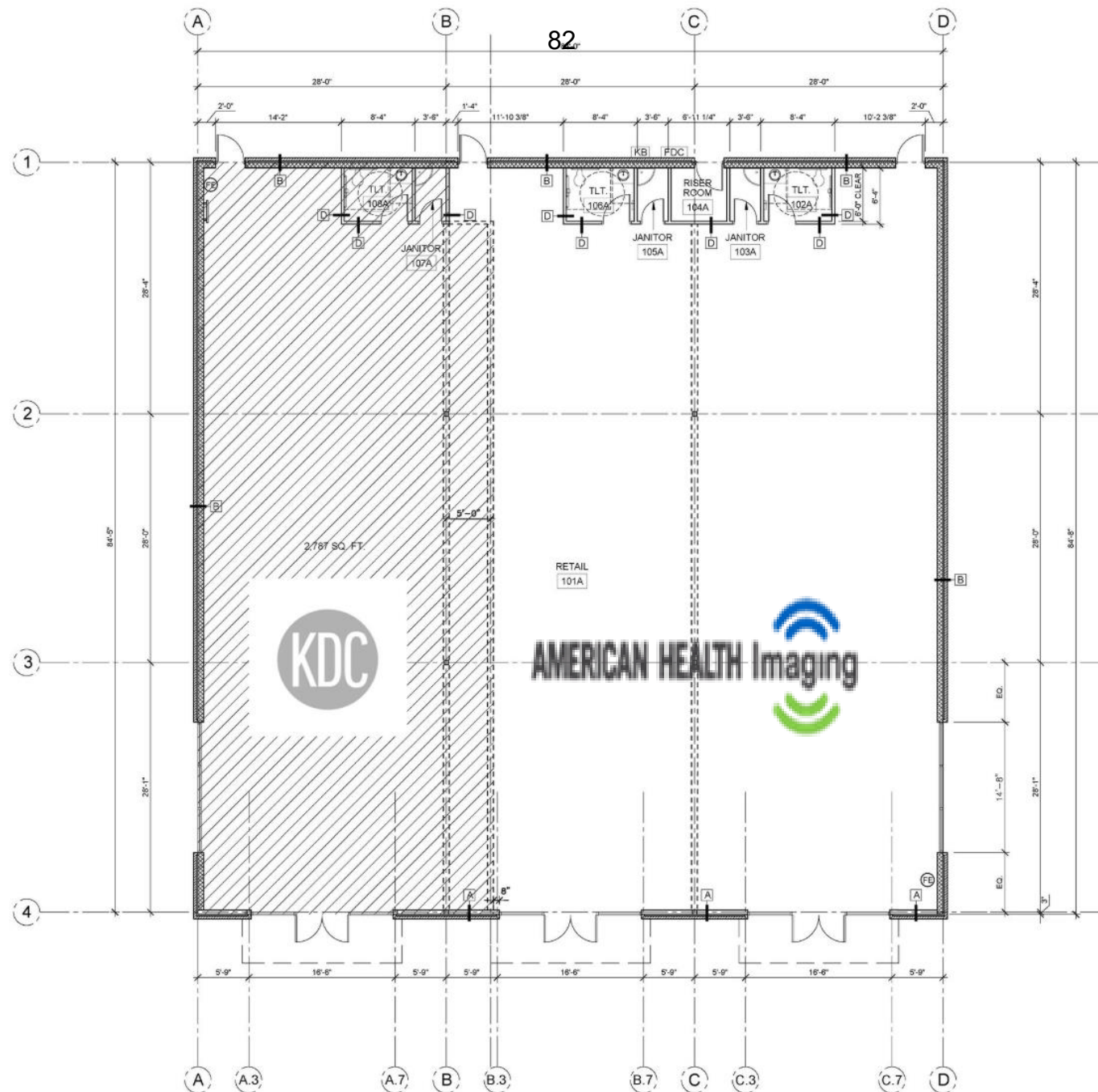
- Complete the Project Completion Forecast Chart below. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
- If the CON is granted and the project cannot be completed within the standard completion time period (3 years for hospital and 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

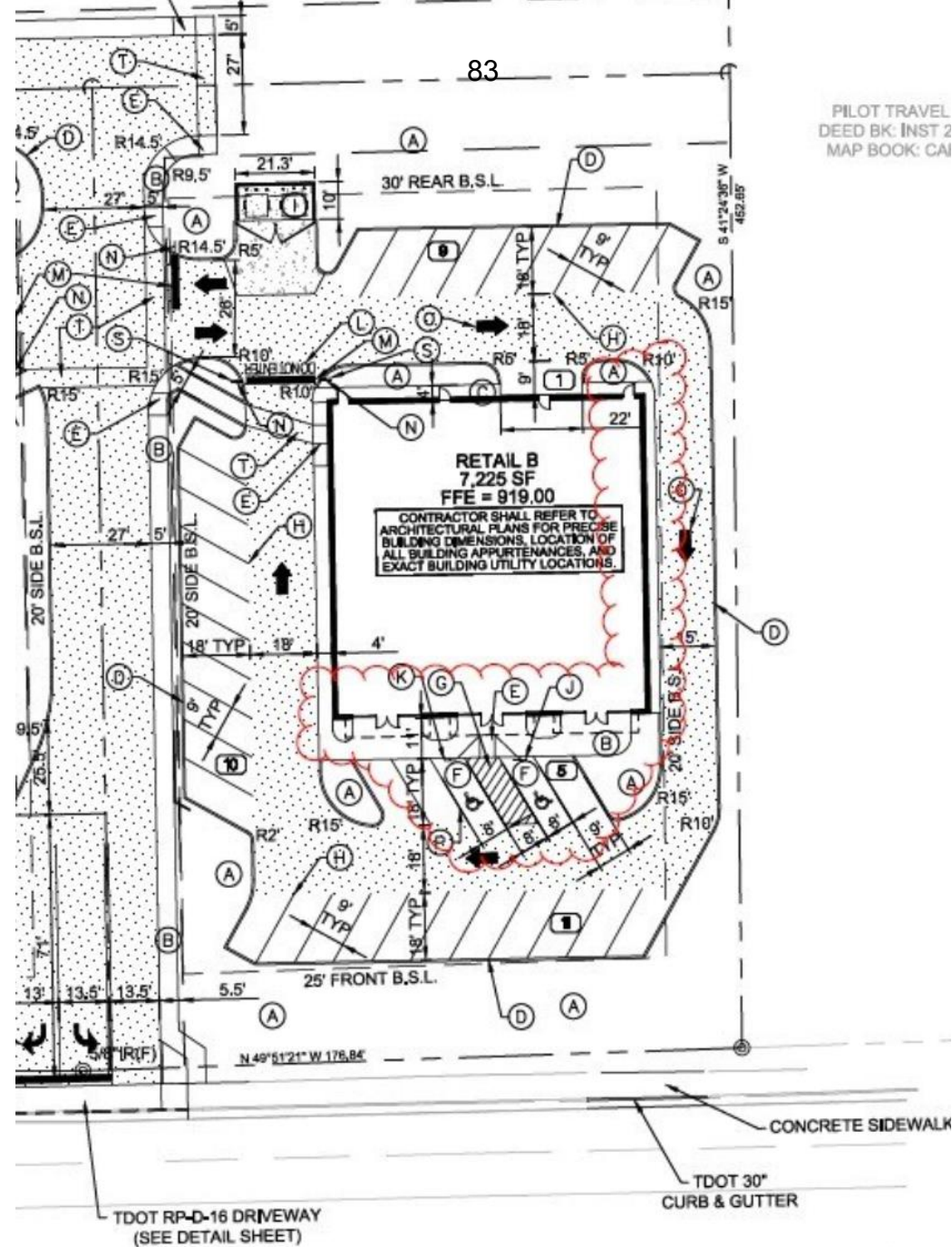
Assuming the Certificate of Need (CON) approval becomes the final HFC action on the date listed in Item 1 below, indicate the number of days from the HFC decision date to each phase of the completion forecast.

Phase	Days Required	Anticipated Date (Month/Year)
1. Initial HFC Decision Date		10/22/25
2. Building Construction Commenced	32	11/22/25
3. Construction 100% Complete (Approval for Occupancy)	147	03/17/26
4. Issuance of License	154	03/24/26
5. Issuance of Service	162	04/01/26
6. Final Project Report Form Submitted (Form HR0055)	345	10/01/26

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



FLOOR PLAN
 326 Lovell Rd
 Knoxville, TN 37934



SITE PLAN
326 Lovell Rd
Knoxville, TN 37934

LOVELL ROAD

Attachment 7A

Organization/Legal Applicant Documents



Tre Hargett
Secretary of State

85
Division of Business and Charitable Organizations
Department of State
State of Tennessee
312 Rosa L. Parks Avenue, 6th Floor
Nashville, Tennessee 37243
Phone: 615-741-2286
sos.tn.gov/

Capital Filing Service
992 DAVIDSON DRIVE SUITE B
NASHVILLE, TN 37205, USA

04/29/2025

Filing Acknowledgment

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

Entity Name:	AMERICAN HEALTH IMAGING OF TENNESSEE, LLC		
SOS Control #:	002017860	Initial Filing Date:	04/29/2025
Entity Type:	Limited Liability Company (LLC)	Formation Locale:	TENNESSEE
Status:	Active	Duration Term:	Perpetual
Fiscal Year Close:	December	Annual Report Due:	04/01/2026
Business County:	(No County on Record)		
Managed By:	Member Managed		
Obligated Member Entity:	No		

Document Receipt

Receipt #: 2025-316310	Filing Fee:	\$300.00
Payment: Credit Card - 3897366603		\$300.00

Registered Agent Address:
COGENCY GLOBAL INC.
992 DAVIDSON DR STE B
NASHVILLE, TN 37205-1051

Principal Office Address:
2200 Century Pkwy NE Ste 600
Atlanta, GA 30345, USA

Congratulations on the successful filing of your Articles of Organization - Limited Liability Company for **AMERICAN HEALTH IMAGING OF TENNESSEE, LLC** in the State of Tennessee which is effective **04/29/2025**. 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

Tracking Number
B2025248012



Tre Hargett
 Secretary of State

Articles Of Organization

Division of Business and Charitable Organizations
Department of State

State of Tennessee
 312 Rosa L. Parks Avenue, 6th Floor
 Nashville, Tennessee 37243
 Phone: 615-741-2286
sos.tn.gov/businesses

Control #: 002017860
 Filed: 04/29/2025 02:52 PM
 Tre Hargett
 Secretary of State

Entity Information

Entity Name: AMERICAN HEALTH IMAGING OF TENNESSEE, LLC

Entity Type: Limited Liability Company

Fiscal Year Ending Month: December

Additional Designation: *(No additional designation)*

Series LLC ?

☐ Yes ☒ No

Principal Office Address

2200 Century Pkwy NE Ste 600
 Atlanta, GA 30345, USA

Mailing Address

2200 Century Pkwy NE Ste 600
 Atlanta, GA 30345, USA

Period of Duration:

Perpetual

Will this filing have a delayed effective date?

☐ Yes ☒ No

Nature of Business (NAICS):

621512 - Diagnostic Imaging Centers

Other Provisions:

(No other provisions)

Do you have additional uploads you would like to attach to this filing?

☐ Yes ☒ No

Registered Agent Information

COGENCY GLOBAL INC.
 992 DAVIDSON DR STE B
 NASHVILLE, TN 37205-1051

Member Information

The Limited Liability Company will be: Member Managed

Do you have six or fewer members at the date of this filing?

☒ Yes ☐ No

Number of Members at the date of filing:

Will this entity be registered as an Obligated Member Entity (OME)

☐ Yes ☒ No

Organizer's Signature

- ☒ By entering my name in the space provided below, I certify that I am authorized to file this document on behalf of this entity, have examined the document and, to the best of my knowledge and belief, it is true, correct and complete as of this day.
- ☒ The undersigned, acting as organizer of the limited liability company under the provisions of the Tennessee Revised Limited Liability Company Act, adopt the above Articles of Organization.

Signed Electronically: JULIE SZEKER

Date: 04/29/2025



Tre Hargett
Secretary of State

Division of Business and Charitable Organizations
Department of State
State of Tennessee
312 Rosa L. Parks Avenue, 6th Floor
Nashville, Tennessee 37243
Phone: 615-741-2286
sos.tn.gov/

Date: 04/29/2025

Invoice: 2025-316310

Customer Information

Capital Filing Service
AMERICAN HEALTH IMAGING OF TENNESSEE, LLC
992 DAVIDSON DRIVE SUITE B
NASHVILLE, TN 37205, USA

Tracking #	Description	Amount Paid
B2025248012	Articles of Organization - Limited Liability Company for AMERICAN HEALTH IMAGING OF TENNESSEE, LLC (LLC Filings)	\$ 300.00
Payment Details		
	Fee Total:	\$ 300.00
	Payment Total:	\$ 0.00
	Amount Due:	\$ 0.00
Payment Method		
	Payment Type: Credit Card	
	Check/Confirmation Number: 3897366603	

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AMERICAN HEALTH IMAGING OF TENNESSEE, LLC

Entity Type: Limited Liability Company (LLC)	Status: Active
Formed in: TENNESSEE	Control Number: 002017860
Term of Duration: Perpetual	Initial Filing Date: 4/29/2025 2:52:18 PM
Managed By: Member Managed	Fiscal Ending Month: December
Series LLC: No	AR Due Date: 04/01/2026
Number of Members: 6 or less	Obligated Member Entity: No

<u>Registered Agent</u>		<u>Principal Office Address</u>	<u>Mailing Address</u>
COGENCY GLOBAL INC. 992 DAVIDSON DR STE B NASHVILLE, TN 37205-1051		2200 Century Pkwy NE Ste 600 Atlanta, GA 30345	2200 Century Pkwy NE Ste 600 Atlanta, GA 30345
AR Standing: Good	RA Standing: Good	Other Standing: Good	Revenue Standing: N/A
History (1) 			

Attachment 9A

Lease: Request for Proposal to Lease 326 Lovell Road

NEWMARK

Newmark
3455 Peachtree Road, NE
Suite 1800
Atlanta, GA 30326

5/12/25

Aaryn Wilson
Vertical Commercial
651 E 4th St
Chattanooga, TN 37403
aaryn.wilson@verticalcommercial.com

RE: AMERICAN HEALTH IMAGING – 326 LOVELL RD, KNOXVILLE, TN 37934

Dear Aaryn,

On behalf of **American Health Imaging**, hereinafter referred to as “Tenant”, we are hereby authorized to submit the following Request for Proposal to lease with your client, (hereinafter referred to as “Landlord”) at 326 Lovell Rd (hereinafter referred to as the (“Property”)), subject to the following terms and conditions. We would appreciate it if you would put your response in redline format.

PREMISES

Tenant shall lease from Landlord suites 324 and 326 consisting of approximately 4,704 rentable square feet (“RSF”) at The Property (the “Premises”). Please identify the BOMA method that will be used to measure the space.

OWNERSHIP

Please describe the ownership entity and any lender on the property.

Lovell Pointe, LLC

BUILDING MANAGEMENT:

Please state the name and address of the management company responsible for managing The Property.

Property Manager: NAI Koella Moore

PERMITTED USE BY TENANT:

Tenant’s permitted use for the Premises shall be general office use and medical office use, services including, but not limited to MRI, CT Scans, X-ray, Ultrasound and/or any other related imaging services (“Tenant’s Permitted Use”). Landlord shall warrant in the Lease that Tenant’s Permitted Use is in compliance with zoning and all other applicable codes and covenants and that it does not violate any matters

of public record, occupancy agreements, and other matters affecting the Premises. Landlord accepts in concept; to be discussed further in the Lease.

LEASE COMMENCEMENT DATE

The Lease shall commence on the Effective Date, hereinafter referred to as the “Lease Commencement Date.” The Lease shall become a binding agreement for both parties upon signature completion and the Landlord’s delivery of the Premises. Landlord and Tenant shall abide by all the covenants and conditions in this Lease upon signature completion.

RENT COMMENCEMENT DATE

Notwithstanding the Lease Commencement Date, the Rent Commencement Date shall be the earlier of One Hundred Sixty-Five (165) days after the Effective Date, or the date Tenant opens the Premises for business, hereinafter referred to as the (“Rent Commencement Date”). The Target Rent Commencement Date is December 1, 2025.

LEASE TERM

One Hundred Twenty (120) month lease term from Rent Commencement. Tenant requests a lease term of ten (10) years.

BASE RENT

Please specify the annual cost per rentable square foot, and any corresponding rental rate escalations.

Base Rent: \$36.75 PSF, NNN with three percent (3%) annual increases of the Base Rent.

RENT ABATEMENT

Please state your proposed rental abatement to entice Tenant to locate here. None

SECURITY DEPOSIT

Subject to review of Tenant’s financials, Tenant shall not be required to provide Landlord with a security deposit.

TENANT IMPROVEMENT ALLOWANCE

Due to the existing conditions of the Premises and the need to bring the building to base building conditions, Tenant shall be allowed to utilize, at its sole discretion, up to \$65.00 per RSF for the following items: a) all customary hard and soft costs associated with design and construction (including permits, engineering fees), b) data telecommunications cabling, equipment and installation the (“Tenant Improvements”).

Improvements shall be constructed in accordance with mutually acceptable plans and specifications.

No construction management fees or other “mark-up” on tenant improvement costs shall be payable to Landlord. Landlord will have 5 business days from the approval of the Tenant’s plans to notify Tenant in writing of any Tenant Improvements that need to be removed at the end of the lease term. Should Landlord

not notify Tenant, then Tenant will have no obligation to remove its Tenant Improvements at the end of the Lease Term. Landlord accepts in concept; to be discussed further in the Lease

REPAIR AND MAINTENANCE:

As part of Operating Expenses, Landlord shall be responsible for maintaining in first-class condition, repairing and replacing (including any portion thereof passing through the Premises):

- a. the roof, roof membrane, foundations, exterior walls and windows, and all structural parts of the Property;
- b. all portions of the Premises affected by structural conditions whose source lies outside the Premises;
- c. all common areas serving The Property;
- d. all of The Property's base utility, sprinkler service, electrical and plumbing lines and HVAC systems outside the Premises but which serve the Premises (collectively, the "The Property Systems");
- e. all of the Property Systems and related components within the Premises.
- f. Landlord is not responsible for HVAC and any other systems servicing the Premises for Tenant's sole use.

SPACE PLANNING

Landlord shall provide Tenant an allowance of fifteen cents (\$0.15) per rentable square foot for the purposes of an architectural "test-fit", pricing notes, and revisions. The cost associated with the performance of these services shall be borne by Landlord outside of any allowance for Tenant Improvements. If available, please provide the CAD drawing of The Property.

DELIVERY

Landlord shall deliver the Premises to Tenant upon the Effective Date of the Lease.

HVAC

Please describe the base building HVAC system servicing The Property. The Premises is currently not served by HVAC.

ROOF RIGHTS:

Tenant shall have the right to install and maintain satellite dishes, antennas, chillers, emergency generators and other trade equipment on the roof of the Property, subject to Landlord's approval, which shall not be unreasonably withheld, conditioned or delayed. There shall be no rent or charges payable for such "roof space." Tenant shall have free access to service/maintain this equipment.

CERTIFICATE OF NEED

Following the Effective Date, Tenant will make good faith efforts to obtain the required Certificate of Need from the State of Tennessee (the "CON"), and Tenant shall promptly notify Landlord when the CON is issued. Notwithstanding anything to the contrary contained in this Lease, if Tenant is unable to obtain the CON, in a form acceptable to Tenant in Tenant's sole discretion, Tenant may terminate this Lease by

providing written notice thereof to in which event this Lease shall terminate and be of no further force and effect. Landlord accepts in concept; to be discussed further in the Lease

OPERATING EXPENSES

Tenant will contract for a NNN lease. Along with your proposal, please provide the 2024 and 2025 (if available) estimates of the building's operating expenses, real estate taxes and property insurance.

Landlord agrees to cap increases in the passthrough of "controllable" operating expenses at five percent (5%) per year on a non-cumulative, non-compounding basis. "Controllable Operating Expenses" shall be defined as all operating expenses except for real estate taxes, insurance, and utilities.

Tenant shall have the right to audit Landlord's operating expense statements at any time during the term of the lease period and can hire their auditor on a percent of savings basis.

SIGNAGE RIGHTS

Please outline all signage rights to Tenant. Per Exhibit A. Landlord accepts in concept; to be discussed further in the Lease

RENEWAL RIGHT

Tenant shall have two (2) options to renew at Fair Market Value for a period of five (5) years each with six (6) months prior written notice. Renewal terms and conditions will be at fair market value.

RIGHT TO ASSIGN OR SUBLEASE - PERMITTED TRANSFER

Tenant may, with Landlord's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed, assign the Lease or sublease all or a portion of the Premises.

Tenant may, without Landlord's consent, assign the Lease or sublet the Premises (i) to any parent, subsidiary, or any affiliate of Tenant or any subsidiary of any parent of Tenant, (ii) to Tenant's successor by merger, consolidation, or acquisition of stock or membership interests, (iii) to any purchaser of substantially all or a material portion of Tenant's assets, or (iv) in connection with the sale of an operating division of Tenant or any parent, subsidiary, or affiliate of Tenant, or any subsidiary of any parent of Tenant. In the event of any such assignment or sublease, Tenant shall provide Landlord notice and a copy of the assignment and assumption agreement, or sublease, after the effective date thereof. Tenant shall be released from all liabilities and obligations if the assignee's net worth is equal to or greater than the net worth of Tenant.

EXCLUSIVE USE

No premises within the Property (other than the Premises) shall have as their primary use medical imaging services, which does not apply to any existing tenants or occupants at the Property or those medical use tenants performing imaging as a related service of their business. In the event of any violation, Tenant shall pay to Landlord fifty percent (50%) of the Rent due on a monthly basis until the violation is cured. If any violation is not cured within six (6) months, then Tenant shall also have the right to terminate the lease.

PARKING

Parking shall be free and unassigned for the duration of the term and any subsequent renewal periods. Please provide the number of spaces available for Tenant's use.

FIBER:

Please indicate the availability and process of accessing fiber and other telecommunication or wireless systems in or on The Property, including rooftop satellite systems. Please describe the security applicable thereto.

CLEANING SPECIFICATIONS:

Tenant, at its sole cost and expense, shall have the right to contract directly with the cleaning company of its choice to clean the Clinic Premises.

HOLDOVER

Landlord shall agree that if Tenant holds over at Lease expiration, its tenancy will be a tenancy from month-to-month, on the same terms and conditions of the Lease, except that for the initial Three (3) months following Lease expiration, each monthly base rent installment will be One Hundred Ten Percent (110%) of the amount of the monthly base rent installment due for the last month of the Term, and thereafter each monthly base rent installment will be One Hundred Twenty-Five Percent (125%) of the amount of the monthly base rent installment due for the latest month of the Term. This holdover rent will be Landlord's sole and exclusive right and remedy against Tenant and will be deemed to cover all liabilities, damages, obligations or charges which may be incurred by Landlord because of any holdover by Tenant.

RELOCATION

Landlord shall waive the right to relocate Tenant for any reason during the initial lease term and any extensions.

EXPANSION

Tenant requires an ongoing Right of First Refusal ("ROFR") on any adjacent contiguous space. Tenant shall have 5 business days to respond to a bona fide Offer.

SUBORDINATION, NON-DISTURBANCE & ATTORNEY AGREEMENTS

Landlord will provide a Non-Disturbance Agreement in a form acceptable to Tenant providing in substance that the holders of any present or future liens agree that so long as Tenant is not in default under the lease (beyond any applicable cure period), Tenant's leasehold estate, use, possession, tenancy rights, options and occupancy under the Lease shall remain undisturbed and shall survive any foreclosure or similar action.

Subject to receiving a Non-Disturbance Agreement, at Landlord's request, Tenant will provide a Subordination and Attornment Agreement in a form reasonably acceptable to Landlord providing in substance that the lease shall be subordinate to any present or future liens and that Tenant shall attorn to any new owner of The Property.

MEMORANDUM OF LEASE

Landlord and Tenant shall execute a mutually agreeable Memorandum of Lease in recordable form, and Tenant may record such Memorandum of Lease in the applicable public registry.

MEDICAL PROVIDER PROVISION.

Customary standard HIPAA and “Stark” provisions shall be included in the lease, as required by Tenant.

CHILLER UNIT

Tenant shall have the right to install and operate a chiller(s) and a quench vent, which shall be installed and maintained outside of the Premises or on the roof in a location mutually approved by Landlord and Tenant, and Tenant shall have the right to install a fence around the Chiller Unit.

MOBILE UNIT

Tenant shall be permitted to, from time-to-time at the Tenant’s determination, commencing on the Effective Date of the Lease and through the Lease Term, operate a Mobile Unit in a mutually agreed upon location between Landlord and Tenant on a portion of the parking on a non-exclusive basis, at no additional cost to Landlord, as shall be further described in the Lease.

AS-BUILT DRAWINGS

Landlord shall deliver to Tenant the as-built drawings of The Property and Premises in CAD format. If CAD files are not available, and Tenant needs to prepare as-built drawings, then Landlord shall reimburse Tenant’s costs thereof.

BROKERS

Tenant represents that Tenant is exclusively represented by Newmark. Landlord is represented by Vertical Commercial. Newmark shall be paid a market commission by Vertical Commercial pursuant to the terms of a separate agreement.

QUALIFYING CONDITIONS

This Request for Proposal is not intended to create any binding obligation on Landlord or Tenant and no such obligation shall arise until Landlord and Tenant sign a definitive Lease Agreement for the Premises.

We look forward to your reply.

A handwritten signature in black ink, reading "Justen Cimino". The signature is fluid and cursive, with the first name "Justen" and last name "Cimino" clearly distinguishable.

Sincerely,

Justen Cimino
Managing Director
Newmark

AGREED AND ACCEPTED:

Landlord:

By:

DocuSigned by:

Nick Patel

42FC13ABD4F4449...

Title: Owner

Date: 05/12/2025 | 2:26 PM PDT

Tenant:

By:

Signed by:

Dan Valentine

58197334178E408...

Title: President

Date: 05/13/2025 | 10:42 AM PDT

Exhibit A

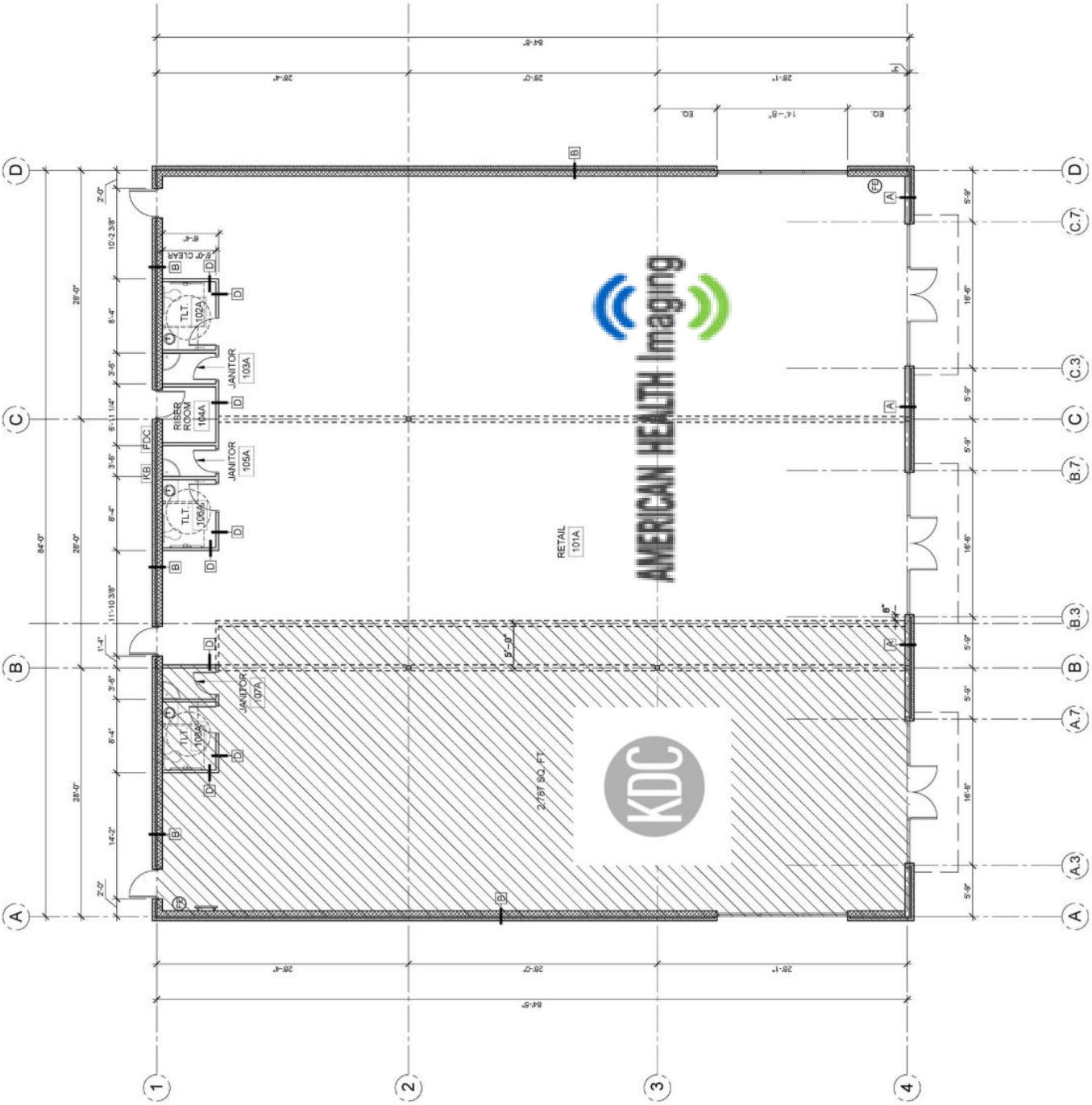
Signage



Attachment 10A

Floor Plan: 326 Lovell Road

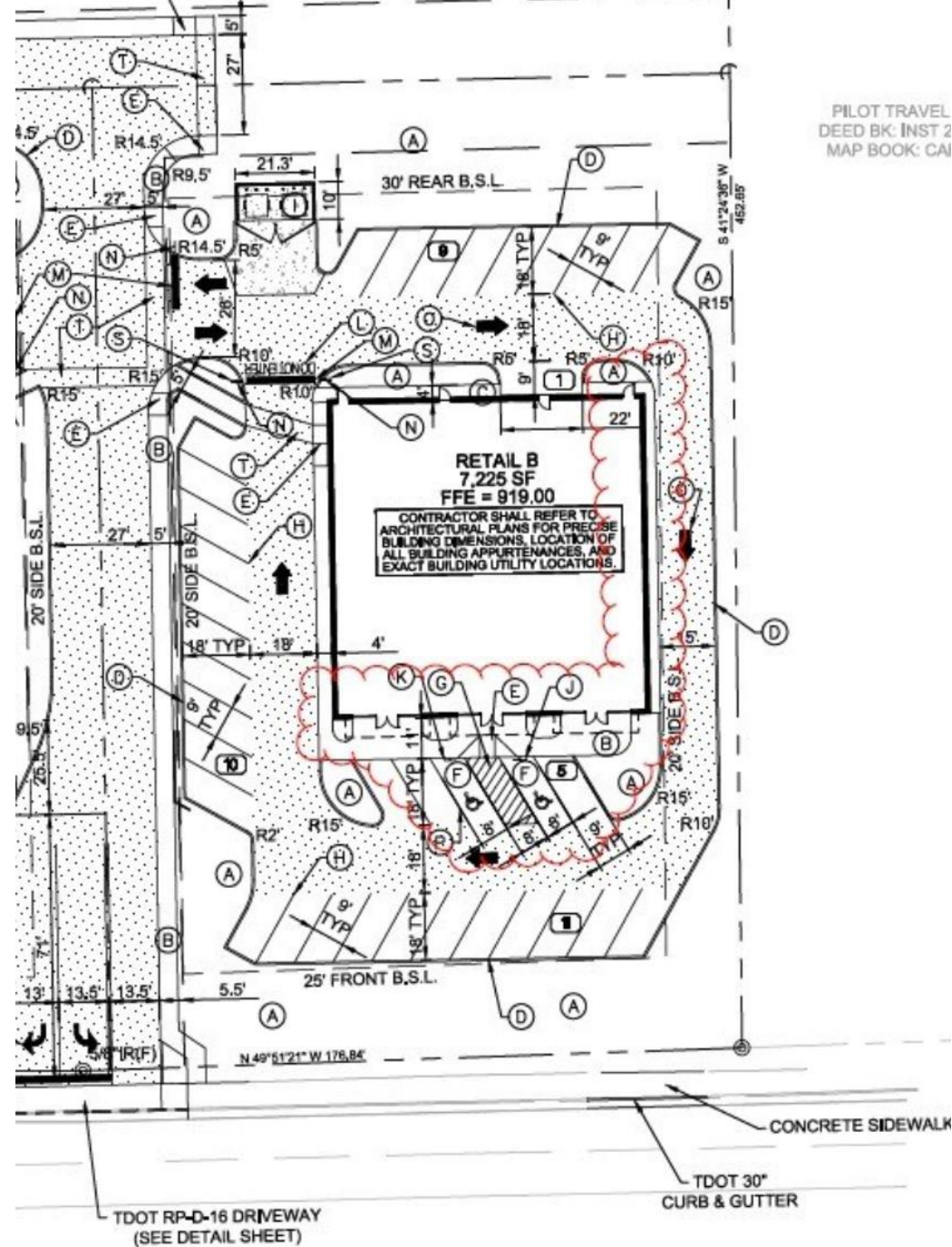
FLOOR PLAN
326 Lovell Rd
Knoxville, TN 37934



Attachment 12A

Location Map: 326 Lovell Road

SITE PLAN
326 Lovell Rd
Knoxville, TN 37934

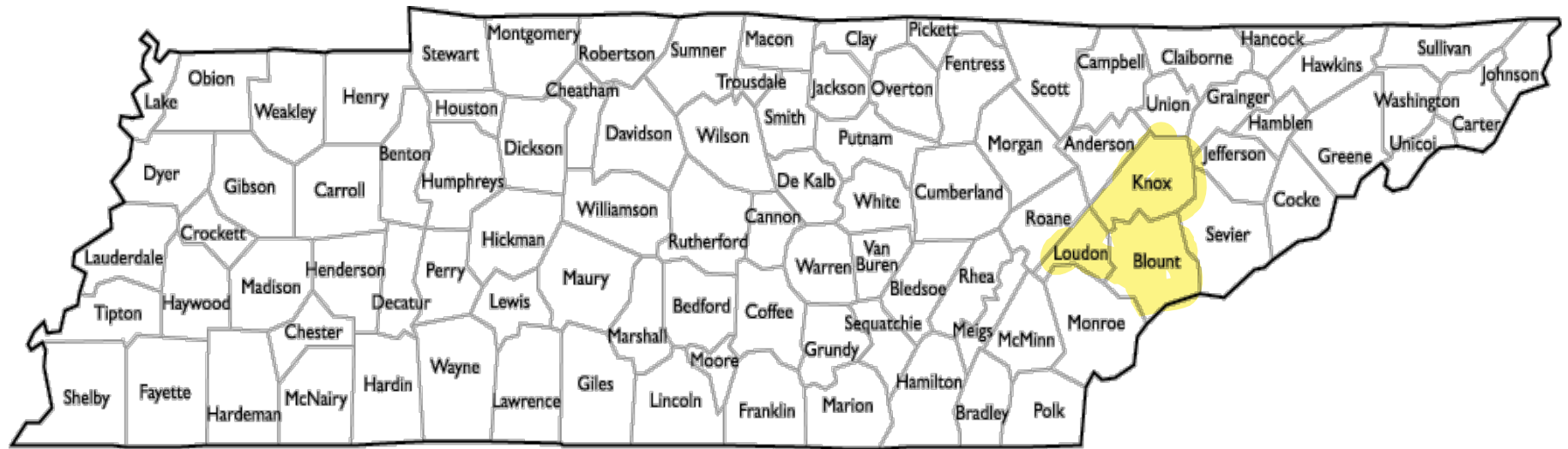




11A. Public Transportation Route

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: The proposed ODC will be located at 326 Lovell Road, Knoxville, TN, 37934. The site is easily accessible via Lovell Road and I-40/75. The proposed location is just 1,000 feet from the intersection of I-40/75 and Lovell Road in the Turkey Creek commercial district of Knoxville. From a public transportation standpoint, the area is served by Knoxville Area Transit ("KAT"). KAT operates fixed route buses and paratransit service across the City of Knoxville and carries around 3 million passengers each year. While KAT fixed route buses do not currently travel to Lovell Road, KAT is introducing a new on-demand transportation service called katConnect. The on-demand transportation service operates similarly to ride-sharing services and will connect passengers to fixed-route services. Finally, the proposed location is near the Parkside Greenway, which is a two-mile pedestrian greenway that begins at Lovell Road (connecting to the road's sidewalk system that links to a multitude of restaurants), runs behind the Turkey Creek commercial district (with several connections to access the stores and restaurants along the way), and ends at the sidewalk system along Campbell Station Rd.





Attachment 3N
Service Area Demographics Detail

Population and Demographic Summary Proposed Service Area Counties Compared to Tennessee

Demographic Variable/Geographic Area	Department of Health/Health Statistics						Census Bureau				TennCare		
	Total Population- Current Year 2025	Total Population- Projected Year 2029	Total Population-% Change	*Target Population- 18+ Current Year 2025	Target Population- 18+ Project Year 2029	Target Population- % Change	Target Population of Total	Median Age	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total
Knox County	497,744	514,586	3.4%	391,934	404,893	3.3%	78.7%	37.3	\$71,662	68,689	13.8%	76,330	15.3%
Blount County	141,393	146,200	3.4%	114,099	118,217	3.6%	80.9%	43.9	\$74,607	13,715	9.7%	20,629	14.6%
Loudon County	58,536	61,179	4.5%	47,946	50,335	5.0%	82.3%	48.7	\$80,296	6,146	10.5%	9,443	16.1%
Service Area Total	697,673	721,965	3.5%	553,979	573,445	3.5%	79.4%	—	—	88,550	12.7%	106,402	15.3%
State of TN Total	7,176,847	7,384,270	2.9%	5,607,941	5,780,535	3.1%	78.3%	38.9	\$67,097	1,004,759	14.0%	1,408,284	19.6%

Sources: Tennessee Department of Health; Census.gov Quick Facts June 2025; and Division of TennCare, enrollment as of March May 2025. Median Age from U. S. Census Bureau as of 2025.

Attachment 5N

Three-Year Summary of Existing Provider Utilization

Item 5N - Service Area Historical Utilization

Facility	Facility Type	Year (2023)	Annual # of Procedures	# MRI Units	MRI Unit Type	Procedures per MRI
Abercrombie Radiology	RPO	2023	2,700	1	Fixed	2,700
Summit Medical Group	PO	2023	4,653	2	Fixed	2,327
Summit Medical Group - Midlake	PO	2023	3,176	1	Fixed	3,176
Covenant Health Dx Center West	HODC	2023	740	1	Fixed	740
Covenant Health Dx Center South	ODC	2023	288	1	Fixed	288
East TN Children's Hospital	HOSP	2023	4,995	1	Fixed	4,995
East TN Community Open MRI	ODC	2023	3,433	2	Fixed	1,717
Fort Sanders Regional Med Ctr	HOSP	2023	10,136	2	Fixed	5,068
Knoxville Comprehensive Breast Ctr	PO	2023	2,110	2	Fixed	1,055
North Knoxville Medical Center	HOSP	2023	3,541	1	Fixed	3,541
OrthoTN - Knox County	PO	2023	7,806	2	Fixed	3,903
OrthoTN - Knox Accelerator Way	PO	2023	4,364	1	Fixed	4,364
OrthoTN - Knox Dannaher Lane	PO	2023	4,756	1	Fixed	4,756
Parkwest Medical Center	HOSP	2023	10,507	2	Fixed	5,254
TN Orthopaedic Clinics - Parkwest MRI	PO	2023	4,552	1	Fixed	4,552
TN Orthopaedic Clinics - Regional MRI	PO	2023	1,861	1	Fixed	1,861
Parkey Creek Medical Center	HOSP	2023	3,401	1	Fixed	3,401
University Dx Hall of Fame	ODC	2023	11,573	2	Fixed	5,787
University Dx Halls	ODC	2023	2,868	1	Fixed	2,868
University of TN Medical Center	HOSP	2023	23,423	5	Fixed	4,685
Fort Loudon Medical Center	HOSP	2023	2,498	1	Fixed	2,498
Blount Memorial Hospital	HOSP	2023	6,396	1	Fixed	6,396
East TN Medical Group	PO	2023	4,677	1	Fixed	4,677

Source: HFC Equipment Registry: <https://www.tn.gov/hsda/hsda-publications-and-reports/medical-equipment-registry/medical-equipment-statistics.htm>

Facility	Facility Type	Year (2022)	Annual # of Procedures	# MRI Units	MRI Unit Type	Procedures per MRI
Abercrombie Radiology	RPO	2022	2,240	1	Fixed	2,240
Summit Medical Group	PO	2022	3,220	1	Fixed	3,220
Summit Medical Group - Midlake	PO	2022	3,201	1	Fixed	3,201
Covenant Health Dx Center West	HODC	2022	625	1	Fixed	625
Covenant Health Dx Center South	ODC	2022	NA	1	Fixed	NA
East TN Children's Hospital	HOSP	2022	4,061	1	Fixed	4,061
East TN Community Open MRI	ODC	2022	3,637	2	Fixed	1,819
Fort Sanders Regional Med Ctr	HOSP	2022	9,839	2	Fixed	4,920
Knoxville Comprehensive Breast Ctr	PO	2022	2,576	1	Fixed	2,576
North Knoxville Medical Center	HOSP	2022	3,517	1	Fixed	3,517
OrthoTN - Knox County	PO	2022	8,247	2	Fixed	4,124
OrthoTN - Knox Accelerator Way	PO	2022	1,538	1	Fixed	1,538
OrthoTN - Knox Dannaher Lane	PO	2022	4,398	1	Fixed	4,398
Parkwest Medical Center	HOSP	2022	9,784	2	Fixed	4,892
TN Orthopaedic Clinics - Parkwest MRI	PO	2022	5,305	1	Fixed	5,305
TN Orthopaedic Clinics - Regional MRI	PO	2022	429	1	Fixed	429
Turkey Creek Medical Center	HOSP	2022	3,097	1	Fixed	3,097
University Dx Hall of Fame	ODC	2022	NA	2	Fixed	NA
University Dx Halls	ODC	2022	NA	1	Fixed	NA
University of TN Medical Center	HOSP	2022	21,102	5	Fixed	4,220
Fort Loudon Medical Center	HOSP	2022	2,434	1	Fixed	2,434
Blount Memorial Hospital	HOSP	2022	5,950	1	Fixed	5,950
East TN Medical Group	PO	2022	4,164	1	Fixed	4,164

Source: HFC Equipment Registry: <https://www.tn.gov/hsda/hsda-publications-and-reports/medical-equipment-registry/medical-equipment-statistics.htm>

Facility	Facility Type	Year (2021)	Annual # of Procedures	# MRI Units	MRI Unit Type	Procedures per MRI
Abercrombie Radiology	RPO	2021	2,857	1	Fixed	2,857
Summit Medical Group	PO	2021	3,207	1	Fixed	3,207
Summit Medical Group - Midlake	PO	2021	3,069	1	Fixed	3,069
Covenant Health Dx Center West	HODC	2021	486	1	Fixed	486
Covenant Health Dx Center South	ODC	2021	NA	1	Fixed	NA
East TN Children's Hospital	HOSP	2021	3,762	1	Fixed	3,762
East TN Community Open MRI	ODC	2021	4,118	2	Fixed	2,059
Fort Sanders Regional Med Ctr	HOSP	2021	9,215	2	Fixed	4,608
Knoxville Comprehensive Breast Ctr	PO	2021	2,676	1	Fixed	2,676
North Knoxville Medical Center	HOSP	2021	4,141	1	Fixed	4,141
OrthoTN - Knox County	PO	2021	9,252	2	Fixed	4,626
OrthoTN - Knox Accelerator Way	PO	2021	NA	1	Fixed	NA
OrthoTN - Knox Dannaher Lane	PO	2021	NA	1	Fixed	NA
Parkwest Medical Center	HOSP	2021	9,863	2	Fixed	4,932
TN Orthopaedic Clinics - Parkwest MRI	PO	2021	4,696	1	Fixed	4,696
TN Orthopaedic Clinics - Regional MRI	PO	2021	1,022	1	Fixed	1,022
Parkey Creek Medical Center	HOSP	2021	3,100	1	Fixed	3,100
University Dx Hall of Fame	ODC	2021	11,254	2	Fixed	5,627
University Dx Halls	ODC	2021	NA	1	Fixed	NA
University of TN Medical Center	HOSP	2021	20,342	5	Fixed	4,068
Fort Loudon Medical Center	HOSP	2021	2,143	1	Fixed	2,143
Blount Memorial Hospital	HOSP	2021	5,382	1	Fixed	5,382
East TN Medical Group	PO	2021	4,243	1	Fixed	4,243

Source: HFC Equipment Registry: <https://www.tn.gov/hsda/hsda-publications-and-reports/medical-equipment-registry/medical-equipment-statistics.htm>

Attachment 6N
Two Year Projected Utilization

Attachment 6N
Projected MRI Utilization, Years 1-3
AHI of Knoxville

	Year 1	Year 2	Year 3
MRI Scans	1,820	2,340	2,990

Attachment 8C

Average Charge per Procedure

Average Charge per Procedure

	Year 1	Year 2
MRI	\$ 1,850	\$ 1,850
CT	\$ 1,250	\$ 1,250

Attachment 9C

**2023 Average Charge per MRI Scan
AHI of Knoxville Service Area Existing Providers**

2023 Average Charge per MRI Scan
AHI of Knoxville Service Area Existing Providers

Provider	County	Provider Type	MRI Procedures		
			2023 Scans	Gross Charges	Average Charge Per MRI Scan
Abercrombie Radiology	Knox	RPO	2,700	NA	NA
Summit Medical Group	Knox	PO	4,653	NA	NA
Summit Medical Group - Midlake	Knox	PO	3,176	NA	NA
Covenant Health Dx Center West	Knox	HODC	740	\$469,188	\$634
Covenant Health Dx Center South	Knox	ODC	288	\$179,899	\$625
East TN Children's Hospital	Knox	HOSP	4,995	\$23,546,124	\$4,714
East TN Community Open MRI	Knox	ODC	3,433	\$2,176,449	\$634
Fort Sanders Regional Med Ctr	Knox	HOSP	10,136	\$22,007,811	\$2,171
Knoxville Comprehensive Breast Ctr	Knox	PO	2,110	NA	NA
North Knoxville Medical Center	Knox	HOSP	3,541	NA	NA
OrthoTN - Knox County	Knox	PO	7,806	\$7,583,343	\$971
OrthoTN - Knox Accelerator Way	Knox	PO	4,364	\$4,449,372	\$1,020
OrthoTN - Knox Dannaher Lane	Knox	PO	4,756	\$4,457,783	\$937
Parkwest Medical Center	Knox	HOSP	10,507	\$23,230,632	\$2,211
TN Orthopaedic Clinics - Parkwest MRI	Knox	PO	4,552	\$5,721,229	\$1,257
TN Orthopaedic Clinics - Regional MRI	Knox	PO	1,861	\$2,318,291	\$1,246
Turkey Creek Medical Center	Knox	HOSP	3,401	NA	NA
University Dx Hall of Fame	Knox	ODC	11,573	\$11,817,517	\$1,021
University Dx Halls	Knox	ODC	2,868	\$2,511,566	\$876
University of TN Medical Center	Knox	HOSP	23,423	\$86,347,914	\$3,686
Knox County Subtotal*			110,883	\$196,817,118	\$2,156
Fort Loudon Medical Center	Loudon	HOSP	2,498	\$5,418,812	\$2,169
Loudon County Subtotal			2,498	\$5,418,812	\$2,169
Blount Memorial Hospital	Blount	HOSP	6,396	\$41,884,227	\$6,549
East TN Medical Group	Blount	PO	4,677	\$17,561,362	\$3,755
Blount County Subtotal			11,073	\$59,445,589	\$5,369
Total, All Units in Three-County Area			124,454	\$261,681,519	\$2,495

Sources: TN HFC Medical Equipment Utilization Reports 10/2/2024; Joint Annual Reports.

Note: Knox County subtotal average charge per MRI scan excludes procedures for facilities that did not report charge information.

Additional Attachment 3

7Q Additional Information

No entity with ownership in American Health Imaging of Tennessee, LLC has been subject to an 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.

In September 2024, American Health Imaging, Inc. and its former founder and CEO, Scott Arant, entered into a settlement agreement with the United States and the State of Georgia to resolve allegations that they violated the False Claims Act. There was no determination of liability nor admission of wrongdoing by American Health Imaging, Inc. Moreover, the settlement resolved acts alleged to have occurred between 2011 and 2019, and Mr. Arant is no longer with American Health Imaging, Inc. AHI of Knoxville does not consider this settlement relevant to the review of this Application; however, in the interest of transparency and upon advice of counsel, makes this disclosure in response to 7Q.



PRESS RELEASE

American Health Imaging, Inc. and Scott Arant to Pay Over \$5 Million to Resolve Allegations of Healthcare Kickbacks

Monday, December 2, 2024

For Immediate Release

U.S. Attorney's Office, Northern District
of Georgia

ATLANTA – American Health Imaging, Inc. (“AHI”) and its former founder and CEO, Scott Arant, will pay the United States and the State of Georgia \$5,250,000 to resolve allegations that they violated the False Claims Act by: (1) providing physicians with meals, tickets to sporting events, and other gifts to induce those physicians to refer diagnostic scans to AHI’s independent diagnostic testing facilities; and (2) entering into above fair market value personal services agreements with referring physicians to induce those physicians to refer scans to AHI.

“The use of inducements to obtain referrals from medical professionals jeopardizes the integrity of our healthcare programs,” said U.S. Attorney Ryan K. Buchanan. “This settlement demonstrates our Office’s commitment to hold accountable

providers who ignore Medicare¹²² and Medicaid's strict prohibition against using kickbacks for personal greed."

"Paying or accepting kickbacks for referrals undermines the integrity of the Medicare program," said Special Agent in Charge Kelly J. Blackmon of the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG). "HHS-OIG, in collaboration with our law enforcement partners, remains committed to safeguarding federal health care programs."

"We won't allow for any provider to take advantage of a system meant to care for our most vulnerable Georgians," said Georgia Attorney General Chris Carr. "We will continue to protect the interests of Georgia patients and taxpayers by putting a stop to Medicaid fraud and abuse in our state."

The government alleges that, between 2011 and 2019, AHI relied on a variety of inducements – sporting events, fishing trips, happy hours, sponsorships of "open houses" at physician offices, and gifts of alcohol, gas cards, and free scans – to generate referrals for diagnostic scans. Many of AHI's marketing events involved no discernible educational purpose. Examples include tickets to the SEC football championship game, tickets to concerts, monthly dinners with referral sources, and outings to nail salons. The government also alleges that AHI entered into personal services agreements with referring physicians that were above fair market value. Under these agreements, physicians were compensated to interpret the scans that they referred to AHI.

The settlement resolves allegations filed by Tanya Benjamin, a former AHI employee, under the *qui tam*, or whistleblower, provisions of the False Claims Act, which authorizes private parties to sue for false claims on behalf of the United States and share in the recovery. The lawsuit was filed in the Northern District of Georgia and is captioned *United States and State of Georgia ex rel. Benjamin v. Arant et al.*, No 1:15-cv-3242-RWS (N.D. Ga.). Ms. Benjamin will receive a share of the settlement.

The U.S. Attorney's Office for the Northern District of Georgia, the U.S. Department of Health & Human Services Office of Inspector General, and the Georgia State Attorney General's Medicaid Fraud Division investigated this case.

The civil settlement was reached by Assistant U.S. Attorney Austin Hall and Georgia State Assistant Attorneys General Sara Vann and Mary Bryan.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

For further information please contact the U.S. Attorney's Public Affairs Office¹²³ at USAGAN.PressEmails@usdoj.gov or (404) 581-6016. The Internet address for the U.S. Attorney's Office for the Northern District of Georgia is <http://www.justice.gov/usao-ndga>.

AHI Settlement Agreement:

[ahi_settlement_agreement.pdf](#)

Updated December 11, 2024

Topic

FALSE CLAIMS ACT

Component

[USAO - Georgia, Northern](#)

Related Content



PRESS RELEASE**Delta Airlines Pays \$8.1 Million To Settle Lawsuit Alleging Misuse of Pandemic-Relief Funds**

Delta Airlines, Inc. ("Delta") paid \$8.1 million to the United States to settle claims that the company violated conditions Congress placed on federal relief funds provided to Delta under the Payroll...

July 15, 2025

PRESS RELEASE**Remote Patient Monitoring Company Settles False Claims Act Lawsuit for \$1.29 Million**

Health Wealth Safe, Inc. and Dr. Subodh Agrawal have paid \$1.29 million to settle allegations that they knowingly caused false claims to be presented to Medicare.

June 26, 2025

PRESS RELEASE**Mahlega Abdsharafat and Creative Hospice Settle Health Care Kickback Claims for \$9.2 Million**

Mahlega Abdsharafat, also known as "Mallie Sharafat," Creative Hospice Care, Inc., and affiliated companies (collectively, the "Creative Hospice entities") have paid \$9.2 million to settle allegations that Abdsharafat and the Creative...

June 11, 2025

**Northern District of Georgia**

Main Office:

Richard B. Russell Federal Building

75 Ted Turner Dr. SW

Suite 600

Atlanta, GA 30303-3309

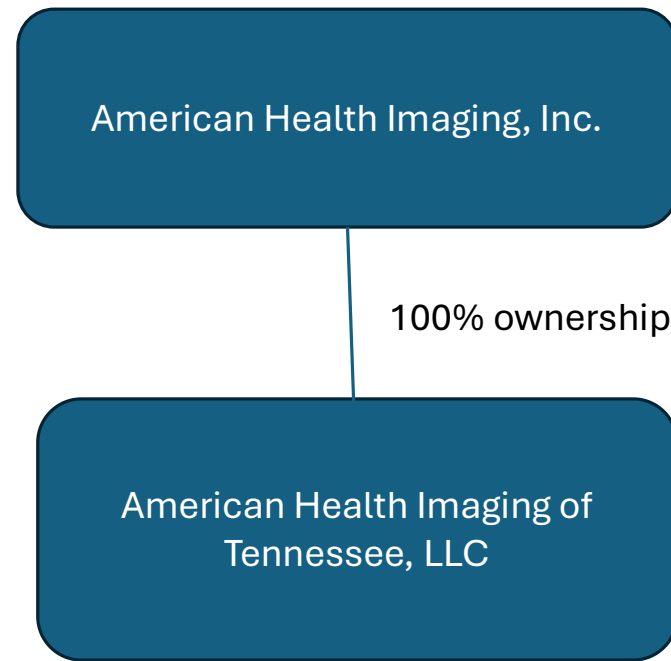


Tel: (404) 581-6000

Fax: (404) 581-6181

Additional Attachment 1

Organizational Chart



**This chart depicts the direct ownership of American Health Imaging of Tennessee, LLC*

OPERATING AGREEMENT
OF
AMERICAN HEALTH IMAGING OF TENNESSEE, LLC

THIS LIMITED LIABILITY COMPANY AGREEMENT (this “Agreement”) of American Health Imaging of Tennessee, LLC, a Tennessee limited liability company (the “Company”) is entered into as of the 29th day of April, 2025 by American Health Imaging, Inc., a Georgia corporation, as the sole member (the “Member”).

WHEREAS, the Company was formed as a limited liability company pursuant to and in accordance with the Tennessee Revised Limited Liability Company Act of 2005, as amended from time to time (Tenn. Code Ann. § 48-249-101, et. seq.) (the “Act”) by the filing of the Articles of Organization of the Company (the “Certificate”) with the Secretary of State of the State of Tennessee on April 29, 2025; and

WHEREAS, the Member and the Company desire to set forth their respective rights and obligations and enter into this Agreement.

NOW, THEREFORE, in consideration of the covenants and conditions set forth herein, the Member and the Company each hereby agree as follows:

Section 1. **Name**. The name of the limited liability company shall be “American Health Imaging of Tennessee, LLC”.

Section 2. **Member**.

(a) The name and the business, residence or mailing address of the Member is as follows:

Name: American Health Imaging, Inc.
Address: c/o US Radiology Specialists, Inc.
700 E Morehead Street, Suite 300
Charlotte, NC 28202
Attn: General Counsel

(b) The percentage of ownership of the Company owned by the Member (the “Percentage Interest”) as of the date hereof is one hundred percent (100%).

Section 3. **Registered Office/Registered Agent**.

(a) The registered office of the Company shall be the office of the initial registered agent named in the Certificate or such other office (which need not be a place of business of the Company) as the Member may designate from time to time in the manner provided by the Act and applicable law.

(b) The registered agent for service of process on the Company in the State of Tennessee shall be the initial registered agent named in the Certificate or such other person or persons as the Member may designate from time to time in the manner provided by the Act and applicable law.

Section 4. **Purpose/Powers.** The Company is formed for the object and purpose of, and the nature of the business to be conducted and promoted by the Company is, engaging in any lawful act or activity for which limited liability companies may be formed under the Act and engaging in any and all activities necessary or incidental to the foregoing. The Company shall have the power and authority to do any and all acts necessary or convenient to or in furtherance of said purpose, including all power and authority, statutory or otherwise, possessed by, or which may be conferred upon, limited liability companies under the laws of the State of Tennessee.

Section 5. **Management.** The management of the Company shall be vested solely in the Member, who shall have all powers to control and manage the business and affairs of the Company and may exercise all powers of the Company. The Member may from time to time:

- (a) appoint, by written designation filed with the records of the Company, one or more persons to act on behalf of the Company as officers of the Company with such titles as may be appropriate, including the titles of Chairman, President, Vice President, Treasurer, Secretary and Assistant Secretary; and
- (b) delegate any and all power and authority with respect to the business and affairs of the Company to any individual or entity, including any officers and employees of the Company.

Any person appointed as an officer of the Company with a title customarily held by an officer of a corporation shall have the same power and authority to act on behalf of the Company as an officer holding the same title would customarily have in a corporation organized under the laws of South Carolina and the assignment of such title shall constitute the delegation to such officer of the authority and duties that are normally associated with that office, subject to any restrictions on such authority imposed by the Member. The Member may at any time, with or without cause, replace any or all officers of the Company. The initial officers of the Company shall be Caitlin Zulla (President and Chief Executive Officer), James Anthony Martin (Vice President and Treasurer) and Julie Szeker (Vice President and Secretary).

Section 6. **Agents.** The Member shall have the power to appoint agents to act for the Company with such titles as the Member deems appropriate, and may remove such agents, by written instrument signed by the Member, at any time, with or without cause.

Section 7. **Capital Contributions.** The Member may make, but shall not be required to make, additional capital contributions to the Company.

Section 8. **Distributions.** Distributions shall be made to the Member at the times and in the aggregate amounts determined by the Member.

Section 9. **Tax Characterization.** As long as the Company has only one member, unless otherwise determined by the Member, the Company shall be disregarded for federal and all relevant state tax purposes and the activities of the Company shall be deemed to be the activities of the Member.

Section 10. **Term and Dissolution.** The Company shall have perpetual existence unless it shall be dissolved and its affairs shall have been wound up upon (a) the written consent of the Member or (b) the entry of a decree of judicial dissolution in accordance with the Act. The existence of the Company as a separate legal entity shall continue until the cancellation of the Certificate as provided in the Act.

Section 11. **Assignment.** The Member may assign its limited liability company interest to any person, which person shall become a Member upon the filing of the instrument of assignment with the records of the Company.

Section 12. **Amendments.** This Agreement may be amended and/or restated from time to time by the Member.

Section 13. **Liability and Indemnification.**

- (a) **Liability of Member.** The Member shall not have any liability for any obligations or liabilities of the Company except to the extent provided in the Act.
- (b) **Liability of Officers.** None of the Member, any officer of the Company, nor any employee, director, officer, agent, shareholder, member, limited partner or general partner of the Member, shall be liable, responsible or accountable in damages or otherwise to the Company by reason of acts or omissions or errors in judgment, except for acts, omissions or errors in judgment that are found by a court of competent jurisdiction to be the result of such person's fraud or willful misconduct.
- (c) **Indemnification.** To the fullest extent permitted by law, the Company shall indemnify, defend and hold harmless the Member, each officer of the Company and each employee, director, officer, agent, member, shareholder, limited partner and general partner of the Member (each, an "**Indemnified Person**") from and against any loss, liability, damages, cost or expense (including legal fees and expenses and any amounts paid in settlement) (each a "**Loss**" and collectively "**Losses**") resulting from a claim, demand, lawsuit, action or proceeding by reason of any act or omission performed or omitted by such Indemnified Person on behalf of the Company in a manner reasonably believed to be within the scope of the authority conferred on such Indemnified Person by this Agreement; provided that such acts or omissions of such Indemnified Person are not found by a court of competent jurisdiction to constitute fraud, gross negligence or willful misconduct. Expenses, including legal fees, incurred by an Indemnified Person and relating to any claim, demand, lawsuit, action or proceeding for which indemnification is sought under this Section shall be paid by the Company upon demand by the Indemnified Person; provided that the Indemnified Person shall reimburse the Company for such expenses if it is ultimately determined that such Indemnified Person is not entitled to indemnification hereunder.

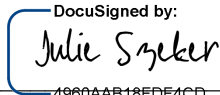
Section 15. **Governing Law.** This Agreement shall be governed by, and construed under, the Laws of the State of Tennessee, all rights and remedies being governed by said laws.

[Remainder of page left intentionally blank. Signature page follows.]

IN WITNESS WHEREOF, the undersigned has executed this Operating Agreement as of the date first written above.

SOLE MEMBER:

AMERICAN HEALTH IMAGING, INC.

By: 
Name: Julie Szeker
Title: Vice President and Secretary

Additional Attachment 2

Letters of Support

**CLYDE C. MATHISON, M.D.
FARRAGUT ENT & ALLERGY
144 CONCORD ROAD
KNOXVILLE, TN 37934**

August 8, 2025

Tennessee Health Facilities Commission
Andrew Jackson Building, 9th Floor
502 Deaderick Street

Re: Certificate of Need Support for Outpatient Diagnostic Center – Knoxville, TN

Dear Members of the Health Facilities Commission,

I am writing to express my support for American Health Imaging of Tennessee, LLC's ("AHI") Certificate of Need ("CON") Application for the development of a new outpatient diagnostic center ("ODC") in Knoxville, Tennessee (American Health Imaging of Knoxville), which will offer advanced 3T MRI technology to the patients of Knox, Blount, and Loudon counties. As a physician board certified in Otolaryngology Head & Neck Surgery, who routinely refers patients for MRI imaging, I can attest first-hand to the need for a new ODC, particularly one located in Farragut, an area of Knoxville that has seen significant growth in the past five years. While there are certainly MRI units based in hospital outpatient centers and physician offices, there are very few freestanding imaging facilities in Knox, and none in Blount or Loudon counties.

The establishment of a new ODC would provide more accessible and affordable options for our community. By way of example, it is my understanding that obtaining an imaging study at a freestanding imaging facility like AHI is up to 70% less than the same study at a hospital-based imaging center (including a hospital outpatient department). Moreover, major commercial payors have now instituted site-of-care medical necessity requirements and will often refuse reimbursement for imaging at hospital-based imaging centers, except under limited circumstances. For these reasons, patients in Knoxville and the surrounding areas may encounter barriers—whether due to cost, coverage requirements, or scheduling delays—which can hinder my ability to provide timely treatment.

I have been impressed to learn that AHI is committed to scheduling patients so that each scan is completed within twenty-four to forty-eight hours of receiving an order from a physician whenever possible, with 23% of all orders being scanned on the same day of receipt. I have also learned that AHI has negotiated rates with 99% of all health plans. AHI's commitment to patient care would greatly benefit my patients and the residents of Knox, Blount, and Loudon counties.

It is my belief that a new ODC would not duplicate existing services but rather fill a gap in accessible, cost-effective imaging services, especially for underserved populations. The

outpatient setting aligns with broader statewide and national efforts to reduce healthcare costs while improving patient outcomes.

I believe this ODC will become an essential part of Knoxville's healthcare ecosystem, providing timely access to diagnostic imaging that supports primary care physicians and specialist providers alike.

For these reasons, I strongly encourage approval of the CON application.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. Mathison', with a stylized, sweeping flourish extending to the right.

Clyde C. Mathison, M.D.

Dr. Steven Ullrick

Board-Certified MSK Radiologist
 Lumexa Imaging
 3200 Six Forks Road, Suite 1000
 Raleigh, NC 27609

July 30th, 2025

Tennessee Health Facilities Commission
 Andrew Jackson Building, 9th Floor
 502 Deaderick Street

RE: Certificate of Need Support for Outpatient Imaging Facility – Knoxville, TN

Dear Members of the Health Facilities Commission,

I am writing to express my support for the American Health Imaging of Tennessee, LLC Certificate of Need (CON) application for the development of a new outpatient imaging facility in Knoxville, Tennessee, which will offer **advanced 3T MRI** and **64-slice CT** technology to the patients of Knox, Blount, and Loudon County where similar services are not widely available in an freestanding setting focused on **affordability, access, and clinical excellence**.

As a practicing Musculoskeletal Radiologist with 16 years of experience interpreting both hospital-based and outpatient imaging studies, I can attest to the critical need for high-quality, accessible imaging services in the region. Patients in Knoxville and the surrounding areas often face significant barriers—whether due to cost, scheduling delays, or limited access to high-quality imaging technology—when trying to obtain the clinical answers needed to support timely diagnosis and expedite their path to recovery. These delays can lead to prolonged uncertainty, deferred treatment, and worsened clinical outcomes.

This proposed facility directly addresses those challenges. By offering **cutting-edge technology** in the form of a **3T MRI scanner** and a **64-slice CT unit**, patients will benefit from faster, clearer, and more accurate diagnostic evaluations. These modalities represent the standard of care in many high-acuity settings and should be equally available in freestanding environments, especially when paired with a mission to serve patients in a more affordable environment. In particular, the 3T MRI has become the standard of care for diagnosing and monitoring the progression of numerous neurological disorders, including Alzheimer's, Multiple Sclerosis, Epilepsy, and Parkinsonism. 3T imaging is also uniquely suited to the early detection of prostate cancer, advanced breast imaging, and the evaluation of small orthopedic joints.

Importantly, this center would not duplicate existing services but rather **fill a gap in accessible, cost-effective imaging services**, especially for underserved populations. The outpatient setting aligns with broader statewide and national efforts to reduce healthcare costs while improving outcomes.

I believe this facility will become an essential part of Knoxville's healthcare ecosystem, providing timely access to diagnostic imaging that supports primary care physicians and specialist providers alike.

For these reasons, I strongly encourage approval of the CON application.

Sincerely,

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Dr. Steven Ullrick, MD
Board-Certified MSK Radiologist

Additional Attachment 4
Letters of Support

**CLYDE C. MATHISON, M.D.
FARRAGUT ENT & ALLERGY
144 CONCORD ROAD
KNOXVILLE, TN 37934**

August 8, 2025

Tennessee Health Facilities Commission
Andrew Jackson Building, 9th Floor
502 Deaderick Street

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Clyde C. Mathison, M.D.

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July 30th, 2025

Tennessee Health Facilities Commission
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Dr. Steven Ullrick, MD
Board-Certified MSK Radiologist



Siemens Medical Solutions USA, Inc.
% Mr. Andrew Turner
Regulatory Affairs Professional
40 Liberty Boulevard, MailCode 65-1A
MALVERN PA 19355

March 11, 2020

Re: K192924

Trade/Device Name: MAGNETOM Vida, MAGNETOM Lumina, MAGNETOM Vida Fit
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: February 7, 2020
Received: February 10, 2020

Dear Mr. Turner:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

<https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2020 See PRA Statement below.
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510(k) Number (if known) **K192924**

Device Name
 MAGNETOM Vida, MAGNETOM Lumina, and MAGNETOM Vida Fit

Indications for Use (Describe)
 Your MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal, and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

Your MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-Safe biopsy needles.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)
 ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21 CFR § 807.92.

1. General Information

Establishment: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared: October 9, 2019

Manufacturer: Siemens Healthcare GmbH
Henkestrasse 127
91052 Erlangen
Germany
Registration Number: 3002808157

2. Contact Information

Andrew Turner
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355, USA
Phone: (610) 850-5627
Fax: (610) 448-1787
E-mail: andrew.turner@siemens-healthineers.com

3. Device Name and Classification

Device name: MAGNETOM Vida, MAGNETOM Lumina and
MAGNETOM Vida Fit
Trade name: MAGNETOM Vida, MAGNETOM Lumina and
MAGNETOM Vida Fit
Classification Name: Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel: Radiology
CFR Code: 21 CFR § 892.1000

Classification: II
Product Code: Primary: LNH
 Secondary: LNI, MOS

4. Legally Marketed Predicate Device

Trade name: MAGNETOM Vida
510(k) Number: K183254
Clearance Date: January 18, 2019
Classification Name: Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel: Radiology
CFR Code: 21 CFR § 892.1000
Classification: II
Product Code: Primary: LNH
 Secondary: LNI, MOS

5. Intended Use

The indications for use for the subject devices is the same as the predicate device:

Your MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Your MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

6. Device Description

MAGMETOM Vida, MAGNETOM Lumina, and MAGNETOM Vida Fit with software *syngo* MR XA20A include new and modified hardware and software compared to the predicate device, MAGNETOM Vida with *syngo* MR XA11B. A high level summary of the hardware and software is provided below:

Hardware

Hardware

- Computer

Coils

- BM Body 18: The new BM Body 18 coil is a receive coil with 18 elements and is based on the Body 18 coil, (cleared with K101347). It is a general purpose coil.

The BM Body 18 coil can be used with two different cables of different length; this capability was introduced with the BM Body 12 coil.

Software

Features and Applications

- SMS for TSE_DIXON: Simultaneous excitation and acquisition of multiple slices with the Simultaneous multi-slice (SMS) technique for TSE Dixon imaging.
- GOLiver is a set of optimized pulse sequence for fast and efficient imaging of the abdomen / liver. It is designed to provide consistent exam slots and to reduce the workload for the user in abdominal / liver MRI.
- Angio TOF with Compressed Sensing (CS): The Compressed Sensing (CS) functionality is now available for TOF MRA within the BEAT pulse sequence type for the 1.5 T MR systems. Scan time can be reduced by an incoherent undersampling of k-space data. The usage of CS as well as the acceleration factor and further options can be freely selected by the user.
- RT Respiratory self-gating for FL3D_VIBE: Non-contrast abdominal and thoracic examination in free breathing with reduced blur induced by respiratory motion.
- SMS for RESOLVE and QDWI: Simultaneous excitation and acquisition of multiple slices with the Simultaneous multi-slice (SMS) technique for readout-segmented echo planar imaging (RESOLVE) and quiet diffusion weighted imaging (QDWI).
- SPACE with Compressed Sensing (CS): The Compressed Sensing (CS) functionality is now available for the SPACE pulse sequence type. Scan time can be reduced by the incoherent under-sampling of the k-space data. The usage of CS as well as the acceleration factor and other options can be freely selected by the user.
- SEMAC: SEMAC is a method for metal artifact correction in ortho imaging of patients with whole joint replacement. Using Compressed Sensing the acquisition can be accelerated.
- TSE_MDME: A special variant of the TSE pulse sequence type which acquires several contrasts (with different TI and TE, i.e. Multi Delay Multi Echo) within a single sequence.

- TSE and GRE with Inline Motion Correction: TSE and GRE with Inline Motion Correction: Tracking of motion of the head during head scans with a nose marker and a camera system. The MR system uses the tracking information to compensate for the detected motion.
- EP_SEG_PHS: pulse sequence type EP_SEG_PHS, based on BEAT_EPI and modified with a silent period that can be used by external devices/applications for synchronization with the MR imaging
- GRE_PHS: pulse sequence type GRE_PHS, is a GRE pulse sequence type, modified to provide a silent period that can be used by external devices/applications for synchronization with the MR imaging.
- GRE_Proj: The GRE projection pulse sequence type "" allows the acquisition of 1-D projection data for different orientations.
- GOKnee2D: GOKnee2D is a set of multi-band pulse sequence types with Simultaneous Multislice TSE for fast and efficient imaging of the knee. It is designed to provide consistent exam slots and to reduce the workload for the user in Knee MRI.
- BEAT_interactive: The BEAT_Interactive pulse sequence type is a modification of the BEAT_IRTTT pulse sequence type in order to interactively increase the slice thickness and switch on and off a magnetization pulse that the user can select prior to the measurement start.
- EP2D_SE_MRE: As an alternative of greMRE, EP2D_SE_MRE pulse sequence type is based on single-shot EP2D_SE_MRE sequence. It offers acquisition of multiple slices in a single, short breath-hold, and it is more robust against signal dephasing effects
- ZOOMit DWI: *syngo* ZOOMit based on EPI diffusion allows diffusion weighted imaging (DWI) while avoiding signal and artifacts from surrounding tissue. The feature is now available for 1-ch-systems and enables improved robustness to infolding artifacts from tissue from outside the excited region.
- SPACE Flair Improvements: SPACE pulse sequence type offers a magnetization preparation mode for brain imaging with FLAIR contrast (FLuid Attenuated Inversion Recovery); improving the image quality of FLAIR images.
- External Phase Correction Scan for EPI Diffusion: Separate N/2 Nyquist ghost correction acquisition method for diffusion imaging in the presence of fat.
- MR Breast Biopsy Workflow improvements: The changes made to MR Breast Biopsy application target two areas: the improved readability of planning results and the ability to handle the planning of multiple biopsy targets.
- GOBrain / GOBrain+: GOBrain (brain examination in short acquisition time) GOBrain+ (adaptation of GOBrain pulse sequences)

Software / Platform

- Dot Cockpit: MR Protocol Manager as part of a scanner fleet with connection via a share.

- Access-i: The interface Access-i allows 3rd party devices to establish a bi-directional communication with the MR scanner via a secure local network connection, supporting data transfer to and triggering of data acquisition from the 3rd party device. It enables the 3rd party client to control and edit a measurement program on the MR.
- Table positioning mode: A new table positioning mode "FIX" is introduced which complements the existing table positioning modes ISO and LOC to support workflows in which the user needs to be in control of a defined Z-position at which measurements get executed.

Other Modifications and / or Minor Changes

- MAGNETOM Vida Fit: The MAGNETOM Vida Fit is a new MRI System which is the result of an upgrade from a MAGNETOM Aera.
- BM Body 12: For MR examinations of head and neck in situations where a rigid rf head coil cannot be used, e.g. with patients positioned in thermoplastic masks used for radiotherapy planning, aiming at higher signal-to-noise and spatial resolution as what can be achieved with 4-channel Flex rf coils
- Body 18: For MR examinations of head and neck in situations, where a rigid rf head coil cannot be used, e.g. with patients positioned in thermoplastic masks used for radiotherapy planning, aiming at higher signal-to-noise and spatial resolution than what can be achieved with 4-channel Flex rf coils
- UltraFlex Large 18, UltraFlex Small 18: For MR examinations of head and neck in situations, where a rigid rf head coil cannot be used, e.g. with patients positioned in thermoplastic masks used for radiotherapy planning, aiming at higher signal-to-noise and spatial resolution than what can be achieved with 4-channel Flex rf coils
- Broad band / narrow band online supervision: The broadband/narrowband supervision checks the correctness of the measurement values used for the SAR calculation. With *syngo* MR XA20A, the supervision cycle is reduced significantly.
- LiverLab Dot Engine - debundling: LiverLab is now offered separately as standalone workflow and is also still available as part of the Abdomen Dot Engine.

7. Substantial Equivalence

MAGNETOM Vida, MAGNETOM Lumina and MAGNETOM Vida Fit with software *syngo* MR XA20A are substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with <i>syngo</i> MR XA11B	K183254, cleared January 18, 2019	LNH LNI, MOS	Siemens Healthcare GmbH

MAGNETOM Vida, MAGNETOM Lumina and MAGNETOM Vida Fit with software *syngo* MR XA20A includes hardware and software already cleared on the following reference devices:

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Skyra with software <i>syngo</i> MR E11C-AP04	K173592, cleared February 13, 2018	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Aera with <i>syngo</i> MR E11C-AP01	K182299, cleared October 26, 2018	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Lumina with software <i>syngo</i> MR XA11B	K183244, cleared January 24, 2019	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Skyra with <i>syngo</i> MR D13C	K123510, cleared May 17, 2013	LNH	Siemens AG

8. Technological Characteristics

The subject devices, MAGNETOM Vida, MAGNETOM Lumina and MAGNETOM Vida Fit with software *syngo* MR XA20A, are substantially equivalent to the predicate device with regard to the operational environment, programming language, operating system and performance.

The subject devices conform to the standard for medical device software (IEC 62304) and other relevant IEC and NEMA standards.

While there are some differences in technological characteristics between the subject devices and predicate device, including new and modified hardware and software, these differences have been tested and the conclusions from the non-clinical data suggests that the features bear an equivalent safety and performance profile to that of the predicate device.

9. Nonclinical Tests

The following performance testing was conducted on the subject devices.

Performance Test	Tested Hardware or Software	Source/Rationale for test
Sample clinical images	coils, new and modified software features	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Image quality assessments by sample clinical images. In some cases a comparison of the image quality / quantitative data was made.	- new / modified pulse sequence types. - comparison images between the new / modified features and the predicate device features	
Performance bench test	mainly new and modified hardware	

Software verification and validation	mainly new and modified software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Biocompatibility	surface of applied parts	ISO 10993-1
Electrical, mechanical, structural, and related system safety test	complete system	- AAMI / ANSI ES60601-1 - IEC 60601-2-33
Electrical safety and electromagnetic compatibility (EMC)	complete system	IEC 60601-1-2

The results from each set of tests demonstrate that the devices perform as intended and are therefore substantially equivalent to the predicate device to which it has been compared.

10. Clinical Tests/Publications

No additional clinical tests were conducted to support substantial equivalence for the subject devices; however, as stated above, sample clinical images were provided. Clinical publications were referenced to provide information on the use of the following features and functions:

Feature/Function	Clinical Publication
ZOOMit DWI	Finsterbusch J. et al., "Improving the performance of diffusion-weighted inner field-of-view echo-planar imaging based on 2D-selective radiofrequency excitations by tilting the excitation plane". J Magn Reson Imaging, 35:984-992 (2012)
	Schneider R. et al., "Asymmetric Two-Dimensional Spatially Selective Excitation in Echo-Planar Imaging". Proc Intl Soc Mag Reson Med 22 (2014), p. 4436
	Alley M. T. et al., "Angiographic Imaging with 2D RF Pulses". Magn Reson Med 37:260-267 (1997)
EP2D_SE_MRE	Wagner M. et al., "Magnetic Resonance Elastography of the Liver: Qualitative and Quantitative Comparison of Gradient Echo and Spin Echo Echoplanar Imaging Sequences". Invest Radiol. 2016 Sep;51(9):575-81.
	Kim Y. S. et al., "Comparison of spin-echo echoplanar imaging and gradient recalled echo-based MR elastography at 3 Tesla with and without gadoxetic acid administration". Eur Radiol. 2017 Oct;27(10):4120-4128.
	Serai S. D. et al., "Spin-echo Echo-planar Imaging MR Elastography versus Gradient-echo MR Elastography for Assessment of Liver Stiffness in Children and Young Adults Suspected of Having Liver Disease". Radiology. 2017 Mar;282(3):761-770.

11. Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to ensure safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971, to identify and provide mitigation of potential hazards early in the design cycle and continuously throughout the development of the product. Siemens Healthcare GmbH adheres to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards. Furthermore, the device is intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

MAGNETOM Vida, MAGNETOM Lumina and MAGNETOM Vida Fit with software *syngo* MR XA20A conform to the following FDA recognized and international IEC, ISO and NEMA standards:

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
19-4	General	Medical electrical equipment - Part 1: general requirements for basic safety and essential performance	ES60601-1:2005/(R) 2012 and A1:2012	AAMI / ANSI
19-8	General	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	60601-1-2, Ed. 4.0:2014-02	IEC
12-295	Radiology	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	60601-2-33, Ed. 3.2:2015	IEC
5-40	General	Medical devices - Application of risk management to medical devices	14971, Ed. 2:2007-10	ISO
5-114	General	Medical devices – Application of usability engineering to medical devices	62366, Ed. 1.0:2015	AAMI ANSI IEC
13-79	Software	Medical device software - Software life cycle processes	62304:2015-06	AAMI ANSI IEC

12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4:2010	NEMA
12-288	Radiology	Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI)	MS 9:2008	NEMA
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	PS 3.1 - 3.20:2016	NEMA
2-220	Biocompatibility	Biological evaluation of medical devices - Part 1: evaluation and testing within a risk management process (Biocompatibility)	10993-1:2009	AAMI ANSI ISO

12. Conclusion as to Substantial Equivalence

MAGNETOM Vida, MAGNETOM Lumina and MAGNETOM Vida Fit with software *syngo* MR XA20A have the same intended use and same basic technological characteristics than the predicate device system, MAGNETOM Vida with *syngo* MR XA11B. While there are some differences in technological characteristics/features compared to the predicate device, the differences have been tested and the conclusions from all verification and validation data suggest that the features bear an equivalent safety and performance profile to that of the predicate device and reference devices.

Siemens believes that MAGNETOM Vida, MAGNETOM Lumina and MAGNETOM Vida Fit with software *syngo* MR XA20A are substantially equivalent to the currently marketed predicate device MAGNETOM Vida with software *syngo* MR XA11B (K183254, cleared on January 18, 2019).



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Customer Number: 0000028898 Date: 06/18/2025

American Health Imaging -Knoxville
326 Lovell Road
Knoxville, TN 37934

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.

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Contract Total: \$ 1,858,279
(total does not include any Optional or Alternate components which may be selected)

Proposal valid throughout the state of Tennessee CON or DET process.



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Accepted and Agreed to by:

Siemens Medical Solutions USA Inc.

By (sign): _____
Name: Chris Gentry
Title: _____
Date: _____

AMERICAN HEALTH IMAGING INC - Knoxville

By (sign): _____
Name: _____
Title: _____
Date: _____

***By signing below, signor certifies that no modifications or additions have been made to the Quotation.
Any such modifications or additions will be void.***

By (Sign): _____

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Quote Nr:	CPQ-740880 Rev. 4
Terms of Payment:	00% Down, 80% Delivery, 20% Installation Free On Board: Destination
Purchasing Agreement:	VIZIENT SUPPLY LLC VIZIENT SUPPLY LLC terms and conditions apply to Quote Nr CPQ-740880 Customer certifies, and Siemens relies upon such certification, that : (a) VIZIENT MRI XR0885 is the sole GPO for the purchases described in this Quotation, and (b) the person signing this Quotation is fully authorized under the Customer's policies to choose and indicate for Customer such appropriate GPO.

MAGNETOM Lumina (DE)

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14461710	MAGNETOM Lumina - System MAGNETOM Lumina leverages the intelligent combination of Tim 4G and the Siemens unique BioMatrix technology to be ready to embrace the unique set of challenges that each and every patient brings to the MRI exam. System Design - Short and open appearance (186 cm total system length cover-to-cover and 70 cm Open Bore Design) to reduce patient anxiety and claustrophobia - Whole-body superconductive Zero Helium Boil-Off 3T magnet - Weight-optimized magnet technology based on high performance 7T magnet design - Actively Shielded water-cooled Siemens gradient system for maximum performance - Tim 4G (Total imaging matrix in the 4th generation) for excellent image quality and speed with Siemens unique DirectRX technology enabling all digital-in/digital-out design and Dual-Density Signal Transfer Technology Push-button exams with GO technologies Select&GO DotGO/ myExam Companion Recon&GO MR View&GO Tim Application Suite allowing excellent head-to-toe imaging for - Neuro - Angio - Cardiac - Body - Onco - Breast - Ortho - Pediatric - Scientific

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Qty	Part No.	Item Description
		Further included - High performance host computer and measurement and reconstruction system - Patient communication including headphones - syngo MR software including: - Turbo Suite Essential - 1D/2D PACE - BLADE - Phoenix - Inline Diffusion - MDDW (Multiple Direction Diffusion Weighting) - CISS - DESS - TGSE - Offline Composing
1	14460161	MR General Engine #Vi syngo.MR General Engine extends Numaris/X by adding dedicated workflows and tools for routine and advanced reading of MR examinations. A generic MR Basic workflow is provided, as well as specific MR Neurology, MR Prostate Reading, MR Breast Reading, and MR Cardio-Vascular workflows.
1	14475308	myExam Brain Assist myExam Brain Assist provides guided and flexible workflows. Optimized scan strategies are provided and can be selected based on the patient's condition, which allows for reproducible, high image quality and time efficient exams. The built-in flexibility allows users to change predefined strategies at any time during the brain workflow, and to personalize to the individual patient's condition and clinical need. myExam Brain Assist is customizable to the site-specific standards of care.
1	14475309	myExam Spine Assist myExam Spine Assist provides guided and flexible workflows for cervical, thoracic and lumbar spine. Optimized scan strategies are provided and can be selected based on the patient's condition, which allows for reproducible, high image quality and time efficient exams. The built-in flexibility allows users to change predefined strategies at any time during the spine workflow, and to personalize to the individual patient's condition and clinical need. myExam Spine Assist is customizable to the site-specific standards of care.
1	14475310	myExam Large Joint Assist myExam Large Joint Assist provides guided and flexible workflows for knee, hip and shoulder. Optimized scan strategies are provided and can be selected based on the patient's condition, which allows for reproducible, high image quality and time efficient exams. The built-in flexibility allows users to change predefined strategies at any time during the scan workflow, and to personalize to the individual patient's condition and clinical need. myExam Large Joint Assist is customizable to the site-specific standards of care.
1	14441748	Quiet Suite #T+D Quiet Suite enables complete, quiet examinations for neurology and orthopedics with at least 70% reduction in sound pressure levels.
1	14460162	Tim Whole Body Suite #Vi Tim Whole Body Suite puts it all together. This suite enables table movement for imaging of up to 205 cm (6' 9") FoV without compromise. In combination with Tim's newly designed ultra-high density array higher spatial and temporal resolution can be achieved along with unmatched flexibility of any coverage up to Whole Body. For faster exams and greater diagnostic confidence.
1	14460227	Tim Planning Suite #Vi With the Tim Planning Suite, multiple regions in the entire body can be examined in a minimum of time through measurement planning on a single FoV of any desired size.
1	14456329	syngo TimCT FastView #Vi

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Qty	Part No.	Item Description
		TimCT FastView is the "one go" localizer for the whole body or large body regions such as the whole spine or the whole abdomen. It acquires the complete extended Field of View in one volume with isotropic resolution. Transverse, coronal and sagittal reformats of the volume are calculated Inline and displayed for planning subsequent exams. - Inline reconstruction of the localizer images during the scan. - Localizing images in three planes over the maximum Field of View available for subsequent planning in all orientations. - TimCT FastView runs without laser light positioning to further streamline the workflow for several indications.
1	14460160	Advanced Diffusion #Vi QuietX DWI and RESOLVE together make up the Advanced Diffusion package. QuietX DWI enables quieter diffusion-weighted imaging of the brain with up to 70% reduction in sound pressure relative to conventional diffusion-weighted imaging. RESOLVE (Readout Segmentation Of Long Variable Echo-trains) is a multi-shot, readout segmented EPI sequence for high-resolution, low-distortion diffusion-weighted imaging (DWI). This technique is largely insensitive to susceptibility effects, providing anatomically accurate diffusion imaging for the brain, spine, breast and prostate. In combination with syngo.MR Tractography, RESOLVE enables excellent white-matter tract imaging even in regions of high susceptibility, such as the spine.
1	14456327	WARP & Advanced WARP #Vi WARP and Advanced WARP (SEMAC) integrates different techniques tailored to reduce susceptibility artifacts caused by orthopedic MR-conditional metal implants.
1	14456323	Inline Composing syngo #Se Automatic anatomical or angiographic composing of multiple adjacent coronal or sagittal images for presentation and further evaluation. Composed images can be automatically loaded into Graphical Slice Positioning for scan planning purposes.
1	14475447	syngo Expert-i XA50/XA51 This software application enables remote access to the system (connected via local area network) for planning and processing.
1	14461711	Tim [180x32] XK-Gradient #Lu Tim [180x32] XK-gradients performance level Tim 4G's RF system and innovative coil architecture enables high resolution imaging and increased throughput. The system provides a maximum number of 180 channels (coil elements) that can be connected simultaneously. Flexible parallel imaging is achieved by 32 independent receiver channels that can be used simultaneously in one single scan and in one single FOV, each generating an independent partial image. XK - gradients The XK 36/200 gradients are designed for high performance and linearity to support clinical whole body imaging at 3T. The XK gradients combine 36 mT/m peak amplitude with a slew rate of 200 T/m/s. The force compensated gradient system minimizes vibration levels and acoustic noise.
1	14468981	High-performance measurement and reconstruction system Coil Package Tim [180x32] #3T This package includes (if not exchanged with different variants via respective quote items): - Head/Neck 16 DirectConnect - BioMatrix Spine 24 - BioMatrix Body 12 - Flex Large 4 - Flex Small 4

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Qty	Part No.	Item Description
		- Flex Coil Interface
1	14468946	BioMatrix Technology #Al,Lu The new and unique BioMatrix technology addresses different aspects of patient bio-variability.
1	14470793	BioMatrix Coil Shim #Al,Lu BioMatrix CoilShim helps to reduce patient induced strongly localized B0 inhomogeneities by dedicated local shim channels.
1	14470794	BioMatrix SliceAdjust #BM BioMatrix SliceAdjust helps to avoid station boundaries and apparent broken spine artifacts as well as to preserve the SNR for whole-body diffusion.
1	14461712	BioMatrix Table #Lu The new BioMatrix Table is designed for smooth patient preparation, high patient comfort and easy cleanability. The unique design of the BioMatrix table can support up to 250 kg (550 lbs) without restricting the vertical or horizontal movement.
1	14470796	BioMatrix Select & GO #Al,Lu Select&GO The Select&GO interface enables fast and easy single-touch patient positioning. Correct positioning saves unnecessary wasted time for repositioning and additional adjustments, therefore shortening the total room time. The ergonomically designed Select&GO touch panel is integrated into the front cover on the left-hand side of the patient tunnel for controlling table movement, guidance for patient setup and comfort features. The Select&GO panel is well illuminated for easy visual recognition. The BioMatrix Select&GO interface enables fast and easy single-touch patient positioning. The interface is integrated left-hand side of the patient into the front covers. Correct positioning saves unnecessary wasted time for repositioning and additional adjustments, therefore shortening the total room time.
1	14461716	Pure White Design #Lu MAGNETOM Lumina is available in an appealing design which perfectly integrate into different environments. The Pure White Design comprises a brilliant white front design ring with integrated unique Select&GO panels. The table cover is presented also in the same color and material selection.
1	14456270	PC Keyboard US English #Vi Standard PC keyboard with 105 keys.
1	14468983	High-End Computing [180x32] #3T This upgrade brings a high-end image reconstruction computer to the Tim [180x32] configuration for highly intensive computational calculations.
1	14475335	SW syngo MR XA50A syngo MR XA50A is the new software platform, bringing the latest features and functionality for daily clinical excellence. syngo MR XA50A guides and enables the user throughout the entire workflow: from patient registration; patient set up with guided workflows on the Select&GO; protocol management and selection; image acquisition and viewing; data handling; and post processing and reporting. This software together with the hardware enables diagnostic excellence for your daily clinical needs. The syngo MR XA50A platform offers myExam Companion which introduces a new MRI operation philosophy by providing built-in expertise and automation for users and clinical questions. myExam Companion provides different workflow modes for tailored assistance: myExam Assist and myExam Cockpit. No matter the user or patient, myExam Companion helps generate consistent, comprehensive results.
1	14461619	Turbo Suite Essential #BM Turbo Suite Essential comprises established acceleration techniques to maximize

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Qty	Part No.	Item Description
		productivity for all contrasts, orientations and all routine imaging applications from head-to-toe.
1	14461558	Simultaneous Multi-Slice Package #BM This license includes: - Simultaneous Multi-Slice EPI - Simultaneous Multi-Slice TSE (from SW MR XA11A and higher and with XA10B) - Simultaneous Multi-Slice RESOLVE (from SW MR XA11B and higher and with XA10B) - Simultaneous Multi-Slice TSE DIXON (from SW MR XA20A and higher) Simultaneous Multi-Slice (SMS) EPI and RESOLVE enables accelerated imaging for diffusion-weighted (DWI/DTI) and BOLD functional MR imaging. With SMS EPI, scan times for DWI can be reduced by up to 68% and/or images with higher spatial/diffusion resolution can be acquired. For BOLD imaging, SMS EPI can enable increased temporal sampling of BOLD data acquisitions and/or improved slice coverage/resolution. From SW MR XA11A and higher and with XA10B: TSE is the most frequently utilized clinical pulse sequence. Simultaneous Multi-Slice TSE is available for reducing scan time, and/or to increase slice coverage/resolution in routine MSK examinations. From SW MR XA11B and higher and with XA10B: Simultaneous Multi-Slice (SMS) RESOLVE provides accelerated RESOLVE protocols for breast and brain imaging. From SW MR XA20A and higher: Simultaneous Multi-Slice (SMS) TSE DIXON extends the SMS TSE with the fat saturation technique DIXON.
1	14475525	Deep Resolve Pro Package The Deep Resolve Pro Package combines the three applications Deep Resolve Gain, Deep Resolve Sharp and Deep Resolve Boost which use intelligent reconstruction algorithms and Deep Learning networks to reconstruct accelerated images with higher signal to noise ratio and better image sharpness.
1	14475529	Deep Resolve Swift Brain as Add-on Deep Resolve Swift Brain offers a set of highly accelerated clinical protocols for T1, T2, T2*, FLAIR and DWI contrasts for routine brain examinations. The acquisition uses, among others, a novel multi-shot EPI sequence including an image reconstruction in which Deep Learning-based algorithms are applied. The total acquisition time of all contrasts allows a drastically reduced table time for routine brain examinations including AutoAlign and the typical contrasts.
1	14402527	SWI #Tim Susceptibility Weighted Imaging is a high-resolution 3D imaging technique for the brain with ultra-high sensitivity for microscopic magnetic field inhomogeneities caused by deoxygenated blood, products of blood decomposition and microscopic iron deposits. Among other things, the method allows for the highly sensitive proof of cerebral hemorrhages and the high-resolution display of venous cerebral blood vessels.
1	14441849	Diffusion Tensor Imaging #T+D Diffusion Tensor Imaging provides a Single Shot EPI sequence for measuring diffusion-weighted data sets with up to 256 directions of diffusion weighting. Based on these data sets, the diffusion tensor itself and parametric maps derived from it (e.g. fractional anisotropy) are calculated automatically and in real-time. The package supports both clinical applications regarding diseases of the white matter (e.g. multiple sclerosis, brain maturation disorders, or displacement of nerve fiber tracts through masses) and advanced research applications. Diffusion spectrum imaging (DSI), an extension of diffusion tensor imaging, is included in this package. DSI expands on the DTI acquisition capabilities by providing the ability to resolve white matter fiber crossings.
1	14456217	Tx/Rx Knee 18 #Vi New 18-channel transmit/receive coil optimized for knee imaging. The spacious design with a flared opening towards the thigh allows scanning even of large and swollen knees with exceptional image quality and signal to noise ratio. Main features : - 18-element design (3x6 coil elements) with 18 integrated preamplifiers - iPAT-compatible - SlideConnect Technology

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Qty	Part No.	Item Description
1	14468948	Head/Neck 16 -> BM Head/Neck 20 #3T This option swaps the standard Head/Neck 16 for a BioMatrix Head/Neck 20 tiltable with CoilShim. The BioMatrix Head/Neck 20 tiltable with CoilShim combines the known benefits of Tim 4G coil technology with those of the new Siemens unique BioMatrix technology, resulting in unmatched image quality, high patient comfort and easy handling. Integrated BioMatrix Tuners: The integrated CoilShim elements minimize patient induced local anatomy-specific B0 field inhomogeneity, thus ensuring excellent image quality. The unique DirectConnect technology allows users to connect the 20 coil elements of the BioMatrix Head/Neck 20 without cables. The possibility to tilt the coil in 3 different positions together with the patient friendly open design allows for maximum patient comfort. The BioMatrix Head/Neck 20 features: - 20-element design with 20 integrated preamplifiers two rings of 8 elements each and one ring with 4 elements in the neck region - First cable-less tiltable head coil with DirectConnect technology - Integrated BioMatrix Tuners: CoilShim technology offering integrated shim elements - Combined head/neck coil for an optimized workflow of the head/neck region - Upper coil part removable - Lower coil part usable without upper part - Smoothly integrated into the patient table with BioMatrix Spine 24 - Open patient-friendly design - Cushioned head stabilizers (removable) - No coil tuning - iPAT-compatible in all directions - Dual-Density Signal Transfer enables ultrahigh density coil designs by integrating key RF components into the local coil - Detachable look-out mirror Applications: - Head examination - Neck examination - MR Head Angiography - MR Neck Angiography - Combined head / neck examination - TMJ (temporo mandibular joints)
1	14469230	Flex -> UltraFlex Upgrade #3T This option exchanges the Flex Small & Large 4 coils incl. the Flex Coil Interface from the standard coil configuration for the superior UltraFlex Small & Large 18. These are two lightweight, iPAT compatible, 18-element no-tune receive coils made of highly flexible and soft material. UltraFlex Large 18 Ideal for examinations of larger extremities (e.g. medium to large shoulder, hip, knee, ankle and hand) and for abdominal examinations. Dedicated positioning aids for larger extremities are delivered with the coil. UltraFlex Small 18 Ideal for examinations of smaller extremities (e.g. small to medium shoulder, smaller ankle, elbow and hand) and for abdominal examinations. Dedicated positioning aids for smaller extremities are delivered with the coil.
1	14456282	Positioning Aids Shoulder&Ankle #Vi This package contains additional positioning aids that can be used for the UltraFlex Large 18 and UltraFlex Small 18.
1	14456241	Separator 60kW/75kW #Vi

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Qty	Part No.	Item Description
		The SEP (Separation cabinet) has to be used if a central hospital chilled water supply is available or if a chiller of any brand/type is already available. The SEP is the interface between the on-site water chiller (of any brand or type) or the interface to the central hospital cooling water supply. For the above-mentioned cases the SEP is mandatory! In these cases, the primary water specifications must fulfill the requirements: XJ: 45kW; water temperature: 6 - 14°C XQ: 60kW; water temperature: 6 - 14°C XT: 75kW; water temperature: 6 - 12°C For all gradient systems: Flow: 100+-10l/min; pH value 6-8; max working pressure 6 bar. Dimensions: 1950mm x 650mm x 650mm (height x width x depth) Weight: approx. 350kg
1	14460249	UPS system #Vi UPS system Liebert GXT5 3000IRT2UXLE for MAGNETOM NumX systems for safeguarding computers. Including Power Cable of 9 m for connecting the UPS. Power output: 3.0 kVA / 3 kW Bridge time: 3 min full load / 12 min half load Input voltage: 230 VAC
1	14456316	UPS Battery module (Liebert GXT4 BATT) UPS battery module Liebert GXT5 72VBATTE for MAGNETOM Aera, Skyra, Prisma, ESSENZA, Amira, Spectra, C! for safeguarding computers. Extension for: Liebert GXT5 3000IRT2UXLE (14456315) Battery type: Closed, maintenance-free Extension of the bridge time to: 21 minutes full load / 48 min half load with one module Dimensions (H x D x W): Battery module: 430 x 540 x 85 mm Weight: approx. 30 kg
1	14456228	System Start Timer #Vi Timer clock that can be installed together with the MAGNETOM MR system to start the system automatically at user-definable times, eliminating waiting times during system boot up.
1	MR_STD_RIG_I NST	MR Standard Rigging and Installation MR Standard Rigging and Installation This quotation includes standard rigging and installation of your new MAGNETOM system Standard rigging into a room on ground floor level of the building during standard working hours (Mon. – Fri./ 8 a.m. to 5 p.m.) It remains the responsibility of the Customer to prepare the room in accordance with the SIEMENS planning documents Any rigging requiring a crane over 80 tons and/or special site requirements (e.g. removal of existing systems, etc.) is an incremental cost and the responsibility of the Customer. All other "out of scope" charges (not covered by the standard rigging and installation) will be identified during the site assessment and remain the responsibility of the Customer.
1	MR_BTL_INSTA LL	MR Standard Rigging & Install
1	MR_PREINST_F IXED	T+D Preinstall kit for fixed table
1	MR_CRYO	Standard Cryogens

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Qty	Part No.	Item Description
1	MR_PM	MR Project Management A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemens equipment. The assigned PM will work with the customer's facilities management, architect or building contractor to assist you in ensuring that your site is ready for installation. Your PM will provide initial and final drawings and will coordinate the scheduling of the equipment, installation, and rigging, as well as the initiation of on-site clinical education.
1	HASKRISFG23041	Haskris OPC24 Chiller- 63kW The Haskris outdoor, air-cooled, water/glycol chiller has been specially designed for medical applications to provide stable, fully dedicated cooling to a single MR system. The Haskris chiller must be used in combination with a Siemens SEP cabinet. The Haskris chiller is suitable for use in all siting conditions: normal, coastal, low-ambient, and/or OSHPD-compliant locations. Specifications Cooling Capacity: 63kW Fluid Supply Temp: 43°F (6°C) to 59°F (15°C) Pump Capacity: 32 GPM (120 LPM) Condenser: Air-cooled (heat dissipated into ambient air) Outdoor ambient air temperature: -40°F (-40°C) to 122°F (50°C) Electrical: 460V-3Ø-60Hz Dimensions: 77"W x 40"D x 74"H (196cm x 102cm x 188cm) Siemens' Pricing Also Includes: Delivery Chiller Start-Up (Post Installation) 1x Preventative Maintenance Service Visit Remote Monitoring Panel with 1-Year Cellular Connectivity and Cloud Service Installation: Customer is responsible for the rigging and installation of the chiller. Customer is responsible for providing a 35% solution of propylene glycol with water; 25 gal (95 L) for the chiller plus 1 gal (3.8 L) per 10 ft (3m) external pipe run assuming 1 ½" pipe diameter. Warranty: 12 months from date of Start-Up
1	HASKRIS_STAR TUP	Haskris Chiller Start-Up Chiller start-up by Haskris vendor after installation of chiller and completion of paperwork.
1	MR_GOBRAIN	GOBrain GOBrain delivers reliable quality at exceptional speed. It enables clinically validated, push-button brain exams, with multiple orientations and all relevant contrasts. This fast exam is more tolerable for patients, and helps reduce motion-related artifacts and the need for rescans and sedation. As a result, GOBrain potentially doubles throughput and reduces costs per scan. Supported by our Tim 4G technology and DotGO, it delivers consistently high quality and maximizes the productivity of your MRI scanner - while improving patient care.
1	MRISMNS0001	MRI Patient Audio System The MRI Patient Audio System is to be installed in the technologist room and is connected to the Siemens intercom system. The package provides the following benefits: • Create custom, commercial-free radio stations based on artist, song or genre

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Qty	Part No.	Item Description
		preferences • Avoid any AM/FM tuning issues that may occur in RF-shielded rooms • Compatible with all popular audio apps Includes all cables and adapters; Bose Companion 2 technologist speakers; 3.5 mm to RCA cable; and customized iPad Mini with all original accessories and iPad stand. The MR Stereo can play internet radio (depending on quality of and access to Wi-Fi signals) and device (iPad) stored audio content. Optimal performance requires access to Wi-Fi signal for Internet radio through the facility's wireless network. The audio system is not MR safe and is only intended for use outside the MRI suite. Installation is not included unless purchased with the Siemens system. Includes 3 year limited liability warranty on all system components through MRI Med.
1	MR_EP1_28	Essential Training PH 1 (Onsite-28) MR Up to (28) hours of on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist if applicable. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund
1	MR_EP2_24	Essential Training PH 2 (Onsite-24) MR Up to (24) hours of on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist if applicable. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	MR_OLCLS_8	VIRTUAL Classroom (MR)(8) Tuition for (1) imaging professional to attend a virtual classroom course for up to 8 hrs. Please view Siemens Healthineers PEPconnect at pep.siemens-info.com for available course options and descriptions. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens Healthineers obligation to provide the training will expire without refund.

System Total

\$ 1,858,279



September 10, 2025

VIA EMAIL

Phillip Earhart
Director of Certificate of Need
Health Facilities Commission
Andrew Jackson Building, 9th Floor
Nashville, TN 37243
phillip.m.earhart@tn.gov

RE: American Health Imaging of Knoxville – CN2508-028: Responses to Supplement Questions

Dear Mr. Earhart:

As you know, I represent American Health Imaging of Knoxville (“AHI”) in the above-referenced CON Application for the establishment of an outpatient diagnostic center, located at 326 Lovell Road, Knoxville (Knox County) Tennessee, 37934.

I am in receipt of your letter of September 3, 2025. Enclosed, please find AHI’s responses to the supplemental questions outlined in your letter, with corresponding attachments.

Of course, please let me know if you have any questions or require further information.

Very truly yours,

Rebecca M. Thornhill

cc: Dan Balentine
David Levitt

Enclosures

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Supplemental Information, CN2508-028
September 10, 2025

1. Item 3.A.

*Please submit the proof of publication that was published on or before August 14, 2025.
The proof of publication that was attached to the application was from July 2025.*

Response: Please see **Attachment 3A Revised** for proof of the most recent newspaper publication.

2. Item 10A., Floor Plan

Please update the floor plan to indicate the location of the MRI, CT, ultrasound, and X-ray.

Response: Please see **Attachment 10A Revised** which includes details showing the location of the proposed imaging services in the leased space. Note that the proposed project initially includes only MRI and CT, with ultrasound equipment budgeted for addition at a later time, once patient demand dictates need for the addition. The project does not include X-ray capabilities.

3. Item 12A., Plot Plan

Please indicate the size of site (in acres) on the plot plan and the location of any construction and renovation.

Response: Please see **Attachment 12A Revised** for a more detailed Plot Plan. As indicated, the site of the retail building is approximately 1 acre.

4. Item 4.E, Project Cost Chart

Total construction costs of \$1,157,256 is noted. Please describe the proposed construction/renovation.

Response: The construction costs include:

- Demolition and site work
- Concrete work including plumbing trench, foundation work and concrete pads
- Cabinetry, countertops and other carpentry as required
- Doors, windows and new storefront
- Flooring, metal framing, insulation, drywall, ceilings, paint and radiation shielding as required
- Fire suppression system
- Plumbing work including supply and installation of plumbing system, fixtures, and pipe insulation
- HVAC work including supply and installation of HVAC gear, chill water piping and quench vent
- Electrical system work including installation of electrical system and lighting

A revised **Attachment 1N-2** is attached.

5. Item 2.N., Projected Utilization, Page 13

It is noted the applicant is projecting 3,315 MRI procedures in Year One of the proposed project on page 13 and in the Projected Data Chart for Year One on page 22. However, the applicant projects 2,340 MRI scans in Year One on page 17 and 1,820 MRI scans in Year One in Attachment 6N. Please clarify which figure is correct and adjust all other projections for years 1-3 in the application for consistency.

Response: The projected volume on Page 12 is for both MRI and CT services. The following figure summarizes the projected utilization by modality for CT and MRI. Note that the proposed project initially only includes MRI and CT, with ultrasound equipment budgeted for addition at a later time, once patient demand dictates need for the addition. The project does not include X-ray capabilities.

	Year 1	Year 2	Year 3
MRI Scans	2,340	2,600	2,990
CT Scans	975	1,560	2,600
TOTAL	3,315	4,160	5,590

6. Item 3.N., Demographics, Page 14

It is noted the applicant expects to provide imaging services to high school aged patients who have experienced a sports injury. Please clarify if the ODC will be accessible after regular business hours for urgent cases.

Response: The proposed ODC will operate during typical business hours but will adjust staff and hours of operation based on patient demand outside of business hours.

7. Item 5N., Service Area Utilization

Please complete the following table for ODCs in the proposed service using Joint Annual Report data.

ODC Facility Name	Facility ID	MRI Procedures	MRI Units	CT Procedures	CT Units	Ultrasound Procedures	X-Ray Procedures
2022							
East Tennessee Diagnostic Center	1061	NA	NA	3,911	1	NA	NA
Outpatient Diagnostic Center of Knoxville	1070	NA	NA	4,873	1	4,895	8,849
East Tennessee Community Open MRI	1060	3,637	2	NA	NA	1,008	1,397
Covenant Health Diagnostic Centers	1464	553	1	1,289	1	1,071	3,242
Total		4,190	3	10,073	3	6,974	13,488
2023							
East Tennessee Diagnostic Center	1061	NA	NA	3,558	1	NA	NA
Outpatient Diagnostic Center of Knoxville	1070	10,039	2	4,382	1	4,137	8,137
East Tennessee Community Open MRI	1060	3,417	2	NA	NA	1,044	1,090
Covenant Health Diagnostic Centers	1464	1,388	1	2,451	1	1,787	4,852
University Diagnostic Northshore	1472	NA	NA	3,004	1	1,122	2,976
University Diagnostics-Halls	1484	2,344	1	3,389	1	1,960	4,491
Covenant Health Diagnostics, LLC	1490	334	1	387	1	277	664
Total		17,522	7	17,171	6	10,327	22,210
2024							
East Tennessee Diagnostic Center	1061	NA	NA	3,192	1	NA	NA
University Diagnostic Hall of Fame	1070	9,449	2	4,591	1	4,936	6,543
East Tennessee Community Open MRI	1060	3,427	2	NA	NA	917	675
Covenant Health Diagnostic Centers	1464	1,694	1	3,274	1	1,644	4,759
University Diagnostic Northshore	1472	NA	NA	5,105	1	2,205	5,751
University Diagnostics-Halls	1484	4,484	1	6,447	1	2,365	7,052
Covenant Health Diagnostics, LLC	1490	1,410	1	1,516	1	1,014	1,937
Total		20,464	7	24,125	6	13,081	26,717
% Change 2022-2024		388.4%	133.3%	139.5%	100.0%	87.6%	98.1%

Sources: 2022-2024 Joint Annual Reports.

What other providers in the proposed service area have a 3.0T MRI?

Response: There are currently six 3.0T MRI scanners located in the proposed service area. However, only two of them are located in an ODC, East Tennessee Community Open MRI, LLC d/b/a Provision Diagnostic Imaging (“Community Open MRI”). The other three Knox County units are hospital-based, and the one 3.0T MRI unit in Blount County is physician practice-based, which limits the accessibility to patients of that practice.

Community Open MRI is not a reasonable alternative to the proposed project for a variety of reasons. First, it is located in the Bearden area of Knoxville, which is approximately 20 minutes from the proposed AHI of Knoxville ODC, assuming favorable traffic conditions. Additionally, the ODC is highly utilized as evidenced by current scheduling delays. On September 8, 2025, a staff member at East Tennessee Community Open MRI reported that there was not an appointment for an MRI scan available until October 2025 – a scheduling delay of at least three weeks. In 2024, East Tennessee Community Open MRI performed 3,427 scans on its two existing units, which calculates to approximately 1,714 scans per unit. While the average utilization per unit does not reach the optimal utilization threshold, the existence of a multi-week scheduling delay is indicative of the lack of available capacity at the center.

The proposed AHI of Knoxville will offer both MRI and CT, which Community Open MRI does not.

It is an MRI-only provider and not a true multi-modality ODC. The proposed AHI of Knoxville ODC will increase access to imaging services needed in the area.

8. Item 6N., Projected Utilization

Please complete the following table for Year One and Year Two projections.

Equipment Type	# Units	Procedure Volumes	
		Year 1 (2026)	Year 2 (2027)
MRI	1	2,340	2,600
CT	1	975	1,560
Ultrasound	*	*	*
X-Ray			
Mammography			
TOTAL		3,315	4,160

*Note that the proposed project initially includes only MRI and CT, with ultrasound equipment budgeted for addition at a later time, once patient demand dictates need for the addition. The project does not include X-ray or mammography capabilities.

9. Item 6.C, Projected Data Chart, Page 22

It is noted the applicant is projecting 3,315 procedures in Year One and 4,160 in Year Two of the proposed project in the Projected Data Chart. Please break out the number of procedures by MRI, CT, ultrasound, X-Ray, and Mammography for the Year One and Year Two totals.

Response: The following figure includes projected utilization by modality. Note that the proposed project initially includes MRI and CT, with ultrasound equipment budgeted for addition at a later time, once patient demand dictates need for the addition. The project does not include X-ray or mammography capabilities.

	Year 1	Year 2	Year 3
MRI Scans	2,340	2,600	2,990
CT Scans	975	1,560	2,600
TOTAL	3,315	4,160	5,590

In 9C. the applicant is projecting \$1,850 per MRI scan in Year One and in Year Two. Please provide a projected data chart for the MRI portion of the proposed project.

Response: The following figure provide projected utilization and charges for the MRI portion of the project only.

	Year 1	Year 2
MRI Scans	2,340	2,600
Gross Charges	\$4,329,000	\$4,810,000
Average Charge	\$1,850	\$1,850

10. Item 7.C., Average gross charge, Deduction from revenue, and Average Net Charge, Page 24

Please provide an additional charge chart for the MRI portion of the CON where the charges calculate to \$1,850 per MRI scan in Year One and in Year Two of the proposed project.

Response: An additional charge chart is provided below, including only the MRI portion the project.

	MRI Only	
	Year 1	Year 2
	2026	2027
Volume	2,340	2,600
Outpatient	\$4,329,000	\$4,810,000
Total	\$4,329,000	\$4,810,000
Contractuals	\$3,794,657	\$3,736,919
Charity care	\$43,290	\$48,100
Bad Debt	\$64,935	\$72,150
Total	\$3,902,882	\$3,857,169
Net Operating Revenue	\$426,118	\$952,831

11. Item 3.Q, Accreditation

Please identify the accreditation entity for the proposed ODC and the proposed MRI service.

Response: AHI of Knoxville will seek accreditation through the Intersocietal Accreditation Commission (IAC). The organization's imaging center's existing CT and MRI programs are accredited by the IAC, which is a nonprofit organization in operation to evaluate and accredit facilities that provide diagnostic imaging and procedure-based modalities, thus improving the quality of patient care provided in private offices, clinics, and hospitals where such services are performed. The proposed imaging center will also participate in this accreditation process.

12. Item 8.Q., Staffing, Page 31

It is noted the Patient Services Representative position is in the direct patient care category. What type of direct patient care will be provided?

Response: The Patient Services Representative is a non-patient care position. The staffing table has been corrected below.

Position Classification	Existing FTEs (enter year)	Projected FTEs Year 1
A. Direct Patient Care Positions		
<i>MRI Tech</i>	0.0	1.0
<i>CT Tech</i>	0.0	1.0
Total Direct Patient Care Positions	0.0	2.0

B. Non-Patient Care Positions		
<i>Manager</i>	0.0	1.0
<i>Sales Representative</i>	0.0	1.0
<i>Patient Services Representative</i>	0.0	1.0
Total Non-Patient Care Positions	0.0	3.0
Total Employees (A+B)	0.0	5.0
C. Contractual Staff	0.0	0.0
Total Staff (A+B+C)	0.0	5.0

Please respond to the following service specific criteria questions as an attachment labeled Attachment 1N-Supplemental #1 – ODC Standards.

13. Service Specific Criteria, (Outpatient Diagnostic Centers, Item 2)

Please complete the following table for Knox County:

Geographic Disbursement of ODCs in Knox County				
Facility	Address	Distance From Proposed site	Quadrant of Knox County (with Knoxville as center)	Distance from Knoxville (center).
East Tennessee Diagnostic Center	1450 Dowell Springs Blvd (37909)	8.6 Miles (14 Minutes)	Western	7.1 Miles (10 Minutes)
University Diagnostic Hall of Fame	601 Hall of Fame Drive (37915)	15.1 Miles (17 Minutes)	Central	2.1 Miles (4 Minutes)
East Tennessee Community Open MRI	1415 Old Weisgarber Road (37909)	10.1 Miles (19 Minutes)	Western	6.9 Miles (10 Minutes)
Covenant Health Diagnostic Centers	210 Fort Sanders West Blvd (37922)	1.9 Miles (7 Minutes)	Western	13.6 Miles (16 Minutes)
University Diagnostic Northshore	1975 Town Center Boulevard (37922)	6.0 Miles (8 Minutes)	Southwest	17.3 Miles (18 Minutes)
University Diagnostics-Halls	7326 Maynardville Pike (37938)	21.6 Miles (29 Minutes)	Northern	10.6 Miles (18 Minutes)
Covenant Health Diagnostics, LLC	7625 Chapman Highway (37920)	20.8 Miles (29 Minutes)	Southeast	9.9 Miles (17 Minutes)

Source: GoogleMaps, weekday, midday, fastest route.

14. Service Specific Criteria, (Outpatient Diagnostic Centers, Item 2)

It is noted the licensed ODC East Tennessee Community Open MRI, LLC currently operates two 3.0T MRIs. What is the distance from the applicant's proposed site to East Tennessee Community Open MRI, LLC's location?

In 2023, East Tennessee Community Open MRI, LLC provided 3,433 MRI procedures on two 3.0T MRIs averaging 1,717 procedures per MRI. Please discuss how the applicant will meet the 2,880 minimum threshold while an existing ODC Knox County 3.0T provider is only meeting 60% of the minimum 2,880 threshold.

Response: As discussed, the proposed AHI of Knoxville ODC will be located in the rapidly growing area of Turkey Creek in southwest Knoxville. Community Open MRI is not a reasonable alternative to the proposed project for a variety of reasons. First, it is located in the Bearden area of Knoxville, which is approximately 20 minutes from the proposed AHI of Knoxville ODC, at low traffic times, and Community Open MRI is at an even further travel distance for residents of Blount and Loudon counties. Additionally, the ODC, while operating at approximately 1,700 procedures per machine, is highly utilized, with facility staff reporting that the first available MRI appointment was not until October 2025, at least a three-week scheduling delay. In 2024, East Tennessee Community Open MRI performed 3,427 scans on its two existing units, which calculates to approximately 1,714 scans per unit. Given the nearly identical utilization in 2023 and 2024, it would appear the center is operating at capacity. While the average utilization per unit does not reach the optimal utilization threshold, the existence of a multi-week scheduling delay is indicative of the lack of available capacity at the center.

AHI has a successful track record of development of outpatient imaging services that are easily accessible for all patients, regardless of ability to pay, and offer competitive pricing, as well as short wait times for scans. Additionally, AHI strives to turn images around quickly, so that patients have rapid access to findings and can work with their private physician to devise a treatment plan based on those imaging results. AHI of Knoxville will work with local physicians to increase access to outpatient imaging services for patients in need of these services.

The proposed AHI of Knoxville will offer both MRI and CT, which Community Open MRI does not. It is an MRI provider and not a true multi-modality ODC. The proposed AHI of Knoxville ODC will increase access to imaging services needed in the area.

15. Service Specific Criteria, (Outpatient Diagnostic Centers, Item 3)

Please describe the capabilities of the proposed CT's (i.e.-4, 6, 8, 16, 32, 40, and 64, 128, 256) slice configurations. How will the proposed CT capabilities differ from those already available at existing ODCs in the proposed service area?

Please discuss if the proposed CT will be used for cardiac, stroke, cancer, or orthopedic diagnostic services.

Please indicate if the proposed MRI unit will be equipped to accommodate claustrophobic, obese, and pediatric patients. If so, please briefly discuss.

Response: The proposed CT scanner will be a Siemens SOMATOM go.Up 64-slice scanner. The result of a major global co-creation project, the SOMATOM go platform is specifically designed to overcome the obstacles associated with acquiring, operating, and maintaining a CT scanner.

Built around a new mobile workflow, the SOMATOM go features a line-up of innovative solutions – tablet, remote control, camera, and a new workplace design – that bring an unparalleled level of flexibility and mobility to daily CT routines. The solutions also help to enhance patient comfort for potentially higher levels of patient satisfaction.

The SOMATOM go platform addresses workflow at the scanner and beyond. By reducing repetitive workflow steps, GO Technologies help standardize and simplify all departmental processes – from patient setup to image distribution, archiving, and reading.

The included Stellar detector lowers image noise in every scan, while advanced iterative reconstruction from SAFIRE delivers excellent image quality at very low doses. The Stellar detector's high-end technology includes fully integrated components and an advanced 3D anti-scatter collimator. It keeps electronic noise low, increases dose efficiency, and improves spatial resolution.

Also inherited from high-end scanners, the Tin Filter (Sn) cuts out lower energies to reduce dose and optimize image quality at the interface between soft tissue and air. This has direct benefits in lung and colon imaging, for example.

SOMATOM go.Up delivers up to 64 reconstructed slices at sub-millimeter collimation across the entire 2.2 cm detector width for faster scanning, fewer motion artifacts, and shorter breath-hold.

SOMATOM go.Up was designed to broaden imaging centers' clinical range with superior images and profound results. The unit delivers results that were previously only available on high-end scanners. SOMATOM go.Up delivers the low-dose scanning that is essential for optimal patient care. It allows scans of long ranges at the speed of a breath-hold while maintaining a high spatial resolution.

SOMATOM go.Up allows high quality angiography exams of central and peripheral arteries with good iodine contrast, sub-millimeter slices, and precise timing. It optimizes image quality and reduces dose in routine neuro examinations, as well as enables low-dose lung cancer screening

with tin filter technology and calcium scoring exams. With sub-millimeter collimation in every scan, it provides high spatial resolution and helps improve the detection of occult lesions.

The proposed CT scanner will be utilized for all types of CT scans, including cardiac, stroke, cancer and orthopedic imaging.

The proposed Siemens MAGNETOM Lumina 3.0T MRI System includes several options that aid in providing patient comfort during the exam, including:

- ✓ Short and open appearance (186 cm total system length cover-to-cover and 70 cm Open Bore Design) to reduce patient anxiety and claustrophobia;
- ✓ Whole-body superconductive Zero Helium Boil-Off 3T magnet;
- ✓ Weight-optimized magnet technology based on high performance 7T magnet design;
- ✓ Actively Shielded water-cooled Siemens gradient system for maximum performance;
- ✓ Tim 4G (Total imaging matrix in the 4th generation) for excellent image quality and speed with Siemens unique DirectRX technology enabling all digital-in/digital-out design and Dual-Density Signal Transfer Technology.

16. Service Specific Criteria, (Outpatient Diagnostic Centers, Item 3.b.)

Using Joint Annual Report Data, please complete the following table for ODC Imaging Services in Knox County. Please place a Y or N for each category.

ODC	MRI	CT	Ultrasound	Echo-Vascular	X-Ray
East Tennessee Diagnostic Center	N	Y	N		N
University Diagnostic Hall of Fame	Y	Y	Y		Y
East Tennessee Community Open MRI	Y	N	Y		Y
Covenant Health Diagnostic Centers	Y	Y	Y		Y
University Diagnostic Northshore	N	Y	Y		Y
University Diagnostics - Halls	Y	Y	Y		Y
Covenant Health Diagnostics, LLC	Y	Y	Y		Y

Please respond to the following service specific criteria questions as an attachment labeled Attachment 1N-Supplemental #1 – MRI Standards.

17. Item 1N., Project Specific Criteria, MRI, Item #1

It is noted in figure 1N-6 on page 8 of the MRI Criterion and Standards the applicant is projecting 1,820 MRI scans in Year One, 2,340 scans in Year Two, and 2,990 scans in Year Three. However, on page 17 of the application the applicant projects 2,340 MRI scans in Year One, 2,600 MRI scans in Year Two, and 2,990 MRI scans in Year Three. Please clarify and correct.

Why will the applicant not be able to meet the minimum 2,160 MRI procedures in Year One and the 2,520 MRI procedures in Year 2 per the MRI standards and criteria?

Response: The projected volumes on page 8 of the CON Application were inadvertently incorrect. The corrected volumes appeared on page 17 of the CON Application and are shown again in the figure below. AHI of Knoxville complies with minimum volume standards consistent with the Rule requirements.

	Year 1	Year 2	Year 3
MRI Scans	2,340	2,600	2,990
CT Scans	975	1,560	2,600
TOTAL	3,315	4,160	5,590

18. Service Specific Criteria, (MRI, Item 1.A., Utilization Standards for Non-Specialty MRI Units)

Please indicate the number of MRI scans projected in Year One and Year Two for patients 14 years of age and under.

Response: While AHI of Knoxville intends to offer services to all appropriate patients, historical experience has shown that patients aged 14 years of age and under comprise a very small portion of the total procedures provided. As a new provider in the market, AHI of Knoxville does not intend to treat patients in this age cohort at the proposed center. High School athletes would typically be aged 15 to 18. Any referral in the 14 and under cohort will be referred to appropriate area pediatric providers.

19. Item 1N., Project Specific Criteria, MRI, Item #4

The tables labeled 1N-10 and 1-N-11 on pages 14-15 of the MRI Criterion and Standards are noted. Please address the following:

- Knoxville Comprehensive Breast Ctr. in 2023 had 1 MRI not 2 as indicated in both tables. Therefore, the average Knox County average utilization per MRI unit is 3,696 (110,888/30) not 3,577 (110,883/31). Please revise both tables and correct narratives throughout the application.*
- In figure 1N-10 the 2021 Fort Sanders Regional Medical Center utilization should be 9,125 not 9,215. Please correct.*
- In figure 1N-11 on page 15, the combined MRI unit average for the proposed service area should be 3,771 per unit (124,454/33) not 3,660. Please correct and revise any references in the application that incorrectly indicates the figure of*

3,660.

- *Please cite the reference for the following MRI numbers that were not included in the 2021 and 2023 Medical Equipment Registry Utilization Report: North Knoxville Medical Center 3,541; Turkey Creek Medical Center 3,100 in 2021 and 3,401 in 2023.*

Response: Corrected CON Application pages including the corrected service area average scans per MRI unit of 3,771, as well as revised Figures 1N-2, 1N-3, 1N-4, 1N-10 and 1N-11 are provided in **Attachment 1N Revised**. The source for the MRI numbers that were not included in the 2021 and 2023 Medical Equipment Registry Utilization Reports were sourced from the individual facility Joint Annual Reports for those years.

20. Item 1N., Project Specific Criteria, MRI, Item 7.B.

Please submit a letter from an architect or construction professional attesting that the physical environment will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements.

Response: A letter stating that the physical environment will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements is provided in **Attachment 1N-2**.

21. Item 1N., Project Specific Criteria, MRI, Item 7E. and 7F.

It is noted in Item 7E the applicant will meet the staffing requirements of the American College of Radiology and in Item 7F. will be accredited by the Intersocietal Accreditation Commission. Will the applicant be accredited by both? Please clarify.

Response: AHI of Knoxville will seek accreditation through the Intersocietal Accreditation Commission (IAC). The organization's imaging center's existing CT and MRI programs are accredited by the IAC, which is a nonprofit organization in operation to evaluate and accredit facilities that provide diagnostic imaging and procedure-based modalities, thus improving the quality of patient care provided in private offices, clinics, and hospitals where such services are performed. The proposed imaging center will also participate in this accreditation process.

Attachment 3A Revised

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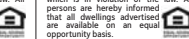
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The Tennessee Department of Transportation is about to make final settlement with the contractor for construction of the above numbered project. All persons wishing to file claims pursuant to Section 54-5-122, T.C.A. must file same with the Director of Construction, Tennessee Department of Transportation, Suite 700 James K. Polk Bldg., Nashville, Tennessee 37243-0226, on or before 9/19/2025.

Public Notices

First Utility District of Knox County Board of Commissioners Meeting will be held at the office on Wednesday, August 20, 2025 at 8:30 a.m.

ORDER OF PUBLICATION

IN THE CIRCUIT COURT FOR ANDROE COUNTY, TENNESSEE AT MADISONVILLE
IN RE: The Adoption of Jeron Allen Frank Sims, DOB: 3/24/2020
By: James McJunkins and wife, Nancy McJunkins,

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 American Health Imaging of Knoxville, a/an Outpatient Diagnostic Center owned by American Health Imaging of Tennessee, 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 an outpatient diagnostic center to serve Knox, Loudon, and Blount counties, and it will provide MRI, CT, and ultrasound services. The location of the project will be 326 Lovell Road, Knoxville, Knox County, Tennessee, 37934. The estimated project cost will be \$5,913,239. The anticipated date of filing the application is 08/29/2025. The contact person for this project is Attorney Rebecca Thornhill who may be reached at Maynard Nexsen PC - 4800 Old Kingston Pike, Knoxville, Tennessee 37919 - Contact No. 865-686-5630. 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 julia.staff@tn.gov

Public Notices

SUCCESSOR TRUSTEE'S NOTICE OF SALE OF REAL ESTATE

ANTHONY R. STEELE is the Successor Trustee of a Deed of Trust executed on July 8, 2014, by **GARY U. POWELL aka Gary U S Powell, a single person, unmarried.** The deed of trust appears of record in the Register's Office of Knox County, Tennessee, at Instrument 201407250005064 ("Deed of Trust"). The Successor Trustee will sell the property described below for cash at a foreclosure sale requested by the current holder of the Deed of Trust and underlying indebtedness, Trust Bank, successor by merger to SunTrust Bank.

Sale Date and Location: September 5, 2025, at 2:00 p.m. at the front door of the Courthouse, designated as near the Main Assembly Room inside the northernmost entrance from Main Avenue to the City-County Building in Knoxville, Knox County, Tennessee. The terms of sale shall be payment by cashier's check or certified funds immediately upon conclusion of the sale.
Third-party internet posting website: foreclosuretennessee.com

Property Description: Abbreviated description per TCA 35-5-104(a)(2) is the property described in the Deed of Trust and additionally referenced at Book 1436, Page 877, and commonly known as 2413 Cecil Avenue, Knoxville, TN 37917.
Property Address: 2413 Cecil Avenue, Knoxville, TN 37917
Tax Map Identification No.: 082AF014 (However, the property description shall control in the event of any inconsistencies between the description and address or tax identification number).

Parties Interested: NONE KNOWN.

All sales of Property are "AS IS" and "WHERE IS" without representation or warranty as to merchantability or fitness for a particular purpose or of any kind, except as to title and authority to convey. The sale of the described property is subject to all matters shown on any recorded plan; any unpaid taxes, any restrictive covenants, easements, set-back lines, prior liens, encumbrances, if any, and any other priority as may appear in the public records.

The right is preserved to adjourn the day of the sale to another day, time and place certain without further publication, upon announcement at the time and place for the sale set forth above.

THE PURPOSE OF THIS COMMUNICATION IS TO COLLECT THE DEBT AND ANY INFORMATION OBTAINED AS A RESULT WILL BE USED FOR THAT EXPRESS PURPOSE ONLY. THIS COMMUNICATION IS FROM A DEBT COLLECTOR.

This the 8th day of August, 2025.

Anthony R. Steele, Successor Trustee

Winchester, Sellers, Foster & Steele, P.C.

P.O. Box 2428

Knoxville, TN 37901

(865) 637-1980

Publication Dates: August 13 and 20, 2025



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Page 1 of 1

Invoice

Agency	Rebecca Thornhill Maynard Nexsen 4800 Old Kingston Pike, Suite 120 Knoxville, TN 37919	Invoice Date	8/18/2025
		PO Number	
		Order	A25.7068
Client	American Health Imaging of Knoxville		
Reps	Direct	Earl Goodman	

Vendor	Run Date	Ad Size	Rate Name	Rate	Color	Rate Name	Color Rate	Discount	Total
Knoxville - Knoxville News Sentinel	8/13/2025	2 x 3	Public Notice Classified	\$25.00			\$0.00	0.0000 %	\$150.00
Caption	Notification Of Intent To Apply For A Certificate Of Need - American Health Imaging of Knoxville								
Total Advertising									\$150.00
Discounts									\$0.00
Misc. Charges									\$0.00
USA Tax									\$0.00
Total Invoice									\$150.00
Payments									\$150.00
Adjustments									\$0.00
Balance Due									0.00

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Maynard Nexsen
Attn: Rebecca Thornhill
4800 Old Kingston Pike, Suite 120
Knoxville, TN 37919

This is to certify that the insert for **Notification of Intent to Apply for a Certificate of Need – American Health Imaging of Knoxville** appeared in the following newspapers on the dates listed here and on the enclosed invoice A25.7068.

Knoxville – Knoxville News Sentinel
08/13/2025 – Knox, Loudon, Blount counties

This Thirteenth day of August, 2025

Alisa Subhakul, Junior Media Buyer

Sworn before me this 13th day of August, 2025

Earl Goodman, Notary Public

My commission expires July 1, 2028



Attachment 10A Revised

Floor Plan

SUITE USABLE AREA -
+1/4,559 SF

326 LOVELL RD, KNOXVILLE
RSF 4,704

SCHEMATIC PLAN

SD 1.0

9/8/2025 9:12:37 AM



AHI KNOXVILLE



JKG COLLABORATIVE
ARCHITECTURE

931 Monroe Drive NE
Suite A-102-181
Atlanta, Georgia 30308-1795
404-537-1832
www.jkgcollaborative.com

Attachment 12A Revised

Plot Plan

Attachment 1N-2 Revised

Construction Letter



September 8, 2025

Mr. Dan Balentine
American Health Imaging.
2200 Century Parkway, NE
Suite 600
Atlanta, GA 30345

Subj: AHI Knoxville – 326 Lovell Rd, Knoxville, TN 37934 – Center Build Out

Dear Dan,

We are pleased to submit the following scope of work and pricing for the build out of a new imaging center located at 326 Lovell Rd Knoxville, TN 37934. The physical environment will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements. The scope of work is clarified as follows:

Division 01 – General Requirements

General Conditions:

- Project Manpower to include:
 - Full Time Superintendence
 - Part Time Project Manager

Construction Requirements:

- Dumpster and proper disposal of all construction debris
- Final cleaning of the building and site
- Continuous cleaning of the project site
- Small tools and construction equipment

Division 02 – Demolition and Sitework

- Demolition as required
- Saw cutting concrete for the MRI slab, foundations and plumbing lines.
- Fence around the chiller pad

Division 03 – Concrete

- Interior concrete as shown including plumbing trench and foundation work
- Exterior concrete as shown including chiller pad and HVAC housekeeping pads

Division 06 – Wood, Plastics and Composites

- Plastic laminate cabinetry as required
- Plastic laminate countertops as required.
- In wall blocking and rough carpentry as required.

Division 08 – Openings

- Supply and install interior doors as required.
- Lead lined doors and windows as required.
- Removal and reinstallation of the storefront to allow MRI access.

Division 09 – Finishes

- Flooring as required.
- Metal framing, insulation and drywall as required.
- ACT ceilings as required.
- Painting as required to provide a finish product.
- Radiation shielding as required.

Division 10 – Specialties

- Fire Extinguishers as required

- Corner guards as required

- Bath accessories as required
- RF Shielding for the MRI room

Division 21 – Fire Suppression

- Fire suppression system as required.

Division 22 – Plumbing

- Supply and installation of plumbing fixtures as required.
- Supply and installation of the plumbing system as required.
- Pipe insulation as required.

Division 23 – Heating, Ventilation and Air Conditioning (HVAC)

- Supply and installation of HVAC gear as required.
- Supply and installation of the chill water piping as required.
- Supply and installation of the Quench Vent, including insulation.

Division 26 – Electrical

- Electrical system to be installed as required.
- Low Voltage cabling to be installed by others.
- Lighting to be provided as required.

Division 32 – Exterior Improvements

- Chain link Fence

Project Price:

Overall Project: \$1,157,256.00
 CT Suite (included above): \$246,897.00
 MRI Suite (included above): \$334,826.00
 Ultrasound (included above): \$49,796.00

Project Duration: **14 weeks from receipt of building permit**

As previously stated, the physical environment will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements.

Sincerely,

Trident Construction Group, LLC

Jay Wicklund

Jay Wicklund
 President

Attachment 1N Revised

MRI Rules

ATTACHMENT 1N
REVISED

MAGNETIC RESONANCE IMAGING

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR
MAGNETIC RESONANCE IMAGING SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Magnetic Resonance Imaging (MRI) services. Existing providers of MRI services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for MRI services.

These standards and criteria are effective immediately as of December 21, 2011, the date of approval and adoption by the Governor of the State Health Plan changes for 2011. Applications to provide MRI services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Capacity: The measure of the maximum number of MRI procedures per MRI unit per year based upon the type of MRI equipment.

Dedicated Breast MRI Unit: An MRI unit that is configured to perform only breast MRI procedures and is not capable of performing other types of non-breast MRI procedures.

Dedicated Extremity MRI Unit: An MRI unit that is utilized for the imaging of extremities only and is of open design with a field of view no greater than 25 centimeters.

Magnetic Resonance Imaging (MRI): A noninvasive diagnostic modality in which electronic equipment is used to create tomographic images of body structure. The MRI scanner exposes the target area to non ionizing magnetic energy and radio frequency fields, focusing on the nuclei of atoms such as hydrogen in the body tissue. Response of selected nuclei to this stimulus is translated into images for evaluation by the physician.

MRI Procedure: A single, discrete MRI study performed on a single patient during a single visit. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition, including the development of a selected set of CPT codes, which shall not include research-only CPT codes for purposes of determining capacity and need.

MRI Study: An MRI scan defined by a CPT procedure code.

MRI Unit: Medical imaging equipment (often referred to as a "scanner") that uses nuclear magnetic resonance to create tomographic images of body structure. MRI units may be differentiated by magnetic field strength ("tesla" or "T"), and also by construction or orientation. A "closed" scanner typically uses a higher strength magnet and an "open" scanner typically uses a lower strength magnet. There are also "multi-position" or "stand-up" scanners (often used for spine and joint evaluation, where weight-bearing is required) and limited-use scanners, such as those designed only to scan the breast or extremities (e.g., elbows, wrists, toes, etc.).

Mobile MRI Unit: An MRI unit and transporting equipment that is moved or able to be moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the United States.

Mobile MRI Unit Capacity: Total capacity of a mobile MRI unit is 600 annual procedures per day of operation per week and is based upon a daily operating efficiency of 12 procedures per day x 50 weeks per year, multiplied by the number of days per week that the equipment is used. The optimal efficiency of a mobile MRI unit is based upon the number of days per week that it is in operation. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of total capacity.

Dedicated Multi-position MRI Unit: An MRI unit that permits the patient to be scanned in various positions, such as sitting, standing, bending, or leaning, as well as lying down, for the purpose of providing weight-bearing scans.

Service Area: The contiguous counties or portions thereof representing a reasonable area in which an applicant intends to provide MRI unit services and in which at least 75% of its service recipients reside. An MRI unit should be located at a site that allows reasonable access for residents of the service area.

Service Area Capacity: The estimate of the number of MRI units needed in a given service area. The estimate is based upon an optimal efficiency of 2,880 procedures per year for a stationary MRI unit and an optimal efficiency of 480 annual procedures per day of operation per week for a mobile MRI unit.

Specialty MRI Unit: A Dedicated Breast, Extremity, or Multi-position MRI unit.

Stationary MRI Unit: A non-moveable MRI unit housed at a single permanent

location.

Stationary MRI Unit Capacity: Total capacity of a stationary MRI unit is 3600 procedures per year and is based upon a daily operating efficiency of 1.20 procedures per hour, 12 hours per day x 5 days a week x 50 weeks of operation per year. The optimal efficiency for a stationary MRI unit is 80 percent of total capacity, or 2,880 procedures per year.

Project Overview and Introduction to the Applicant

American Health Imaging of Tennessee, LLC proposes to develop an Outpatient Diagnostic Center in Knoxville (Knox County), under the Facility name American Health Imaging of Knoxville, including the initiation of outpatient MRI service. The proposed ODC will offer a 3.0T MRI unit, CT, and ultrasound. The proposed ODC will be located at 326 Lovell Road in Knoxville, TN, 37934.

AHI is a developer and operator of freestanding imaging centers. Headquartered in Atlanta, GA, American Health Imaging (AHI) invests in the most up-to-date imaging equipment to enhance the patient experience and provide the highest quality diagnostic images since 1998. Today, AHI owns and operates over 45 best-in-class diagnostic imaging facilities in Alabama, Georgia, Florida, South Carolina and Texas.

American Health Imaging of Tennessee, LLC (AHI TN), a Tennessee Limited Liability Corporation, is a wholly owned subsidiary of American Health Imaging, Inc. (AHI). AHI is wholly owned by Lumexa Imaging Outpatient, Inc., which is wholly owned by Lumexa Imaging Outpatient Intermediate Holdings, Inc., which is wholly owned by Lumexa Imaging Equity Holdco, LLC.

The proposed service area for the project includes three counties: Knox County (the project location), as well as Blount and Loudon Counties, which are contiguous. Knox County has a mix of hospital, physician office and ODC imaging centers, but none of the ODC units are located in Turkey Creek, which is the fastest growing area of Knoxville. Additionally, the aggregate utilization standard set forth in the Certificate of Need Standards and Criteria for Magnetic Resonance Imaging services is met in Knox County, indicating a need for access to additional MRI services. Neither Loudon, nor Blount have any freestanding ODC MRI units. In Loudon, the only MRI unit is hospital-based and in Blount, there is one hospital-based unit and one physician office practice-based unit. Blount County units' utilization exceeds the aggregate minimum volume standard. The proposed ODC in Knox County will increase access to freestanding MRI and other imaging services for residents of the area.

The proposed project is needed for a variety of reasons, including:

1. High utilization of existing MRI units in the area;
2. Lack of freestanding ODCs in the area; and
3. Enhanced technology offering, including a 3.0T MRI unit.

The total cost of the project is estimated to be \$5,913,239.

Standards and Criteria

1. Utilization Standards for non-Specialty MRI Units.

- a. An applicant proposing a new non-Specialty stationary MRI service should project a minimum of at least 2160 MRI procedures in the first year of service, building to a minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2880 procedures per year by the third year of service and for every year thereafter.

Response: The proposed project includes a new non-specialty MRI unit. However, the proposed MRI unit will be a Siemens MAGNETOM Lumina MRI system, which includes a 3.0T magnet. This unit is particularly notable with its unique, high performance 3.0T clinical technology. This technology is particularly unique at freestanding imaging centers; market research shows that the vast majority of 3.0T MRIs are located in the hospital or hospital outpatient department settings. Increasing access to this type of advanced imaging technology in the freestanding imaging setting such as American Health Imaging of Knoxville will offer numerous benefits, including enhanced convenience such as 24-hour scheduling, a strong emphasis on personalized care in a smaller environment, ease of navigation with readily available parking, improved patient satisfaction, and contained costs.

The 3.0T technology embraces the unique set of challenges each patient brings to the exam and overcomes patient variability, resulting in the following:

- ✓ Fewer rescans;
- ✓ Predictable scheduling; and
- ✓ Consistent, high quality, personalized exams for high end clinical routine.

The higher magnetic field strength of a 3.0T MRI scanner can produce clearer, more detailed images with a better signal-to-noise ratio (SNR) and contrast. This can help identify smaller structures and lesions that might not be visible with a 1.5T MRI, which can lead to more accurate diagnoses. With lower image noise it decreases the risk of image distortion and the need to rescan a patient which can lead to lower overall healthcare cost.

3.0T MRI technology can be particularly helpful for specific sites and studies, including the following:

- ✓ A 3.0T MRI is a powerful tool in cancer detection. For early prostate cancer detection, a urologist will order a non-invasive Prostate Imaging Reporting and Data

System (PI-RADS) exam to categorize lesions, which can reduce unnecessary biopsies and treatment for benign and subclinical diseases. This exam is typically only able to be performed on a 3.0T MRI.

- ✓ New and novel monoclonal antibody (MAB) immunotherapies are now available for treatment of Alzheimer disease. These new therapies require up to five brain MRIs for each patient to monitor for ARIA-E and ARIA-H lesion side effects. These brain MRIs for side effect monitoring inform the physician whether the patient can continue the Alzheimer's therapy for the treatment of the disease.
- ✓ For body exams, the 3.0T scan enables free-breathing high-resolution magnetic resonance cholangiopancreatography (MRCP) to pancreatic and pelvic studies to diagnose pancreatic cancer, pancreatitis, gallstones, and bile duct problems.
- ✓ Orthopedic physicians prefer the 3.0T for smaller structures to exam ligament tears to cartilage degeneration.

The distinct capabilities of the 3T have become even more necessary in recent years, as Alzheimer's and prostate cancer diagnoses continue to rise. For instance, according to the Alzheimer's Association, 10.9 percent of individuals age 65 and older have been diagnosed with Alzheimer's. Similarly, one in eight men will be diagnosed with prostate cancer during his lifetime.

Differences in 1.5T and 3.0T MRI Technology

While 3.0T MRI technology has become more widespread in recent years, the majority of MRI units currently in use are 1.5T units. When comparing 1.5T with 3.0T MRI technology, field strength is the biggest difference. According to Radiology Today, a 1.5T MRI system is approximately 30,000 times stronger than the Earth's magnetic field, whereas a 3.0T MRI system is double that. 3.0T systems allow for higher signal to noise ratio as well as increased image resolution capabilities, which is crucial for MRI imaging.

Benefits of a 3.0T MRI scanner over a 1.5T MRI scanner are particularly distinct for clinical areas such as neuroradiology and musculoskeletal studies. In these cases, 3.0T MRI technology gives higher resolution images and more possibilities to do advanced work like looking at degenerative diseases, brain connectivity, or sports medicine. As a result, 3.0T MRI technology is quickly becoming the standard of care for neurological diseases and disorders.

Finally, the proposed 3.0T scanner promotes cost efficient energy management with a power management system that disables power-consuming components during scan breaks, resulting in up to 30 percent energy savings compared to the industry average. This

proposed innovative imaging technology will promote high quality clinical care and outcomes, foster patient safety and satisfaction, and encourage optimal operational efficiencies.

Overview of Three-County Area

The proposed service area for AHI of Knoxville will be Knox, Blount and Loudon Counties. The service area is currently home to nearly 700,000 total residents in 2025 and is projected to grow to more than 720,000 residents by 2029. The three-county area currently accounts for approximately 9.7 percent of the total population of Tennessee. **Figure 1N-1** shows the 2025-2029 population in the proposed service area.

Figure 1N-1
2025-2029 AHI of Knoxville Service Area Population

County	2025	2029	Actual Growth	CAGR
Knox	497,744	514,586	16,842	0.8%
Blount	141,393	146,200	4,807	0.8%
Loudon	58,536	61,179	2,643	1.1%
Three County Total	697,673	721,965	24,292	0.9%

Source: Boyd Center for Business and Economic Research, University of Tennessee, Knoxville.

The proposed ODC will serve all patients, but will primarily adult patients. In 2025, the service area is home to more than 553,000 adult residents (ages 18 and over) and is projected to increase to more than 573,000 in the next four years. The growth in the adult population in the proposed service area is projected to outpace statewide growth between 2025 and 2029, with the service area increasing by 3.5% while Tennessee's adult population is only projected to increase by just 3.1% during the same period.

It is important to note that high school sports are very active and important, particularly in Knox County. As a result, AHI of Knoxville expects that it will receive referrals of high school athletes in need of imaging studies resulting from sports injuries. According to the state demographer, there are more than 33,000 residents of Knox County who fall into ages 15-19.

The service area population's median age differs by county, with Knox County's population being notably younger than both Blount and Loudon's populations. The median age of the Knox County population is 37.3 years, with Blount's median age at 43.9 years and Loudon's at 48.7

years. Knox County is more in line with the overall median average of the state of Tennessee, which is 38.9 years.

The proposed three-county service area has a strong economy, as well as strong socio-economic indicators. Currently, the median household income of Knox County (\$71,662) is consistent with the statewide average (\$67,097). Blount and Loudon have higher median household income than Knox at \$74,607 and \$80,296, respectively. Knox County's poverty rate (13.8%) is consistent with the state of Tennessee (14.0%), while Blount and Loudon have slightly lower rates of poverty. Finally, the service area's rate of TennCare enrollees is lower than the state average.

Overall, the proposed three-county service area has a large and growing population that will continue to drive the need for outpatient imaging services, including MRI.

Historical Utilization of Existing Service Area MRI Units

There are currently 33 MRI units in the three-county area. The units are located primarily in hospitals or hospital-based outpatient centers, with some units located in private physician offices. **Figure 1N-2** provides a current inventory of MRI units throughout the three-county area.

REVISED Figure 1N-2
Inventory of Three-County Service Area MRI Units

Provider	County	Provider Type	2023 No of Units
Abercrombie Radiology	Knox	RPO	1
Summit Medical Group	Knox	PO	2
Summit Medical Group - Midlake	Knox	PO	1
Covenant Health Dx Center West	Knox	HODC	1
Covenant Health Dx Center South	Knox	ODC	1
East TN Children's Hospital	Knox	HOSP	1
East TN Community Open MRI	Knox	ODC	2
Fort Sanders Regional Med Ctr	Knox	HOSP	2
Knoxville Comprehensive Breast Ctr	Knox	PO	1
North Knoxville Medical Center	Knox	HOSP	1
OrthoTN - Knox County	Knox	PO	2
OrthoTN - Knox Accelerator Way	Knox	PO	1
OrthoTN - Knox Dannaher Lane	Knox	PO	1
Parkwest Medical Center	Knox	HOSP	2
TN Orthopaedic Clinics - Parkwest MRI	Knox	PO	1
TN Orthopaedic Clinics - Regional MRI	Knox	PO	1
Turkey Creek Medical Center	Knox	HOSP	1
University Dx Hall of Fame	Knox	ODC	2
University Dx Halls	Knox	ODC	1
University of TN Medical Center	Knox	HOSP	5
Knox County Subtotal			30
Fort Loudon Medical Center	Loudon	HOSP	1
Loudon County Subtotal			1
Blount Memorial Hospital	Blount	HOSP	1
East TN Medical Group	Blount	PO	1
Blount County Subtotal			2
Total, All Units in Three-County Area			33

Sources: TN HFC Medical Equipment Utilization Reports 10/2/2024; Joint Annual Reports.

The 33 existing MRI units are highly utilized, with increasing utilization over the past three years for which data is available (2021-2023). **Figure 1N-3** shows the annual number of MRI scans performed by area MRI units in 2021, 2022 and 2023, as well as the compound annual

growth rate for the period.

REVISED Figure 1N-3
2021-2023 Three-County Service Area MRI Utilization

	MRI Scans			
	2021	2022	2023	CAGR
Knox	92,970	86,816	110,883	9.2%
Blount	9,625	10,114	11,073	7.3%
Loudon	2,143	2,434	2,498	8.0%
Three-County Total	104,738	99,364	124,454	9.0%

Sources: TN HFC Equipment Utilization Report.

Utilization is high and increasing, with associated use rates increasing, as well. In 2021, the number of MRI scans per 1,000 population in Knox County (which accounts of the majority of scans in the service area) was 193.3 scans per 1,000. By 2023, the use rate had increased by approximately 17% to 226.5 scans per 1,000 population. Overall, the three-county use rate is increasing, which is indicative of the continued demand for MRI services in the area. **Figure 1N-4** details the three-year use rates per 1,000 population by county for the proposed AHI of Knoxville service area.

REVISED Figure 1N-4
2021-2023 MRI Scans per 1,000 Population
AHI of Knoxville Proposed Three-County Service Area

	MRI Scans					Total Population					Use Rate per 1,000 Pop		
County/Area	2021	2022	2023	CAGR		2021	2022	2023	CAGR		2021	2022	2023
Knox	92,970	86,816	110,883	9.2%		481,352	485,407	489,496	0.8%		193.1	178.9	226.5
Blount	9,625	10,114	11,073	7.3%		136,715	137,872	139,039	0.8%		70.4	73.4	79.6
Loudon	2,143	2,434	2,498	8.0%		55,986	56,615	57,250	1.1%		38.3	43.0	43.6
Three-County Total	104,738	99,364	124,454	9.0%		674,053	679,894	685,785	0.9%		155.4	146.1	181.5

Sources: TN HFC Equipment Utilization Report; Boyd Center for Business and Economic Research, University of Tennessee, Knoxville.

Overall, area MRI units are very highly utilized and there is a need for additional capacity in the area. Additionally, there is a lack of freestanding ODCs in the area. The proposed AHI of Knoxville ODC will increase access to MRI and other imaging services in a lower cost setting with often quicker access for patients.

Projected Utilization

In order to project utilization, three-county area MRI scans were forecasted to increase

conservatively at the projected compound annual growth rate of the area population by county from 2025-2029. Additionally, AHI of Knoxville assumed utilization levels (MRI scans per day) consistent with other comparable markets served by the applicant's related entities. **Figure 1N-5** shows the projected market MRI scans projected into the future, including the first three years of operation of the proposed MRI unit (2026-2028).

Figure 1N-5
Projected Market MRI Scans
AHI of Knoxville Three-County Service Area

					<i>Year 1</i>	<i>Year 2</i>	<i>Year 3</i>
County	2023 MRI Scans	2025-2029 Pop CAGR	2024	2025	2026	2027	2028
Knox	110,883	0.8%	111,809	112,743	113,685	114,635	115,593
Blount	11,073	0.8%	11,166	11,260	11,354	11,449	11,546
Loudon	2,498	1.1%	2,526	2,554	2,582	2,611	2,640
Three-County Total	124,454		125,501	126,557	127,621	128,695	129,779

AHI of Knoxville utilized both internal data regarding ramp up and utilization of MRI units in similar markets, including average scans per day in order to project its annual volume of MRI scans. **Figure 1N-6** below shows the projected utilization for AHI of Knoxville's proposed 3.0T MRI unit.

Figure 1N-6
Projected MRI Utilization, Years 1-3
AHI of Knoxville

	Year 1	Year 2	Year 3
MRI Scans	2,340	2,600	2,990

The projected utilization of AHI of Knoxville's proposed 3.0T MRI unit results in very conservative market share of the three-county area's projected MRI scans. **Figure 1N-7** shows the resulting market share based on AHI of Knoxville's internal ramp up and utilization projections.

Figure 1N-7
Projected MRI Market Share, Years 1-3
AHI of Knoxville

	Year 1	Year 2	Year 3
Market MRI Scans	127,621	128,695	129,779
AHI of Knoxville Scans	2,340	2,600	2,990
Market Share	1.8%	2.0%	2.3%

The projected ODC will bring much needed MRI capacity to the market and will provide a truly freestanding setting for patients, which will increase access to affordable MRI scans for residents of the three-county area. The need for additional capacity is evident based on the exceedingly high utilization of existing units in each of the three counties, as well as the lack of truly freestanding ODCs in the market.

- b. Providers proposing a new non-Specialty mobile MRI service should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.

Response: Not applicable. The proposed project is not a mobile MRI service.

- c. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.

Response: Not applicable. The applicant projects that it will meet the standard number of procedures required under Criterion 1a, above.

- d. Mobile MRI units shall not be subject to the need standard in paragraph 1 b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's Service Area are not adequate and/or that there are special circumstances that require these additional services.

Response: Not applicable. The proposed project is not a mobile MRI service.

- e. Hybrid MRI Units. The HSDA may evaluate a CON application for an MRI "hybrid" Unit (an MRI Unit that is combined/utilized with another medical equipment such as a megavoltage radiation therapy unit or a positron emission tomography unit) based on the primary purposes of the Unit.

Response: Not applicable. The proposed project is not a hybrid MRI unit.

2. Access to MRI Units. All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the Service Area's population. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRI units that service the non-Tennessee counties and the impact on MRI 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 that data are available).

Response: The proposed MRI unit will be easily accessible to residents of the proposed three-county service area. AHI of Knoxville will be located at 326 Lovell Road, which is located just off I-40 at TN 131 near the Parkside Greenway in the Turkey Creek area of western Knoxville/Knox County. **Figure 1N-8** shows the proposed location of AHI of Knoxville within the proposed service area.

Figure 1N-8
Proposed AHI of Knoxville Location
Within Three-County Service Area



Knox County is currently home to nearly half a million residents. In total, the three-county service area is home to approximately 700,000 residents in 2025. By 2029, the population is expected to increase to more than 721,000. The rate of population growth in the service area is projected to outpace statewide population growth during the same period.

Knox County is the proposed location for AHI of Knoxville. Knox County accounts for more than 70% of the service area population in 2025. It is approximately 27 miles from the proposed AHI of Knoxville location to the extreme eastern edge of Knox County, meaning that the majority of Knox County population is located less than 27 miles away from the proposed center. Additionally, Blount and Loudon are located to the south of central and western Knox County, proximate to the proposed center.

The proposed location is widely accessible to service area ZIP Codes. In fact, the average drive time from the geographic center of service area ZIP Codes to 326 Lovell Road is

slightly less than 25 minutes, with many ZIP Codes within a 15-20 minute drive time. **Figure 1N-9** shows the weekday midday driving distances and times from service area ZIP Codes to the proposed AHI of Knoxville ODC.

Figure 1N-9
Driving Distances and Times from Service Area ZIP Codes
To AHI of Knoxville

ZIP Code	County	To: 326 Lovell Road	
		Miles	Minutes
37721	Knox	27.8	34
37754	Knox	26.1	30
37806	Knox	28.7	34
37849	Knox	21.4	26
37902	Knox	14.4	18
37909	Knox	8.3	15
37912	Knox	15.8	19
37914	Knox	25.6	29
37915	Knox	16.1	22
37916	Knox	15.3	21
37917	Knox	16.8	22
37918	Knox	19.8	27
37919	Knox	11.8	20
37920	Knox	19.6	30
37921	Knox	11.5	20
37922	Knox	6.4	13
37923	Knox	4.5	10
37924	Knox	23	26
37929	Knox	14.7	21
37930	Knox	5.2	12
37931	Knox	6.9	15
37932	Knox	7.1	13
37934	Knox	3.5	9
37938	Knox	26	37
37995	Knox	9.3	15
37996	Knox	13.9	17
37997	Knox	15.6	18
37998	Knox	28.1	38
37701	Blount	18.4	24
37737	Blount	23.5	31
37777	Blount	19.4	25
37801	Blount	30.6	44
37803	Blount	28.3	39
37804	Blount	19.4	26
37853	Blount	17	21
37882	Blount	42	59
37742	Loudon	25.6	36
37771	Loudon	12.3	14
37772	Loudon	10.7	20
37774	Loudon	23.9	27
37846	Loudon	30.3	37
Average Minutes		24.7	

Source: GoogleMaps; weekday midday; fastest route.

The proposed imaging center will be easily accessible for the service area population.

3. Economic Efficiencies. All applicants for any proposed new MRI Unit should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

Response: In an environment of increasingly higher patient co-pays and deductibles, the applicant complements existing hospital-based and HOPD imaging services such as MRI and CT. Shifting clinically appropriate imaging services from the hospital setting to the freestanding imaging setting will enhance scheduling and operational efficiencies while achieving cost containment, as freestanding imaging centers do not carry the costly overhead required for 24/7 care at hospitals. Furthermore, Medicare has long incentivized its patients to use freestanding imaging centers such as the applicant through lower patient co-pays and deductibles.

Recently, major commercial payors have instituted site of care medical necessity requirements. For example, some payors will no longer reimburse for advanced radiology imaging procedures like CT and MRI at HOPDs unless patients are at higher risk such as pediatric or obstetrical patients or those with a known contrast allergy. Thus, there is a demand for the MRI and CT services that will be offered at American Health Imaging of Knoxville, and for a wide range of procedures that are more appropriate for the proposed state-of-the-art equipment in the outpatient setting.

Additionally, the project will bring a 3.0T MRI unit to the service area, in an independent, non-hospital-affiliated ODC. 3.0T MRI services provide faster scan time, increased accuracy/fewer rescans, and enhanced capabilities for a wide range of conditions.

4. Need Standard for non-Specialty MRI Units.

A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelvemonth period reflected in the provider medical equipment report maintained by the HSDA. The total capacity **per MRI unit is based upon the following formula:**

Stationary MRI Units: 1.20 procedures per hour x twelve hours per day x 5 days per week x 50 weeks per year = 3,600 procedures per year

Mobile MRI Units: **Twelve (12) procedures per day** x days per week in operation x 50 weeks per year. For each **day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.**

Response: Knox County has a mix of hospital, physician office and ODC imaging centers, but no ODC located in Turkey Creek, which is the fastest growing area of Knoxville. Additionally, all of the ODC's affiliated with hospitals and are not truly freestanding facilities. Neither Loudon, nor Blount have any freestanding ODC MRI units. In Loudon, the only MRI unit is hospital-based and in Blount, there is one hospital-based unit and one physician office practice-based unit. The MRI units are highly utilized and accommodated more than 124,000 scans in 2023. **Figure 1N-10** shows the most recent three years' utilization for all MRI units in the proposed three-county service area.

Figure 1N-10
2021-2023 MRI Unit Utilization Summary
All MRI Units in Knox, Blount and Loudon Counties

Provider	County	Provider Type	2023 No of Units	MRI Procedures			2021-2023 Growth
				2021	2022	2023	
Abercrombie Radiology	Knox	RPO	1	2,857	2,240	2,700	(157)
Summit Medical Group	Knox	PO	2	3,207	3,220	4,653	1,446
Summit Medical Group - Midlake	Knox	PO	1	3,069	3,201	3,176	107
Covenant Health Dx Center West	Knox	HODC	1	486	625	740	254
Covenant Health Dx Center South	Knox	ODC	1	NA	NA	288	NA
East TN Children's Hospital	Knox	HOSP	1	3,762	4,061	4,995	1,233
East TN Community Open MRI	Knox	ODC	2	4,118	3,637	3,433	(685)
Fort Sanders Regional Med Ctr	Knox	HOSP	2	9,125	9,839	10,136	1,011
Knoxville Comprehensive Breast Ctr	Knox	PO	1	2,676	2,576	2,110	(566)
North Knoxville Medical Center	Knox	HOSP	1	4,141	3,517	3,541	(600)
OrthoTN - Knox County	Knox	PO	2	9,252	8,247	7,806	(1,446)
OrthoTN - Knox Accelerator Way	Knox	PO	1	NA	1,538	4,364	NA
OrthoTN - Knox Dannaher Lane	Knox	PO	1	NA	4,398	4,756	NA
Parkwest Medical Center	Knox	HOSP	2	9,863	9,784	10,507	644
TN Orthopaedic Clinics - Parkwest MRI	Knox	PO	1	4,696	5,305	4,552	(144)
TN Orthopaedic Clinics - Regional MRI	Knox	PO	1	1,022	429	1,861	839
Turkey Creek Medical Center	Knox	HOSP	1	3,100	3,097	3,401	301
University Dx Hall of Fame	Knox	ODC	2	11,254	NA	11,573	319
University Dx Halls	Knox	ODC	1	NA	NA	2,868	NA
University of TN Medical Center	Knox	HOSP	5	20,342	21,102	23,423	3,081
Fort Loudon Medical Center	Loudon	HOSP	1	2,143	2,434	2,498	355
Blount Memorial Hospital	Blount	HOSP	1	5,382	5,950	6,396	1,014
East TN Medical Group	Blount	PO	1	4,243	4,164	4,677	434
Total, All Units in Three-County Area			33	104,738	99,364	124,454	19,716

Sources: TN HFC Medical Equipment Utilization Reports 10/2/2024; Joint Annual Reports.

As shown in the Figure, MRI utilization increased significantly from 2021 to 2023. It is reasonable to assume that it will continue to increase into the future.

The Certificate of Need Standards and Criteria for MRI units set forth a minimum aggregate volume threshold of 2,880 MRI scans per unit per year. In 2023, the most recent twelve-month period reflected in the medical equipment report, the combined average utilization of Knox County units was 3,696 and the combined average utilization of Blount County units was 5,537, meaning that the minimum volume was met in both counties. Further, in Loudon County, the combined average utilization was 2,498 scans, which is very close the minimum volume threshold. **Figure 1N-11** shows the 2023 utilization per unit for all MRI units in the proposed three-county service area and the county-level aggregate utilization for Knox, Blount and Loudon Counties.

REVISED Figure 1N-11
2023 MRI Scans per Unit
All MRI Units in Knox, Blount and Loudon Counties

Provider	County	Provider Type	2023 No of Units	MRI Procedures	
				2023 Scans	2023 Per Unit
Abercrombie Radiology	Knox	RPO	1	2,700	2,700
Summit Medical Group	Knox	PO	2	4,653	2,327
Summit Medical Group - Midlake	Knox	PO	1	3,176	3,176
Covenant Health Dx Center West	Knox	HODC	1	740	740
Covenant Health Dx Center South	Knox	ODC	1	288	288
East TN Children's Hospital	Knox	HOSP	1	4,995	4,995
East TN Community Open MRI	Knox	ODC	2	3,433	1,717
Fort Sanders Regional Med Ctr	Knox	HOSP	2	10,136	5,068
Knoxville Comprehensive Breast Ctr	Knox	PO	1	2,110	2,110
North Knoxville Medical Center	Knox	HOSP	1	3,541	3,541
OrthoTN - Knox County	Knox	PO	2	7,806	3,903
OrthoTN - Knox Accelerator Way	Knox	PO	1	4,364	4,364
OrthoTN - Knox Dannaheer Lane	Knox	PO	1	4,756	4,756
Parkwest Medical Center	Knox	HOSP	2	10,507	5,254
TN Orthopaedic Clinics - Parkwest MRI	Knox	PO	1	4,552	4,552
TN Orthopaedic Clinics - Regional MRI	Knox	PO	1	1,861	1,861
Turkey Creek Medical Center	Knox	HOSP	1	3,401	3,401
University Dx Hall of Fame	Knox	ODC	2	11,573	5,787
University Dx Halls	Knox	ODC	1	2,868	2,868
University of TN Medical Center	Knox	HOSP	5	23,423	4,685
Knox County Subtotal			30	110,883	3,696
Fort Loudon Medical Center	Loudon	HOSP	1	2,498	2,498
Loudon County Subtotal			1	2,498	2,498
Blount Memorial Hospital	Blount	HOSP	1	6,396	6,396
East TN Medical Group	Blount	PO	1	4,677	4,677
Blount County Subtotal			2	11,073	5,537
Total, All Units in Three-County Area			33	124,454	3,771

Sources: TN HFC Medical Equipment Utilization Reports 10/2/2024; Joint Annual Reports.

As shown in the Figure, MRI units in the three-county area are highly utilized. In 2023, the three-county units' aggregate utilization was 3,771 per unit, which exceeds both the total utilization standard (3,600) and the optimal utilization standard (2,880). There is clearly a need for increased access to MRI services in the three-county area. The proposed ODC in Knox County will increase access to freestanding MRI and other imaging services for residents of the area.

5. Need Standards for Specialty MRI Units.

- a. Dedicated fixed or mobile Breast MRI Unit. An applicant proposing to **acquire a dedicated fixed or mobile breast MRI unit shall not receive a CON to use the MRI unit for non-dedicated purposes and shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:**
 1. It has an **existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound, and MM unit equipment, and** that is trained to interpret images produced by an MRI unit configured exclusively for mammographic studies;
 2. Its existing **mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit are in compliance with the federal Mammography Quality Standards Act;**
 3. It is part of or has a formal affiliation with an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is **based in the proposed service area.**
 4. It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, **and primary care providers.**

Response: Not applicable. The proposed project does not include a specialty MRI unit.

- b. Dedicated fixed or mobile Extremity MR1 Unit. An applicant proposing to institute a Dedicated fixed or mobile Extremity MR1 Unit shall provide documentation of the total capacity of the proposed MR1 Unit based on the

number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Extremity MRI Unit and a CON granted for this use should so state on its face.

Response: Not applicable. The proposed project does not include a dedicated fixed or mobile extremity MRI unit.

- c. Dedicated fixed or mobile Multi-position MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Multi-position MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Multi-position MRI Unit and a CON granted for this use should so state on its face.

Response: Not applicable. The proposed project does not include a dedicated fixed or mobile multi-position MRI unit.

6. Separate Inventories for Specialty MRI Units and non-Specialty MRI Units. If data availability permits, Breast, Extremity, and Multi-position MRI Units shall not be counted in the inventory of non-Specialty fixed or mobile MRI Units, and an inventory for each category of Specialty MRI Unit shall be counted and maintained separately. None of the Specialty MRI Units may be replaced with non-Specialty MRI fixed or mobile MRI Units and a Certificate of Need granted for any of these Specialty MRI Units shall have included on its face a statement to that effect. A non-Specialty fixed or mobile MRI Unit for which a CON is granted for Specialty MRI Unit purpose use-only shall be counted in the specific Specialty MRI Unit inventory and shall also have stated on the face of its Certificate of Need that it may not be used for non-Specialty MRI purposes.

Response: The proposed project is for a non-specialty MRI unit. Currently, there are 33 such units in the proposed service area, the majority of which (30) are located in Knox County. The non-specialty MRI units in the proposed service area are highly utilized, with the aggregate utilization in both Knox and Blount exceeding the optimal utilization standard for the most recent year (2023). Additionally, the one hospital-based unit in Loudon County is very highly utilized at 2,498 scans in 2023, which is close to the minimum volume threshold.

7. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRI Unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed MRI Unit for clinical use.

Response: A letter showing FDA approval for the proposed MRI unit is provided in **Attachment 1N1**.

- b. The applicant should demonstrate that the proposed MRI Procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

Response: The proposed MRI unit will be installed in an existing office building at 326 Lovell Road, Knoxville, Tennessee, 37934. The applicant proposes to lease 4,704 square feet of space to establish the center. Proposed renovation of the rentable square footage will conform to all applicable federal standards, manufacturer's specifications and licensing agencies' requirements.

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

Response: AHI staff members are trained to perform emergency response procedures. For patients experiencing an emergency that exceeds staff expertise, local EMS will be called to transport the patient to a hospital emergency department. AHI of Knoxville staff will attempt to stabilize the patient until EMS arrival.

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

Response: Consistent with other AHI imaging centers, AHI of Knoxville will implement guidelines and protocols for ensuring that MRI procedures are medically necessary. Additionally, most insurance companies require prior authorization for imaging procedures such as MRI. Insurance company approval for an MRI scan indicates medical necessity or clinically appropriate treatment. A copy of AHI's policy for Ordering Exams is provided in **Attachment 1N7d**. The policy's purpose is: To establish written guidelines for the order of diagnostic tests by treating physicians and practitioners. The policy also states: orders must be provided in writing by the physician treating the beneficiary, i.e., the physician furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in managing the beneficiary's specific medical problem. AHI of Knoxville will implement the AHI policy and will ensure that all MRI tests are medically necessary and will not unnecessarily duplicate other services.

- e. An applicant proposing to acquire any MRI Unit or institute any MRI service, including Dedicated Breast and Extremity MRI Units, shall demonstrate that it meets or is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, including staff education and training programs.

Response: AHI is a large, multi-state imaging company with a long history of quality of care. Additionally, AHI has numerous programs in place to ensure that it recruits and retains highly qualified staff to provide care within its numerous imaging centers. AHI centers maintain accreditation and the proposed center will follow the same staffing guidelines as other AHI facilities.

The applicant will offer competitive salaries and benefits and will be committed to minimizing turnover through educational opportunities and other benefits. Staff members will be recruited through a variety of channels, including in-house listings of available positions, local and regional newspaper listings, advertisements in professional publications and recruitment through local training programs as well as colleges.

- f. All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.

Response: American Health Imaging has a history of the provision of high-quality imaging. The organization's imaging center's existing CT and MRI programs are

accredited by the Intersocietal Accreditation Commission (IAC), which is a nonprofit organization in operation to evaluate and accredit facilities that provide diagnostic imaging and procedure-based modalities, thus improving the quality of patient care provided in private offices, clinics, and hospitals where such services are performed. The proposed imaging center will also participate in this accreditation process.

- g. 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 transfer agreement hospital medical staff.

Response: In the unlikely event of an emergency, AHI staff will use 911 emergency services to initiate a transfer of patients who need care in a hospital emergency room. AHI staff members are trained to perform emergency response procedures. For patients experiencing an emergency that exceeds staff expertise, local EMS will be called to transport the patient to a hospital emergency department. AHI of Knoxville staff will attempt to stabilize the patient until EMS arrival.

- 8. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

Response: AHI of Knoxville will submit all data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

- 9. 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: According to the Health Resources and Services Administration, Knox County is a medically underserved area, as are Blount and Loudon Counties. Specifically:

- Knox is a medically underserved area
- Blount is a medically underserved area for low-income population; and
- Loudon is a non-rural medically underserved area.

American Health Imaging of Knoxville will provide services to all patients, regardless of their ability pay, and does not discriminate based upon race, gender, creed, nationality, or disability.

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

Response: Not applicable. The applicant proposes to develop an ODC and is not a safety net hospital or children's hospital.

- 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: AHI contracts with Medicaid Managed Care Organizations in the states in which it operates imaging centers. Additionally, AHI participates in the Medicare program. The proposed AHI of Knoxville ODC commits that it will contract with at least one TennCare MCO and will participate in the Medicare program.

- d. Who is proposing to use the MR1 unit for patients that typically require longer preparation and scanning times (e.g., pediatric, special needs, sedated, and contrast agent use patients). The applicant shall provide in its application information supporting the additional time required per scan and the impact on the need standard.

Response: Not applicable. The applicant does not propose to use the MRI unit for patients that typically require longer preparation and scanning times.

Rationale for Revised and Updated Standards and Criteria for Magnetic Resonance Imaging Services

Definitions

Specialty MRI Units. The Office of Health Planning recognizes that certain MR1 Units dedicated for breast, extremity, and multi-position purposes do not reach the level of utilization that standard MRI Units do. Consequently, definitions for these Specialty Units have been created and specific standards for each have been developed.

MRI Procedure. To provide for uniform procedure reporting, the Health Services and Development Agency is responsible for setting CPT code reporting requirements consistent with the definition of MRI Procedure. Research CPT codes are excluded from capacity and need calculations.

Capacity. The Office solicited operating schedule information from owners/operators of MRI Units. From this information, while total capacity of a non-Specialty MRI Unit could conceivably be based on an operating schedule of 24 hours per day, 7 days per week, usual practice does not cover such extended hours of operation. It appears that physician offices and outpatient diagnostic centers more usually operate their MRI Units Monday-Friday; inpatient facilities typically operate Monday-Friday, with the potential to operate on Saturdays as needed. There are exceptions, however, with both outpatient and inpatient MRI Units operating more than five days a week. Hours of operation vary and seem to not be dependent upon outpatient or inpatient use, usually from 12 to 16 hours per day. Utilization and operating practices can and do vary widely.

Additionally, from the information received, the length of time per scan varies depending on a variety of circumstances, including protocols in place, whether a patient is sedated or needs longer time to be placed in the unit, whether the scan is with or without contrast, etc. A scan may take as little as 30 minutes or as long as 80 (or more) minutes. Typically, due to sedation and/or contrast requirements, an inpatient facility will take longer to perform its scans. However, Tennessee does not collect sufficient data on these scans in order to develop a total capacity formula based on them.

We are basing a total non-Specialty MR1 unit capacity number on the performance of 1.20 scans per hour, Monday through Friday utilization, 12 hours a day, 50 weeks a year, for a total capacity number of 3,600. Using an 80% optimal efficiency number, we arrive at 2,880 as the number of scans a year that a typical stationary non-Specialty MRI Unit should be able to perform.

Standards and Criteria Regarding Certificate of Need Applications for Magnetic Resonance Imaging Services

- . Exceptions to Utilization Standards: Exceptions to the standard number of procedures has been retained for new or improved technology and diagnostic applications, and for mobile MRI Units in operation fewer than 150 days of service per year. Applications for hybrid MRI Units (e.g., MRI Units combined with PET Units or MRT Units) may be assessed under the primary use of the hybrid unit.
2. Other Access Issues: The provision of health care doesn't recognize state boundaries. Accordingly, applicants may include non-Tennessee counties in proposed service areas if that data are available.
3. Economic Efficiencies: To support the goal of reducing health care costs, applicants should document that other options have been investigated and found less advantageous.
4. Specialty **MRI** Units Standards: Dedicated Breast MRI Units have a proposed total capacity estimate of 2,000 procedures per year. Dedicated Extremity and Dedicated Multi-position MRI Units do not have a defined estimate; an applicant must demonstrate total capacity as well as its estimated annual utilization that, by the third year, will be at least 80% of total capacity.
5. Inventories: Given that there are proposed different standards for Specialty and non-Specialty MRI Units, separate inventories should be maintained. Additionally, a CON granted for the institution of a Specialty MRI Unit should not be permitted to be used for non-Specialty MRI purposes; it is recommended that any CON granted for Specialty MRI purposes so state on its face.
6. Quality of Care: Specific staffing, training, and education standards are included to help ensure patient safety and quality of care provided.