HEALTH FACILITIES COMMISSION
SEPTEMBER 28, 2022
APPLICATION REVIEW

NAME OF PROJECT:	University Diagnostics, LLC
PROJECT NUMBER:	CN2207-031
ADDRESS:	7326 Maynardville Pike Knoxville (Knox County), TN 37938
LEGAL OWNER:	University Diagnostics, LLC 2121 Medical Center Way Knoxville (Knox County), TN 37920
OPERATING ENTITY:	Outpatient Imaging Affiliates, LLC 800 Crescent Centre Drive, Suite 400 Franklin, TN 37067
CONTACT PERSON:	Jerry W. Taylor (615) 716-2297
DATE FILED:	July 29, 2022
PROJECT COST:	$6,025,458
PURPOSE FOR FILING:	Establishment of an Outpatient Diagnostic Center and the Initiation of MRI Services to persons aged 14 and younger.

PROJECT DESCRIPTION:

This application is for the establishment of an Outpatient Diagnostic Center (ODC) and the initiation of MRI services to persons aged 14 and younger. Imaging services to be provided are MRI (adults and pediatrics), CT, X-ray and Ultrasound. The ODC will be located at 7326 Maynardville Pike, Knoxville (Knox County), TN 37938. The proposed service area consists of Anderson, Knox and Union Counties.

Executive Summary

- If approved, the applicant projects the proposed project will open for service in December 2022.

- The applicant proposes to establish an outpatient diagnostic center with MRI, CT, X-Ray and Ultrasound services to be located in northern Knox County to better serve patients of University of Tennessee Medical Center (UTMC) residing in northern Knox County, Anderson County, and Union County. The facility will also implement MRI services for a limited number of pediatric patients aged 14 and under which requires CON approval.
- Please see application Item 1E. on pages 6-8 for the applicant's executive summary overview that includes project description, ownership, service area, existing similar service providers, project cost, and staffing.

History

- This applicant states that the facility space was originally intended to be licensed as a hospital outpatient department. The facility was designed and submitted for approval through the Office of Plans Review as a hospital-based outpatient department (HOPD). The applicant believes that the project will not require additional review as an ODC as the standards for an HOPD are more stringent than those for an ODC. See Supplemental #1, Page 8, Question #8 for additional information.

Consent Calendar: ☐ Yes √ No

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

Facility Information

- The proposed ODC will be located in space which is currently leased to the University of Tennessee Medical Center. UTMC will utilize approximately 47,500 square feet of the facility for the operation of a hospital outpatient imaging department. The facility space dedicated to the operation of the ODC will occupy approximately 5,500 square feet of building space.
- The applicant, University Diagnostics LLC has signed an Option to Sublease Agreement with University Health Systems/University of Tennessee Medical Center for the 1st floor of the building.

Ownership

The applicant is owned by affiliates of the University of Tennessee Medical Center (72.5%), Outpatient Imaging Affiliates (22.5%), and an affiliate of Associated University Radiologists (5%).

Project Cost Chart

- The total project cost is $6,011,931. Of this amount, the highest line-item costs of the project are Fixed Equipment Costs ($2,245,659), Total Construction Costs ($2,117,119) and Facility Lease Costs ($615,496).

- For additional information, please see Project Costs Chart on page 10 of the application.

NEED

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

- This project will improve accessibility to imaging services for patients residing in northern Knox County, Anderson County and Union County as it will be the only ODC in the northern part of Knox County.
- The proposed project allows for lower charges for patients than is possible under a hospital-based charge structure.
- It allows for shared ownership among UTMC and groups affiliated with radiologists.

(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 were met except for the following:

   Regarding Standard #3, Economic Efficiencies, the standard states the following: "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." The applicant states that the "alternative of sharing services was not considered", but that the joint ownership of the ODC will support the operation of a high-quality and efficient ODC.

   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 Anderson, Knox and Union Counties (*see Attachment 2N for a county level map*).
- The target population is individuals aged 18 and older although a small number of pediatric MRI patients are expected to be served. (*See page 12R in the original application for more demographic detail.*)

	2022 Population		2026 Population		% Change		TennCare %
	Total	18+	Total	18+	Total	18+	
Service Area	580,063	456,757	597,088	470,629	2.94%	3.04%	20.2%
Tennessee Total	6,997,493	5,455,516	7,203,404	5,629,600	2.94%	3.19%	24.1%

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 2.94% from 2022 to 2026. The target population (18+) is also projected to increase by 3.04%.
- The service area has a lower rate of TennCare enrollment (20.2%) than the statewide rate (24.1%).
- Please see Page 13R in the application for special needs of the services area population including health disparities.

Service Area- Historical Utilization

Utilization trends for providers in the primary service area are shown below:

ODC Facility Name	Facility ID	MRI Patients	MRI Proced	# MRI Units	CT Patients	CT Proced	# CT Units	UltraSnd Patients	UltraSnd Proced	X-Ray Patients	X-Ray Proced
2021*											
East Tenn Community Open MRI	47034	3,908	4,118	2	NA	NA	0	905	954	1,000	1,252
East Tenn Diagnostic Center	47014	NA	NA	0	3,006	3,989	1	NA	NA	0	0
Outpatient Diagnostic Center	47024	9,409	11,255	2	3,610	4,057	1	3,139	3,602	4,486	7,556
TOTAL		**13,317**	**15,373**	**4**	**6,616**	**8,046**	**2**	**4,044**	**4,556**	**5,486**	**8,808**
2020											
East Tenn Community Open MRI	47034	3,628	3,887	2	NA	NA	0	955	1,011	18	22
East Tenn Diagnostic Center	47014	NA	NA	0	3,159	4,108	1	NA	NA	0	0
Outpatient Diagnostic Center	47024	7,030	8,909	2	2,702	3,155	1	2,439	2,732	4,289	7,278
TOTAL		**10,658**	**12,796**	**4**	**5,861**	**7,263**	**2**	**3,394**	**3,743**	**4,307**	**7,300**
2019											
East Tenn Community Open MRI	47034	3,886	4,167	2	NA	NA	0	1,264	1,209	947	1,030
East Tenn Diagnostic Center	47014	NA	NA	0	3,015	4,031	1	NA	NA	0	0
Outpatient Diagnostic Center	47024	7,624	9,895	2	2,552	3,007	1	2,463	2,978	3,886	6,222
TOTAL		**11,510**	**14,062**	**4**	**5,567**	**7,038**	**2**	**3,727**	**4,187**	**4,833**	**7,252**
% Change 19-21		**+15.6%**	**+9.3 5**		**+18.8%**	**+14.3%**		**+8.5%**	**+8.8%**	**+13.5%**	**+21.4%**

Source: CN2207-031, Supplemental #1, Page 13R1,
Note: *2021 Joint Annual Report Data compiled by HFC Staff as 2021 ODC was released after application was deemed complete.

- Combined, the three ODC facilities in the service area reported an increase of (9.3%) from 14,062 MRI procedures in 2019 to 15,373 MRI procedures in 2021.
- CT Scan procedures increased by (14.3%) from 7,038 procedures in 2019 to 8,046 procedures in 2021.

- Ultrasound procedures increased by (8.8%) from 4,187 procedures in 2019 to 4,556 procedures in 2021.
- X-Ray procedures increased by (21.4%) from 7,252 procedures in 2019 to 8,808 procedures in 2021.

Service Area MRI Procedures per Unit 2021

County	Provider Type	Provider	# MRI Units	Total Procedures	Procedures per Unit
Anderson	HOSP	Methodist Medical Center – Oak Ridge	2	5,372	2,686
Anderson	PO	OrthoTennessee – Anderson County	1	9	9
Anderson	PO	Tennessee Orthopedic Clinics – Oak Ridge	1	954	954
Knox	RPO	Abercrombie Radiology	1	2,857	2,857
Knox	PO	Ancillary Services, Summit Medical Group	1	3,207	3,207
Knox	PO	Ancillary Services – Summit Medical Group - Midlake	1	3,069	3,069
Knox	HODC	Covenant Health Diagnostic Center West	1	486	486
Knox	HOSP	East Tennessee Children's Hospital	1	3,762	3,762
Knox	ODC	East Tennessee Community Open MRI, LLC	2	4,118	2,059
Knox	HOSP	Fort Sanders Regional Medical Center	2	9,125	4,563
Knox	PO	Knoxville Comprehensive Breast Center	2	2,675	1,338
Knox	HOSP	North Knoxville Medical Center	1	4,141	4,141
Knox	PO	Ortho Tennessee Knox County	2	9,252	4,626
Knox	ODC	Outpatient Diagnostic Center of Knoxville	2	11,254	5,627
Knox	HOSP	Parkwest Medical Center	2	9,863	4,932
Knox	PO	Tennessee Orthopedic Clinics - Parkwest MRI	1	4,696	4,696
Knox	PO	Tennessee Orthopedic Clinics – Regional MRI	1	1,022	1,022
Knox	HOSP	Turkey Creek Medical Center	1	3,100	3,100
Knox	HOSP	University of Tennessee Medical Center	5	20,342	4,068
		TOTAL for 2021	**30**	**99,304**	**3,310**

Source: CN2207-031, Supplemental #1, Attachment 5NR

- There were 30 MRI units operating in the service area in 2021 which performed 99,304 procedures, averaging (3,310 MRI procedures per unit).

Service Area ODC Imaging Services Available or Pending

Facility	County	MRI	CT	Ultrasound	Echo-Vascular	X-Ray
University Diagnostics (Proposed Facility)	Knox	Yes	Yes	Yes	No	Yes
University Diagnostics (CN2109-028A)	Knox	No	Yes	Yes	Yes	Yes
Covenant Health Diagnostic Center*	Knox	NA	NA	NA	NA	NA
East Tennessee Community Open MRI	Knox	Yes	No	Yes	No	Yes
East Tennessee Diagnostic Center	Knox	No	Yes	No	No	No
Outpatient Diagnostic Center of Knoxville	Knox	Yes	Yes	Yes	Yes	Yes

*Note: There is no JAR data reported for this facility as it opened after the close of the 2020 JAR reporting period.

- Please refer to Item 5N in the application Need Section for a complete listing of each provider's specific three-year utilization in the proposed service area.

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 (2023) and Year 2 (2024)

	Procedure Volumes			Patient Volumes		
Equipment Type	**Year 1 (2023)**	**Year 2 (2024)**	**% Year 2**	**Year 1 (2023)**	**Year 2 (2024)**	**% Year 2**
CT	3,830	4,007	34.3%	2,347	2,455	34.3%
Ultrasound	1,260	1,285	11.0%	772	787	11.0%
X-Ray	3,024	3,074	26.3%	1,853	1,884	26.3%
MRI	2,596	3,326	28.4%	1,590	2,038	28.4%
TOTAL	**10,710**	**11,693**	**100%**	**6,562**	**7,164**	**100%**

Source: CN2207-031, Original Application, Page 14

- Projected procedure volumes for all procedure types are expected to increase by (9.2%) from 10,710 in Year 1 (2023) to 11,693 in Year 2 (2024) of the project.
- Projected patient volumes for all procedure types are expected to increase by (9.2%) from 6,562 in Year 1 (2023) to 7,164 in Year 2 (2024) of the project.
- CT Scans are projected to represent the largest number of procedures (34.3%) followed by MRI (28.4%) and X-Rays (26.3%).

Projected Utilization (Patients and Procedures) by Service Area County
Year 1 (2023) and Year 2 (2024)

	Procedure Volumes			Patient Volumes		
County	**Year 1 (2023)**	**Year 2 (2024)**	**% Year 2**	**Year 1 (2023)**	**Year 2 (2024)**	**% Year 2**
Knox	9,798	10,697	91.5%	6,003	6,554	91.5%
Anderson	609	665	5.7%	373	408	5.7%
Union	303	331	2.8%	186	203	2.8%
TOTAL	**10,710**	**11,693**	**100%**	**6,562**	**7,164**	**100%**

Source: CN2207-031, Original Application, Page 14

- Knox County represents the largest number of projected patients in Year 2 for both procedure and patient volumes (91.5%) followed by Anderson County (5.7%) and Union County (2.8%).

County	Zip Code	UTMC Patient Volume	ODC Patient Volume	Total Patient Volume
Knox	37918	4,497	1,154	5,651
Knox	37917	3,966	845	4,811
Anderson	All	2,660	717	3,377
Knox	37912	2,236	602	2,838
Knox	37849	1,875	456	2,331
Knox	37938	1,567	378	1,945
Knox	37924	1,442	461	1,903
Knox	37721	1,355	360	1,715
Union	All	1,318	360	1,678
Total		**20,916**	**5,333**	**26,249**

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

- The applicant provides a ZIP Code level historical utilization chart to demonstrate the demand for imaging services among residents of the service area seven ZIP Codes closest to the northern Knox County facility as well as Anderson County and Union County. The largest number of combined patients (5,651) utilized Outpatient Diagnostic Center – Knoxville (1,154 patients) and UTMCs HOPD imaging center (4,497 patients) resided in ZIP Code 37918.

CONSUMER ADVANTAGE ATTRIBUTED TO COMPETITION

Charges

- The applicant's projected charges for Year 1 and Year 2 of are provided below:

	Projected Data Chart	
	Year 1 (2023)	Year 2 (2024)
Gross Charges	$824	$869
Deduction from Revenue	$674	$711
Average Net Charges	$150	$158

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

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

Average Charge per Procedure – ODCs in the Service Area	
Facility	**Average Net Charge**
East Tennessee Community Open MRI	$235.67
East Tennessee Diagnostic Center	$707.11
Diagnostic Centers of Tennessee	$221.56
University Diagnostics LLC (Project Site)	$149.85

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

- The applicant's proposed average net charges per procedure are lower than the other ODC facilities in the service area ($149.85 per procedure)

County	Provider Type	Provider	# MRI Units	Total Procedures	Total Gross Charges	Average Charge 2021
Anderson	HOSP	Methodist Medical Center – Oak Ridge	2	5,372	$11,685,103	$2,715
Anderson	PO	OrthoTennessee – Anderson County	1	9	$6,809	$757
Anderson	PO	Tennessee Orthopedic Clinics – Oak Ridge	1	954	$1,133,342	$1,188
Knox	RPO	Abercrombie Radiology	1	2,857	$0*	NA
Knox	PO	Ancillary Services, Summit Medical Group	1	3,207	$2,041,908	$637
Knox	PO	Ancillary Services – Summit Medical Group - Midlake	1	3,069	$1,971,860	$643
Knox	HODC	Covenant Health Diagnostic Center West	1	486	$1,081,781	$2,226
Knox	HOSP	East Tennessee Children's Hospital	1	3,762	$15,983,933	$4,249
Knox	ODC	East Tennessee Community Open MRI, LLC	2	4,118	$2,944,360	$715
Knox	HOSP	Fort Sanders Regional Medical Center	2	9,125	$19,757,567	$2,165
Knox	PO	Knoxville Comprehensive Breast Center	2	2,675	$0*	NA
Knox	HOSP	North Knoxville Medical Center	1	4,141	$22,932,392	$5,537
Knox	PO	Ortho Tennessee Knox County	2	9,252	$6,710,687	$725
Knox	ODC	Outpatient Diagnostic Center of Knoxville	2	11,254	$15,590,754	$1,385
Knox	HOSP	Parkwest Medical Center	2	9,863	$21,635,568	$2,194
Knox	PO	Tennessee Orthopedic Clinics - Parkwest MRI	1	4,696	$5,748,847	$1,224
Knox	PO	Tennessee Orthopedic Clinics – Regional MRI	1	1,022	$1,189,564	$1,164
Knox	HOSP	Turkey Creek Medical Center	1	3,100	$17,279,008	$5,574
Knox	HOSP	University of Tennessee Medical Center	5	20,342	$72,883, 099	$3,583
		TOTAL for 2021	**30**	**99,304**	**$147,693,483**	**$1,487**

Source: CN2207-031, Supplemental #1, Attachment 5NR
*Note: Total procedures and gross charges are not included in the average charge calculation for 2021 for Abercrombie Radiology or Knoxville Comprehensive Breast Center which did not report any gross charges.

- The average gross charge per procedure for service area MRI units in 2021 was $1,487. The applicant's proposed gross charges in Year 1 (2023) $824 per procedure, and Year 2 (2024) $869 pre procedure are lower that the average for MRI procedures across all facility types.

Project Payor Mix

	Percentage of Gross Operating Revenue				
	Medicare	**Medicaid**	**Commercial**	**Self-Pay**	**Charity Care**
Year 1	41.1%	13.8%	40.4%	4.7%	0.8%
Year 2	41.1%	13.8%	40.4%	4.7%	0.8%

Source: CN2207-031, Original Application, Page 21

- Please refer to Item 9C. in the Consumer Advantage section of the application for specific Payor Mix information.

Agreements

- The applicant plans to establish a transfer agreement with the University of Tennessee Medical Center.
- 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. on Page 16.

Staffing

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

	Year One
Direct Patient Care Positions	5.1
Non-Patient Care Positions	4.83
Contractual Staff	0
Total	**9.93**

Source: CN2207-031, Original Application, Page 23

- Direct Care positions includes the following: Multi-Modality Imaging Technologists (4.1 FTEs); and a Clinical Manager (1.0 FTE).
- Non-Patient Care positions includes the following: Business Office Specialists (3.5 FTEs); Marketer/Sales Representative (1.0 FTE); and Administrator (0.33 FTE).
- Please refer to Item 8Q. on Page 23 of the application for additional detail regarding project staffing.

QUALITY STANDARDS

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

Licensure	**Certification**	**Accreditation**
TN Health Facilities Commission	Medicare and TennCare	American College of Radiology

Source: CN2207-031, Original Application, Page 22

LICENSING AGENCY COMMENTS

Licensing Agency: ☒ Health Facilities Commission

☐ Department of Mental Health and Substance Abuse Services

☐ Intellectual and Developmental Disabilities

Licensing Agency Comments Attached: ☐ Yes ☒ No

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT:

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

Outstanding Certificates of Need

Project Name	**University Diagnostics, CN2109-028A**
Project Cost	$2,371,020
Approval Date	December 15, 2021
Description	The establishment of an Outpatient Diagnostic Center (ODC) providing CT, ultrasound, Echo Vascular and X-ray services located at 1975 Town Center Boulevard, Knoxville (Knox County), TN 37922.
Project Status	September 7, 2022- Renovations are underway with an anticipated opening date of October 1, pending required approvals.
Expiration	February 1, 2024

Project Name	**The University of Tennessee Medical Center Off-Campus Radiation Therapy Service, CN2103-010A**
Project Cost	$13,546,526
Approval Date	June 23, 2021
Description	The initiation of linear accelerator services at an existing satellite facility located at 5779 Creekwood Park Boulevard, Lenoir City (Loudon County), Tennessee 37772. The proposed service area includes Loudon, McMinn, Monroe, and Roane Counties, and three ZIP codes (37922, 37932, and 37934) in West Knox County.
Project Status	July 25, 2022-The Annual Progress Report submitted by the applicant indicated the design and cost estimation phases and construction has not begun. The anticipated date of service implementation remains December 2023.
Expiration	August 1, 2024

Project Name	**University of Tennessee Medical Center, FSED, CN2106-020A**
Project Cost	$5,549,225
Approval Date	August 25, 2021
Description	The establishment of a free–standing emergency department (FSED) to be located at 208 Central Avenue West, Jamestown (Fentress County), Tennessee 38556. The proposed service area consists of Fentress County.
Project Status	July 25, 2022- The Annual Progress Report submitted by the applicant indicated construction on the facility has begun. The applicant will submit a request sometime in the future for an increase in approved costs due to supply chain issues that resulted in higher prices for materials and various vendor delivery surcharges.
Expiration	October 1, 2024

Project Name	**Cherokee Farm Orthopedic Surgery Center - CN1909-037AE**
Project Cost	$19,829,307
Approval Date	December 11, 2019
Description	The establishment of an ambulatory surgical treatment center (ASTC) located at an unaddressed lot on the University of Tennessee Farm Campus east of the intersection of Osprey Way and Accelerator Way, Knoxville (Knox County), TN 37920. The ASTC will include five operating rooms with two additional shelled ORs for future use. The five operating rooms subject to this application will primarily be used for orthopedic surgical cases performed by OrthoTennessee, P.C. d/b/a University Orthopedic Surgeons. Cherokee Farm Orthopedic Surgery Center's primary service area (PSA) consists of Knox and Sevier Counties.
Project Status	May 2022 -A three-month project extension to November 1, 2022 was approved by the Agency due to supply chain issues.
Expiration	November 1, 2022

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

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

Outstanding Certificates of Need

Project Name	**Covenant Health Diagnostic Center – South, CN2010-031A**
Project Cost	$11,432,952
Approval Date	February 24, 2021
Description	The establishment of an Outpatient Diagnostic Center (ODC), at a currently unaddressed site on the southeast corner of Chapman Highway (US-441/SR-71) and Mountain Grove Drive in Knox County, TN 37920. The proposed service area is Knox and Sevier Counties. The applicant is owned by Covenant Health.
Project Status	September 7, 2022-Construction is underway and on schedule with building almost "dried in" and finish work underway.
Expiration	April 1, 2023

TPP (9/15/2022)

CRITERION AND STANDARDS

Original Application

NOTE: Supplemental responses to criterion and standards follows in the supplemental attachments.

ATTACHMENT 1N(1)R

RESPONSES TO

CRITERIA AND STANDARDS FOR 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.

The need analysis is based on the need in the PSA, which is Knox County, Anderson County, and Union County. There are no ODCs in any of the seven counties contiguous to Knox County. The demographics table later in this application is based upon a four-year planning horizon.

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.

There are 4 ODCs operational in the PSA (all in Knox County), and there is one certified but not yet operational ODC, which is also owned by University Diagnostics, LLC (CN2109-028) ("UD ODC #1). That ODC is located approximately 25 miles West/Southwest of the site of the proposed ODC (UD ODC #2). UD ODC #1 does not offer MRI services, whereas the proposed UD ODC #2 will have MRI services.

The applicant is owned by affiliates of the University of Tennessee Medical Center ("UTMC") (72.4%), Outpatient Imaging Affiliates ("OIA") (22.5%) and URAD, LLC (5%). OIA is also the sole owner of the Outpatient Diagnostic Center of Knoxville ("ODC-K"), located in the downtown area of Knoxville.

A substantial number of patients who receive imaging services at UTMC's on-campus imaging center (near downtown Knoxville) and at ODC-K reside in Northern Knox County and in Anderson and Union counties. These patients would benefit from having diagnostic imaging services closer to their homes.

The ODCs in Knox County are dispersed throughout Knox County, and the Northern corridor of Knox County represents a gap in the ODC disbursement area, as reflected in the table below.

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)
U.D. Imaging (Proposed)	7326 Maynardsville Pk.	N/A	North	11.0 miles
U.D. Imaging (CN2109-028)	1975 Town Center Blvd.	25.1 miles	Southwest	16.0 miles
Covenant Health ODC	210 Ft. Sanders W. Blvd.	21.6 miles	West	14.3 miles
E. Tenn. Community Open ODC	1415 Old Weisgarber Rd., St. 150	13.1 miles	West/Central	7.0 miles
E. Tenn. Diagnostic Center	1415 Old Weisgarber Rd., St. 120	13.1 miles	West/Central	7.0 miles
Outpatient ODC of Knoxville	800 Cresent Center Dr.	9.1 miles	Central	0.7 miles

On the other hand, the UTMC on-campus imaging center and the ODC-K are both located in central Knox County, just a few miles apart. This proposed ODC will decompress both those imaging centers, and also bring services to the relatively underserved area of North Knox County.

3. Any special needs and circumstances:

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

University Diagnostics ODC will not provide medical services beyond the scope of the diagnostic imaging services offered, i.e., MRI, CT, Ultrasound, and X-ray services. The need for outpatient diagnostic facilities and services is addressed in the immediately preceding response and elsewhere in the application.

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

There are no significant disparities in socioeconomic factors such as income, poverty level, and TennCare enrollment between residents of the service area and those of the state as a whole. (Please see the table in response to Question 3N of the application). University Diagnostics will participate in Medicare and TennCare and will not discriminate against anyone based on non-clinical factors such as race, ethnicity or gender.

c. **The applicant must provide evidence that the proposed diagnostic outpatient services will meet the needs of the potential clientele to be served.**

The three participants in the joint venture company are ideally qualified and situated to meets the needs of the clientele. UTMC currently provides the diagnostic imaging services at its on-campus site, and at other off-campus

sites (not including MRI). OIA is the sole owner of the ODC-K, which is a full-service imaging center. In addition, OIA owns and/or manages numerous other imaging centers throughout the U.S. and is a nationally recognized leader in the field of imaging services. Association of University Radiologists, PC, an affiliate of which is a part owner of the applicant, is a Radiology group practice which provides professional services for the imaging services of both UTMC and ODC-K

4. The applicant must demonstrate how emergencies within the outpatient diagnostic facility will be managed in conformity with accepted medical practice.

A draft emergency protocol is attached following this response. This is based on protocols utilized by UTMC in its various outpatient facilities.

5. The applicant must establish protocols that will assure that all clinical procedures performed are medically necessary and will not unnecessarily duplicate other services.

Imaging services are provided only upon the orders of a physician, who has determined the procedure is medically necessary. Also, in many cases the insurance imaging procedure requires advance authorization by Medicare, a health plan, or another a third-party payor which will only give approval for medically necessary procedures.

THE UNIVERSITY OF TENNESSEE MEDICAL CENTER

Hospital-wide	Environment of Care
Emergency Management	**EM-135**
SUBJECT:	**EMERGENCIES & INCIDENT MANAGEMENT PLAN IN SATELLITE FACILITIES**
Reviewed:	2/19, 2/20
Revised:	2/19*, 2/20*
Approved:	UHS Building Management 6/18 Emergency Management Committee 6/18 Environment of Care Committee 7/18 System Management Team 8/18 *Revised with no substantial changes

Policy

University Health System is committed to the safety and security of all team members, patients, and visitors at all satellite facilities. The UTMC Emergency Operations Plan allows for the possibility that any emergency could arise at an off campus building which could disrupt the normal operations of patient care services. This policy defines possible emergencies and the procedures to mitigate their effect at UTMC properties and to provide guidelines to staff members on how to respond to emergency situations.

Effective implementation on this policy relies heavily on reliable, advanced preparation and detailed communication with staff and our community law enforcement and emergency response partners. A disaster response coordinator should be identified for each clinic/office, and the clinic should have a back-up disaster response coordinator. These should be team members that are normally at the location.

Procedure

A. A disaster response coordinator should be identified for each clinic/office, and the clinic should have a disaster response coordinator. These should be team members that are normally at the location.
B. An Emergency Response Team should be developed for each area/building. See Appendix C.
C. In the event of an internal disaster at a satellite facility, the disaster response coordinator or back-up disaster response coordinator will be responsible for initiating the Emergency Plan.
D. Tenants who are not part of UHS need develop to their own emergency plan; however, they may use this as a guidance document.

University Health System Satellite Facilities Emergency Plan

Table of Contents

For non-emergency situations, know your local responder agencies and phone numbers:

Agency Type	**Agency**	**Non-Emergency Phone Number**
911 Center		
City Law Enforcement		
County Law Enforcement		
EMS		
Fire Department		

For any utility emergency, know your utility company and phone numbers:

Agency Type	**Agency**	**Phone Number(s)**
Electric		
Gas		
Water		
Sewage		
Phone		
Internet		

Notification System to Realty Trust Group or UTMC Security

Contact	Name	Primary Number	Secondary Number
Property Manager	Cat Scussel	865-305-9975	865-250-2313
Operations Manager	Holly Sparks	865-660-9988	
UTMC Security	Dispatch	865-305-9540	865-305-9110

EMERGENCY AND DISASTER PLAN

University Health System Satellite Facilities

I. TENANT EMERGENCY PROCEDURES

1. In the event of an emergency (Medical, Fire, Police) always dial **911**.
2. Tenants are urged to call the numbers shown above to report emergencies including but not limited to fires, bomb threats, acts of physical violence, including purse snatching, auto theft, and life threatening, critical medical emergencies.
3. When calling, you should be prepared to provide the following information:
   a. Your name and telephone number
   b. The nature of the emergency
   c. The exact location of the emergency, the victim or other persons involved.
4. When it is safe and possible, notify the Property Manager at 865-305-9975 or 865-250-2313. If Property Manager is unavailable, notify Operations Manager at 865-660-9988. If you are unable to contact Realty Trust Group, contact UT Medical Center Security at 865-305-9540.

II. MEDICAL EMERGENCY (CODE BLUE or CODE 5: PEDIATRIC CARDIAC/RESPIRATORY ARREST)

1. If an accident or illness of a team member or visitor takes place in your office area, you should:
   a. Call 911
   b. Do not move the victim
   c. If trained, immediately start BLS (CPR) and ACLS.
   d. If possible, have someone meet responding personnel in the corridor to lead them to the victim's location.
   e. Notify Property Manager of the incident.

III. FIRE PROCEDURE (CODE RED)

If you see flames or smoke, or smell something that is definitely burning:

1. Remove anyone from immediate danger, then go to the nearest fire alarm manual pull station (red fire alarm box) or in common area and pull handle. This will cause alarm to sound.
2. Notify the local fire department by telephone at **911**.

a. Identify what is on fire.
b. Give the address and the type of building
c. Give the floor
d. Answer any questions that the dispatcher may ask.

3. Close doors around the fire to contain it.
4. Alert other persons nearby who may be in danger
5. Extinguish the fire if the fire is a small fire.
6. Evacuate through the nearest stairwell/exit.
7. Notify Property Manager, of the incident.

HOW TO USE A FIRE EXTINGUISHER

1. Locate the nearest fire extinguisher and check the gauge.
2. Stand approximately 8 feet away from the fire

3. **P**ull the pin
4. **A**im the nozzle at the base of the fire
5. **S**queeze the Handle
6. **S**weep side to side

THINGS TO DO:
1. Keep calm. Remember to walk down the stairs, or out the exit quietly
2. If caught in heavy smoke, get low to the floor and cover your mouth and nose with a handkerchief or cloth. Take short breaths and crawl to the nearest exit.
3. Remove any type of shoes that may impede a swift decent down the stairs.
4. Some buildings are designed with Area of Refuge/Rescue. Follow the signage that state "Area of Refuge" or "Area of Rescue" to evacuate patient, visitors, or team members who need assistance to these approved areas.

THINGS NOT TO DO:
1. Do not use more than 2 fire extinguishers on a small fire.
2. Do not attempt to fight large fires.
3. Do not attempt to use the elevators.

IV. FIRE ALARM ACTIVATION

1. Upon the activation of fire alarm, follow the Fire Procedure.
2. You should be familiar with stairwell locations and evacuation routes.

THINGS TO DO:
a. Upon notification to evacuate, use a stairwell/exit for evacuation, unless otherwise directed.
b. Remain calm. Keep talking to a minimum.
c. If you need special assistance, seek the help of another team member, or Building Management/Maintenance
d. Each person should proceed directly to their department's designated meeting place and check in with their representatives.

THINGS NOT TO DO:
a. Do not use elevators to evacuate unless directed to do so.
b. Do not run
c. Do not smoke
d. Do not carry items out of the building
e. Do not attempt to remove vehicles from the parking area. This will interfere with emergency response personnel.

OTHER NOTES:
a. You should leave the building via the nearest stairwell/exit.
b. If you or someone else will need special assistance during an evacuation, notify Property Manager.

V. SEVERE WEATHER/TORNADO (CODE GRAY)

1. In the event of severe weather, the National Weather Service (NWS) will issue a weather alert. The local radio and television stations will make an announcement. The NWS will send a text alert based upon the affected zip code(s). It is recommended to have weather radio in your area.
2. Should a severe weather condition (tornado or flash flood) threaten normal business operations, the decision to cease normal operations should be made by the Practice Administrator/Manager. Should this decision be made, team members should be immediately notified.
3. In offices with exterior windows, take these actions prior to leaving the premises.

a. Remove all loose items from the tops of the desks, credenzas, cabinets, shelves, and window ledges.
b. Secure all department records and lock all file cabinets
c. Put the blinds down and turn slats to shut position
d. Cover open shelving with plastic
e. Move artwork and personal items to interior space
f. Disconnect all electrical office equipment
g. If possible, move computer hardware away from windows to interior spaces. Computer hardware should be properly secured prior to physically moving them.
h. Close all doors to exterior offices.

4. Should a severe weather condition be so imminent as to make evacuation unadvisable, you should:
   a. Close all doors to exterior offices.
   b. Move quickly to the core of the building for shelter, i.e., the center-most corridors and rooms
   c. Sit down and protect yourself by putting your head between your knees and covering your head
   d. Remain in a safe area until directed to resume normal activities
5. Monitor TV or radio for further announcement or instructions.

VI. EVACUATION (CODE ECHO)

1. An evacuation may occur during any emergency. Local responders, Property Manager, or designated University Health System Team Members (Maintenance, Security, Safety, Practice Administrators, Managers, or Directors) will advise when needed to evacuate unless otherwise noted in emergency procedures.
2. You should be familiar with stairwell/exit locations and evacuation routes, and you should know your Building Management/Maintenance Personnel.
3. Have an evacuation plan to follow.

THINGS TO DO:

a. Upon hearing the alarm, use a stairwell/exit for evacuation, unless otherwise directed.
b. Remain calm. Keep talking to a minimum.
c. If you need special assistance, seek the help of another team member, or Building Management/Maintenance
d. Each person should proceed directly to their department's designated meeting place and check in with their representatives.

THINGS NOT TO DO:

a. Do not use elevators unless directed to do so.
b. Do not run
c. Do not smoke
d. Do not carry items out of the building, such as food or drinks, other than briefcases or purses.
e. Do not attempt to remove vehicles from the parking area. This will interfere with emergency response personnel.

OTHER NOTES:

a. You should leave the building via the nearest stairwell/exit.
b. Some buildings are designed with Area of Refuge/Rescue. Follow the signage that state "Area of Refuge" or "Area of Rescue" to evacuate patient, visitors, or team members who need assistance to these approved areas.
c. If you or someone else will need special assistance during an evacuation, notify Property Manager.

VII. BOMB THREAT (CLODE BLACK)

Bomb Threats – Telephone Threats

1. A bomb threat is generally made by someone with a close connection to the involved department. The police can quickly narrow down suspects if provided the basic clues that the terrorist might inadvertently provide in a short telephone conversation. Note the following procedures:
   a. Provide the enclosed bomb threat checklist (Appendix B) to your receptionist and/or other relevant people who handle your department's phones.
   b. When a bomb threat is received by phone, never transfer the call. Never assume the threat is a hoax. Never argue with or ridicule the caller. Calmly address the key points provided by the bomb threat checklist and keep the caller talking as long as possible. Ask the caller to repeat parts of his/her message. Never be the first to hang up.
   c. Have a prearranged signal with others in the office. This will allow another to attempt to have the call traced and notify the Management Office while the call is being received.
   d. If possible, record the conversation or have another listen in without the caller's knowledge.
   e. Immediately call 911.
   f. Immediately notify Property Manager that you have received a bomb threat. Property Manager will notify UTMC Security and appropriately notify representatives of other tenants in the building.

Bomb Threats – Written Threats

1. Written threats are less frequent than telephone threats, but must be considered just as carefully. Note the following procedures:
   a. Avoid physical handling of the written threat. Retain all evidence. This evidence will be analyzed by the police department for fingerprints, postmarks, handwriting, and typewriting.
   b. Immediately call 911.
   c. Immediately notify Property Manager that you have received a bomb threat. Property Manager will notify UTMC Security and appropriately notify representatives of other tenants in the building.

Bomb Threats – Mail Bombs

1. Although bomb threats usually are associated with telephone calls announcing that a bomb has been placed on the property, bombs are also sent through the mail or by special delivery or messenger services.
   a. Individuals receiving mail for your department should be alert for packages with oddities in the address and oddities in the packaging.
   b. Packages with oddities in the address:
      i. No return address
      ii. Undue restrictive warnings, such as packages marked "Personal", "Private", "Handle with Care"
      iii. Addressee who never gets personal mail at that address
      iv. Distorted or unusual handwriting
   c. Oddities in packaging
      i. Odd shape, size, wrapping, or color
      ii. Stains on the wrapper, particularly oil stains
      iii. Odors
      iv. Bulges
      v. Unbalanced or excessive weight
      vi. Contents that slosh
      vii. Any sound, particularly a ticking or buzzing
      viii. Wire, tin foil, or strings protruding
2. Immediately call 911.

3. Immediately notify Property Manager that you have received a bomb threat. Property Manager will notify UTMC Security and appropriately notify representatives of other tenants in the building.

Bomb Threats – Evacuation

Evacuation of the building is a decision to be made by each Tenant. However, the authority of the police or fire department officer exceeds that of the Tenant or Landlord and any such instructions are to be followed immediately.

1. Should evacuation be in order, evacuate at a distance, safe from flying glass and debris – at least 300 feet.
2. In the event of an evacuation pursuant to the instructions of a police or fire department official, do not return to the building until you are cleared to do so by such official.
3. Do not make statements to the newspapers or radio or television news.

VIII. PUBLIC/CIVIL DISTURBANCES

Public disturbances are inherently unpredictable and can occur in any number of ways, including pickets, protests and riots.

Should you or your department become aware of a situation that might affect your premises or team members, please contact the Property Manager immediately.

In the event of a public disturbance, it may be necessary to limit some services or restrict access to the building to protect tenants and their property. The Property Manager will make every effort to give as much notice to you as possible, but due to the nature of these situations immediate action may be needed. Among the actions that could be taken is locking exterior doors, activation of the card access system, or interrupting regular elevator service.

Upon notification of a public disturbance, building occupants may want to consider the following actions:

1. Notify 911
2. Locking all entrance doors
3. Securing all cash, sensitive information, and valuable materials
4. Do not leave your suite or the building unless you are certain it is safe to do so.
   a. Notify Property Manager.
   b. Property Manager will notify UTMC Security.

IX. VIOLENT PERSON/WORKPLACE VIOLENCE (CODE GREEN)

1. If a patient, visitor, or team member is causing a disturbance, immediately dial 911.
2. If your department or an individual team member is involved in workplace violence incident:
   a. Get as much information as possible about the threat.
      - What exactly was said?
      - Was a time or day mentioned (such as “I’ll be there this afternoon”)
      - Was a weapon mentioned? Does the person making the threat have weapons?
      - What is the prior history with the threat maker? (history of violence, domestic situation, upset team member or customer)
      - Is there any court ordered restrictions concerning this situation? (restraining order)
      - Are there any photographs or descriptions available? (driver’s license copy, ID card)
3. Document as much of the above information as possible and contact the Police by dialing 911 and then the Property Manager. Property Manager will notify UTMC Security.
4. Have a plan in place if a threatening person does arrive in your space.

X. HAZARDOUS MATERIAL/CHEMICAL, BIOLOGICAL, RADIOLOGICAL, NUCLEAR, EXPLOSIVE INCIDENT: (CODE ORANGE)

1. In the event of a chemical/hazardous material release, immediately dial 911 and provide pertinent information.
2. If trained, contain the spill.
3. Evacuate the area and isolate the area.
4. Notify Property Manager.
   a. Property Manager will notify UTMC Environment, Health, Safety & Emergency Management Office at 865-305-9537 or 865-305-9363.

How to handle Biological Agent Threat for suspicious package/envelope:

1. Immediately dial 911 and provide pertinent information.
2. Do not panic.
3. Do not shake or empty the contents of any suspicious envelope or package.
4. Place the envelope or package in a plastic bag or container to prevent leakage of contents.
5. If you do not have a container, cover the envelope or package with anything (e.g., clothing, paper, trash can, etc.) and do not remove.
6. If contents have been spilled, do NOT try to clean it up. Cover the spilled contents immediately with anything.
7. Leave the area and close the door.
8. Wash exposed skin with soap and water.
9. If clothing has been heavily contaminated, remove clothing as soon as possible and place in a plastic bag or other sealable container.
10. List all people who were in the room or area when the envelope or package was identified as suspicious or who were exposed to spilled contents.

How to handle Chemical Agent Threat for suspicious package/envelope:

1. Immediately dial 911 and provide pertinent information.
2. Notify Property Manager who will inform Administrator On-Call, Environment, Health, Safety and Emergency Management, and UTMC Security.
3. Do not panic.
4. If contents have been spilled, do NOT try to clean it up.
5. Leave the area and close the door.
6. Remain in safe area to wait for further instructions for decontamination from the Emergency Responders.
7. List all people who were in the room or area who were exposed to the chemical agent.

XI. INFANT/CHILD ABDUCTION/MISSING (CODE PINK)

1. In the event of a child/infant is abducted or missing, immediately dial 911 and provide pertinent information.
2. Secure area where abduction occurred.
3. Secure witnesses separately so that they do not inadvertently influence each other's recollection of the event.
4. Remain with the parent(s), guardian(s), or care giver(s) until instructed by emergency responders arrive and speak with the individual(s)
5. Secure the exterior exits.
6. Begin a search for the child/infant and watch for suspicious person with a baby, child, or large package that could hold a baby.
7. Ask to verify infant or child identity or see contents of package.
8. Report any suspicious activity to local law enforcement and emergency responders.
9. If an individual refuse to stay and are expected to have abducted child or infant, get a clear description of the individual and note direction of travel. Give updated information to 911.

10. Notify Property Manager.
    a. Property Manager will notify UTMC Security.

XII. LOST PERSON (MISSING ADULT/ELDERLY PERSON WITH ALTERED MENTAL STATUS) (CODE LOST)

1. In the event of a missing adult/elderly person with altered mental status, immediately dial 911 and provide pertinent information.
2. Secure the exterior exits.
3. Begin a search for the individual.
4. Report any suspicious activity to local law enforcement and emergency responders.
5. Notify Property Manager.
    a. Property Manager will notify UTMC Security.

XIII. HOSTAGE/ACTIVE SHOOTER (CODE PURPLE)

Code Purple Hostage - An individual is being held against their will by an armed perpetrator.

1. Call 911 to initiate response from local law enforcement and provide pertinent information
2. Clear the area to prevent others from becoming hostages or victims.
3. Keep others out of the area.
4. If there is no opportunity for escape or hiding, it might be possible to negotiate with the hostage taker.
5. Don't do anything to provoke them. If they are not shooting, do what they say and don't make any sudden movements.
6. Only you can draw the line on what you will or will not do to preserve your life or the lives of others.
7. Attempting to overpower the /hostage taker with force should be considered only as a last resort when it is imminent that your life is in danger. This is very dangerous, but depending on your situation, this could be your last option.
8. If you are caught by the hostage taker and you are not going to fight back:
    a. Do not look the intruder in the eyes, and obey all commands.
    b. Don't speak unless spoken to and then only when necessary.
    c. Do not talk down to the captor who may be in an agitated state.
    d. Avoid appearing hostile.
    e. Remain calm.
    f. Avoid speculating.
    g. Comply with instructions the best you can.
    h. Avoid arguments.
    i. Expect the unexpected.
    j. Be observant. You may be released or escape. The personal safety of others may depend on your memory.
    k. Be prepared to answer Law Enforcement on the phone.
    l. Be patient and wait.
9. Keep in mind that any option you choose may still result in a negative consequence.
10. Be aware that a hostage situation can turn into an active shooter situation. In that event, move to a safe area and call 911.
11. Notify Property Manager when it is safe and possible.
    a. Property Manager will notify UTMC Security.

Code Purple Active Shooter - A person(s) displaying a firearm in an aggressive or threatening manner with the motivation or intent to injure or kill people in your vicinity. Exit the area if possible. Take others with you, but if they will not leave do not waste valuable time in trying to convince them to go.

1. Do not take anything with you. Prevent others from entering the area. Call 911 to initiate the response from local law enforcement.

2. If you cannot exit the area:
   a. Secure the immediate area by moving all patients, visitors and staff members to a safer location (if possible).
   b. Secure unit doors (if possible) to isolate the incident.
   c. Stay out of sight and keep others calm and quiet
   d. Turn off lights
   e. Silence radios, pagers, cell phones
   f. If your area is involved in the incident, designate one person to call 911 to initiate response from local law enforcement as soon as possible and provide the following information: your name, your location, location of the event, if the perpetrator is still on the scene, the number of perpetrators, victims, hostages, etc., the type of weapon(s) involved, & ID of the shooter (if known), shooter's physical description, race/gender, clothing, etc.
   g. Arm yourself with items that could be used as a weapon and prepare to fight.
   h. If the perpetrator has fired on victims, you are faced with a life or death situation. Only you can consider your next course of action.
   i. If you are caught by the perpetrator and you are not going to fight back: do not look the intruder in the eyes, and obey all commands, don't speak unless spoken to and then only when necessary, do not talk down to the captor who may be in an agitated state, avoid appearing hostile, remain calm, avoid speculating, comply with instructions the best you can, avoid arguments, expect the unexpected, be observant, you may be released or escape, the personal safety of others may depend on your memory, be prepared to answer Law Enforcement on the phone, and be patient and wait.
   j. Response from law enforcement agencies may include multiple agencies with different uniforms. Responding officers will be giving loud verbal commands to you and will not be assisting with injured persons until the scene is deemed completely safe. Always keep your hands shown and avoid sudden movements or shouting towards officers. Do not respond to voice commands until you can verify they are law enforcement or other rescue personnel
   k. Follow all instructions given to you by law enforcement personnel and allow them to assist you out of the building or area
3. Notify Property Manager when it is safe and possible.
   a. Property Manager will notify UTMC Security.

XIV. Earthquake - An earthquake can be felt for many miles and can cause severe damage that can be widespread. Aftershocks can occur at any time without warning and can cause additional damage. The main concern during an earthquake is falling objects.

1. Stay away from windows, glass, and outside doors and walls.
2. Open all interior doors. This is to prevent doors from being jammed shut by structural damage. In case of fire, remove the patient(s) and close the door.
3. Take cover under a desk or strong table or sit/stand against an inside wall. Move all patients to an inside room or hallway against an inside wall.
4. Stay near the center of the building.
5. Do not use elevators during or after an earthquake.
6. Do not use the telephone. Use of the telecommunication systems following an earthquake may cause the lines to jam, preventing emergency communications.
7. If an earthquake if followed by a fire, follow the procedures in your building/office Fire Plan.
8. Avoid lighting a cigarette or striking a match for any reason until gas lines have been checked.
9. Do not attempt to evacuate patients or leave the building. Hazards such as downed power lines, debris from buildings, etc. make it dangerous. Listen to local news media to obtain additional information concerning the status of the environment.
10. Evaluate all utilities including gas, water, electricity, medical gases, etc. and notify the appropriate individuals as necessary.

XV.OTHER CODES USED BY UT MEDICAL CENTER

- **Lockdown/Shelter in Place (CODE KEY)**
  Lockdown: If warned to lock down the building, the following actions should be taken:
  1. Close all exterior doors and secure the doors.
  2. Prevent entry to the facility.
  3. Close all windows, secure them, and close blinds/curtains.

  Shelter in Place: If warned to "shelter in place" from an outside airborne hazard, the following actions should be taken:
  1. Direct patients, visitors, and team members outside to enter the building.
  2. Close all exterior doors and windows.
  3. Shutdown HVAC and close air-intakes.
     a. Please ensure trained personnel can close these and are aware of the location to close the HVAC and air-intakes.
  4. Move patients, visitors, and team members to interior space above the first floor (if possible).
  5. An individual needs to monitor news sources (TV or Radio) for updated emergency instructions.

- **Mass Casualty/Surge Event (CODE YELLOW)**
  The code when the hospital has a large influx of patients over a relatively short period of time from a mass casualty event.

  If warned about this event, your facility or space may be used by UHS to provide medical care to non-critical patients or team members from your area may be recruited to assist with the event.

XVI. UTILITY EMERGENCIES

- **ELEVATOR INCIDENT**
  In the event you are in an elevator that stops between floors, or if the doors will not open, do not attempt to force the doors open. The elevators are equipped with numerous safety devices that are designed to safely shut down and secure an elevator in the event of a malfunction. Under no circumstance should you attempt to force open the doors. In the event elevator entrapment of a patient, visitor, or team member, use the emergency push button in the elevator and notify 911. In the event of a breakdown, trained elevator technicians will be dispatched to remove any persons stuck in an elevator.

  If you observe an elevator malfunctioning, call Property Manager, giving your name, telephone number, which elevator and on which floor the cab is located and a description of the malfunction. The Property Manager will then contact elevator repair personnel.

  In the event of a power interruption to the building, the elevators will proceed to the next floor where the doors will open.

- **WATER LEAKS**
  Water can cause significant damage to the finishes and fixtures within the building. Should you discover a water leak, contact the Property Manager immediately at (865) 305-9975. Building personnel will be dispatched to resolve the situation and begin a clean-up process if necessary.

- **ELECTRICAL OUTAGES**
  In the event of electrical outage/electrical failure, contact the Property Manager immediately at (865) 305-9975. Building personnel will be dispatched to resolve the situation and begin restoring the power.

- **IT/TELECOMM OUTAGES**
  In the event of IT or Telecomm Outage, the CIO, CMIO or Information Technology representative will contact the Property Manager or Practice Administrator to initiate downtime procedures. Please report IT or Telecom related incidents to the IT help desk at 865-305-4357.

XVII. Appendix A
Important Phone Numbers

Realty Trust Group:
Cat Scussel, Property Manager: 865-305-9975 or 865-250-2313
Holly Sparks, Operations Manager: 865-660-9988

University Health System/UT Medical Center:
Security: 865-305-9540
Security Emergency: 865-305-9110
Environment, Health, Safety & Emergency Management: 865-305-9537 or 865-305-9363
Maintenance: 865-305-2580 option 1
Biomedical Engineering: 865-305-2580 option 2
Telecom: 865-305-2580 option 1
IT Helpdesk: 865-305-4357 (305-HELP)
Administrator on Call (AOC): 865-305-9000 ask PBX Operator for the AOC
Nursing Supervisor: 865-305-9800
Respiratory Therapy: 865-305-8700
Central Supply (Supply Chain Management): 865-305-4338
Disaster Hotline: 865-305-8693

Appendix B
ATF BOMB THREAT CHECKLIST

(Adapted from the Treasury, Bureau of Alcohol, Tobacco, and Firearms)

1. When is the bomb going to explode? _____
2. Where is the bomb right now? _____
3. What does it look like? _____
4. What kind of bomb is it? _____
5. What will cause it to explode? _____
6. Did you place the bomb? Why? _____
7. Where are you calling from? _____
8. What is your address? _____
9. What is your name? _____

EXACT WORDING OF BOMB THREAT

_____
_____
_____
_____

Sex of Caller: _____ Race: _____
Age: _____ Length of Call: _____
Time Call Received: _____ Date Call Received: _____

CALLER'S VOICE

_____ Calm
_____ Soft
_____ Stutter
_____ Excited
_____ Laughter
_____ Rasp
_____ Rapid
_____ Normal
_____ Slurred
_____ Ragged
_____ Deep Breathing
_____ Disguised
_____ Familiar (If voice is familiar, who did it sound like?)
_____ Nasal
_____ Angry
_____ Loud
_____ Lisp
_____ Slow
_____ Crying
_____ Deep
_____ Distinct
_____ Whispered
_____ Clearing Throat
_____ Cracking Voice
_____ Accent

BACKGROUND SOUNDS

_____ Street Noises
_____ Voices
_____ Animal Sounds
_____ PA System
_____ Music
_____ Long Distance
_____ Motor
_____ Booth
____ Factory Machinery
_____ Crockery
_____ Clear
_____ Static
_____ House Noises
_____ Local
_____ Office Machinery
_____ Other (Please specify) _____

BOMB THREAT LANGUAGE

_____ Well Spoken (educated)
_____ Foul
_____ Taped
_____ Incoherent
_____ Message read by threat maker
_____ Irrational

REMARKS: _____
_____
Your Name: _____
Your Position: _____
Your Telephone Number: _____
Date checklist completed: _____

ATTACHMENT 1N(2)

Responses to Criteria & Standards for MRI

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.**

      The applicant projects 2,596 MRI scans in Year 1 and 3,326 in Year 2.

   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.**

      N/A

   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.**

      N/A

   d. **Mobile MRI units shall not be subject to the need standard in paragraph 1b 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.**

      N/A

   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.

N/A

2. **<u>Access to MRI Units.</u> 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).**

   It is impractical to accurately quantify a percent of a given population to which a facility or service is "accessible." As a policy, the proposed ODC will be accessible to everyone who has a physician order for an imaging procedure. There could be limitations based on insurance coverage or other issues, the facility is other wase accessible to all.

   From a geographic perspective, the ODC will be within 20 miles or so of most of the PSA population. Below is a table showing the distances from each county seat of the PSA counties to the proposed ODC site.

DISTANCES FROM PSA COUNTY SEATS TO PROPOSED ODC SITE		
County	**County Seat**	**Distance to Site**
Knox	Knoxville	10.8 miles
Anderson	Clinton	16.7 miles
Union	Maynardville	15.2 miles

3. **<u>Economic Efficiencies.</u> 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.**

   The alternative of sharing services was not considered. However, this proposed ODC does involve joint ownership by three disciplines, each of which will help assure a high-quality and efficient ODC.

4. **Need Standard for <u>non-Specialty</u> 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 twelve- month 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.

Complete utilization data for all MRIs in the PSA is attached as an Addendum to this Attachment. It shows that in 2021, the MRIs in the PSA operated at an average of 3,2891 scans per unit. This exceeds the utilization benchmark of 2,880 per unit.

5. Need Standards for <u>Specialty</u> MRI Units.

Criteria No. 5 and all its sub-parts are Not Applicable to this application.

a. <u>Dedicated fixed or mobile Breast MRI Unit.</u> 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 MRI 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.**

b. **Dedicated fixed or mobile Extremity MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Extremity 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 Extremity MRI Unit and a CON granted for this use should so state on its face.**

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.**

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 MRJ 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.**

   N/A, or no response called for.

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.**

      The MRI unit is a traditional 1.5 Tesla which has been approved by the F.D.A. for many years.

   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.**

      The applicant, and OIA in particular, has many years of experience of developing ODCs and installing MRI units. All applicable safety and building specifications will be followed, and compliance will be maintained.

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

      A copy of an emergency protocol is included as an Addendum to Attachment 1N(1).

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

Imaging services are provided only upon the orders of a physician, who has determined the procedure is medically necessary. Also, in many cases the insurance imaging procedure requires advance authorization by Medicare, a health plan, or another a third-party payor which will only give approval for medically necessary procedures.

8. An applicant proposing to acquire any MRI Unit or institute any MRI service, <u>including</u> 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.

The ODC will be accredited by the ACR, and will comply with all accreditation standards, including those relating to staffing.

a. 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.

The applicant commits to do so.

b. 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.

The ODC will have a transfer agreement with UTMC, the majority owner of the applicant.

9. 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.

The applicant will timely comply with such data requests.

10. 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;

Each of the PSA counties are designated as MUA or an MUP by the HRSA. Please see the table below.

County	Designation Type	MUA/P ID	Discipline
Knox County:	MUA	3263	Primary Care
Anderson County:	MUP Low Income	1471221106	Primary Care
Union County:	MUA	1477829966	Primary Care

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

N/A

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

The applicant commits this ODC will participate in TennCare, and will contract with at least one, if not all, of the TennCare MCOs operating in the region.

d. Who is proposing to use the MRI 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.

N/A

LETTER OF INTENT

State of Tennessee
Health Facilities Commission
502 Deaderick Street, 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 County, Tennessee, on or before July 15, 2022 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 University Diagnostics, LLC, owned by University Diagnostics, LLC, a Delaware limited liability company authorized to do business in Tennessee, to be managed by Outpatient Imaging Affiliates, LLC intends to file an application for a Certificate of Need for the establishment of an Outpatient Diagnostic Center (ODC), and the initiation of MRI services to persons age 14 and younger. Imaging services to be provided are MRI (adults and peds) , CT, X-ray, and Ultrasound. The ODC will be located at 7326 Maynardville Pike, Knoxville, Knox County, Tennessee 37938. It will be licensed as an Outpatient Diagnostic Center by the Tennessee Board for Licensing Health Care Facilities. The estimated project cost is $6,025,458.

The anticipated date of filing the application is on or before August 1, 2022.

The contact person for this project is Jerry W. Taylor, Attorney, who may be reached at Thompson Burton, PLLC, One Franklin Park, 6100 Tower Circle, Suite 200, Franklin, Tennessee 37067, Telephone number (615) 716-2297.

Signature of Contact	7/14/22 Date	jtaylor@thompsonburton.com Contact's Email Address

The published Letter of Intent contains 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.

ORIGINAL APPLICATION

CERTIFICATE OF NEED APPLICATION

FOR

UNIVERSITY DIAGNOSTICS, LLC

Establishment of an Outpatient Diagnostic Center
and the Initiation of MRI Services

In the Halls Area of Knoxville,
Knox County, Tennessee

July 29, 2022

Contact Person:

Jerry W. Taylor, Esq.
Thompson Burton, PLLC
6100 Tower Circle, Suite 200
Franklin, Tennessee 37067
615-716-2297

State of Tennessee
Health Facilities Commission
Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Email: hsda.staff@tn.gov

CERTIFICATE OF NEED APPLICATION

1A. Name of Facility, Agency, or Institution

University Diagnostics, LLC		
Name		
7326 Maynardville Pike		Knox
Street or Route		**County**
Knoxville	Tennessee	37938
City	**State**	**Zip**
N/A		
Website Address		

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

2A. Contact Person Available for Responses to Questions

Jerry W. Taylor		Attorney
Name		**Title**
Thompson Burton, PLLC		jtaylor@thompsonburton.com
Company Name		**Email Address**
One Franklin Park, 6100 Tower Circle, Suite 200		
Street or Route		
Franklin	Tennessee	37067
City	**State**	**Zip**
Attorney		615-716-2297
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: July 14, 2022

Date LOI was Published: July 15, 2022

RESPONSE: A Publisher's Affidavit is attached as Attachment 3A.

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

X Establish New Health Care Institution
☐ Addition of a Specialty to an Ambulatory Surgical Treatment Center (ASTC)
☐ Change in Bed Complement
☐ Initiation of Health Care Service as Defined in §TCA 68-11-1607(3) Specify: _____
☐ Relocation
X Initiation of MRI Service
☐ MRI Unit Increase
☐ Satellite Emergency Department
☐ Addition of ASTC Specialty
☐ Initiation of Cardiac Catheterization
☐ Addition of Therapeutic Catheterization
☐ Establishment/Initiation of a Non-Residential Substitution Based Opioid Treatment Center
☐ Linear Accelerator Service
☐ Positron Emission Tomography (PET) Service

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 (Specify): _____
☐ 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
X Outpatient Diagnostic Center
☐ Rehabilitation Facility
☐ Residential Hospice
☐ Nonresidential Substitution Based Treatment Center of Opiate Addiction
☐ Other (Specify): _____

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

University Diagnostics, LLC		
Name		
2121 Medical Center Way		865-305-9000
Street or Route		**Phone Number**
Knoxville	Tennessee	37920
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
- X 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)

RESPONSE: University Diagnostics, LLC is a Delaware limited liability company authorized to do business in Tennessee. The requested documents are attached as 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: Ownership interests in the company are: University Health Systems, Inc. (72.5%); OIA of Knoxville, a wholly owned subsidiary of Outpatient Imaging Affiliates, LLC, (22.5%); and URAD, LLC, an affiliate of Association of University Radiologists, PC (5%). An ownership chart is included in Attachment 7A.

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

Outpatient Imaging Affiliates, LLC		
Name		
800 Crescent Centre Drive, Suite 400		Williamson
Street or Route		**County**
Franklin	Tennessee	37067
City	**State**	**Zip**
www.oiarad.com		
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)

RESPONSE: A copy of a management agreement is attached as 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.
- X Option to Lease - Attach a fully executed Option that includes the anticipated terms of the Option and anticipated lease expense.
- ☐ Other (Specify) _____

RESPONSE: The ODC will be located in a one story building which is already leased to University Health System, d/b/a The University of Tennessee Medical Center, ("UTMC"), which will operate a hospital outpatient department ("HOPD") with numerous health care services, which is scheduled to open in mid-November 2022. UHS/UTMC will sub-lease the space to University Diagnostics, LLC for the ODC. Copies of the master lease and sub-lease, and a copy of the deed vesting title in the landlord, are attached as Attachment 9A.

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: A floor plan for the ODC is attached as 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: The site is not on a public bus route. It is located on Maynardville Pike which is U.S. Highway 441. It near the intersection with another major thoroughfare, Highway 131 (also known as East Emory Road). The site is easily accessible by private vehicles, which is the mode of transportation most patients will be using to reach the facility.

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.

RESPONSE: A plot plan with the required information is attached is 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 X 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 X 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: University Diagnostics proposes to establish an ODC which will offer MRI, CT, X-ray and Ultrasound imaging services. Pediatric patients aged 14 and under will be served if they present to the facility with a parent or guardian and if the imaging is clinically indicated. It is expected pediatrics will represent approximately .01%, or less, of annual patients. It will be located in approximately 5,500 square feet of space in a building consisting of approximately 53,000 square feet. The remainder of the building will be utilized as an HOPD of the University of Tennessee Medical Center ("UTMC") which will offer a variety of outpatient health care services. This will create a comprehensive outpatient center for the use of UTMC's patients and others needing services.

- Ownership structure

RESPONSE: The applicant is limited liability company with ownership/membership interests being held as follows: University Health System, Inc. (the owner of UTMC) (72,5%); OIA of Knoxville, LLC, a wholly owned subsidiary of Outpatient Imaging Affiliates, LLC, (22.5%); and URAD, LLC, an affiliate of Association of University Radiologists, PC (5%).

- Service Area

RESPONSE: The primary service area (PSA) consists of Knox, Anderson, and Union Counties. These counties are expected to account for 100% of the Year1 patients. The location of the ODC in Northern Knox County makes it extremely unlikely patients wooed travel there from other counties at least to any appreciable extent.

- Existing similar service providers

RESPONSE: There are 4 ODCs operational in the PSA (all in Knox County), and there is one certified but not yet operational ODC, which is also owned by University Diagnostics, LLC (CN2109-028) ("UD ODC #1). That ODC is located approximately 25 miles from the site of the proposed ODC (UD ODC #2). UD ODC #1 does not offer MRI services, whereas the proposed UD ODC #2 will have MRI services. The table below reflects the existing and proposed ODCs, and the services available at each.

SERVICES OFFERED BY OUTPATENT DIAGNOSTIC CENTERS IN THE PSA						
Facility	**County**	**MRI**	**CT**	**Ultrasound**	**Echo-Vascular**	**X-Ray**
University Diagnostics at Halls Proposed)	Knox	Yes	Yes	Yes	No	Yes
University Diagnostics (CN2109-028)	Knox	No	Yes	Yes	Yes	Yes
Covenant Health Diagnostic Center	Knox	N/A*	N/A	N/A	N/A	N/A
East Tennessee Community Open MRI	Knox	Yes	No	Yes	No	Yes
East Tennessee Diagnostic Center	Knox	No	Yes	No	No	No
Outpatient Diagnostic Center of Knoxville	Knox	Yes	Yes	Yes	Yes	Yes
*This center opened after the close of the 2020 JAR reporting period, so no JAR is on file.						

➢ Project Cost

RESPONSE: The total estimated project cost is $6,011,931 not including the application fee. The largest single cost is the total cost of imaging equipment, $2,245,659. The next largest cost is the buildout/renovation cost of $2,117119.

➢ Staffing

RESPONSE: The staffing plan calls for 9.93 FTE positions. 5.1 are direct patient care positions, and 4.83 are non-patient care positions.

2E. Rationale for Approval

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

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

➢ Need

RESPONSE: There are 4 ODCs operational in the PSA (all in Knox County), and there is one certified but not yet operational ODC, which is also owned by University Diagnostics, LLC (CN2109-028) ("UD ODC #1). That ODC is located approximately 25 miles West/Southwest of the site of the proposed ODC (UD ODC #2). UD ODC #1 does not offer MRI services, whereas the proposed UD ODC #2 will have MRI services.

The applicant is owned by affiliates of the University of Tennessee Medical Center ("UTMC") (72.4%), Outpatient Imaging Affiliates ("OIA") (22.5%) and an affiliate of Associated University Radiologists

(5%). OIA is also the sole owner of the Outpatient Diagnostic Center of Knoxville ("ODC-K"), located in the downtown area of Knoxville.

A substantial number of patients who receive imaging services at UTMC's on-campus imaging center (near downtown Knoxville) and at ODC-K reside in Northern Knox County and in Anderson and Union counties. These patients would benefit from having diagnostic imaging services closer to their homes.

The ODCs in Knox County are dispersed throughout Knox County, and the Northern corridor of Knox County represents a gap in the ODC disbursement area, as reflected in the table below.

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)**
U.D. Imaging (Proposed)	7326 Maynardsville Pk.	N/A	North	11.0 miles
U.D. Imaging (CN2109-028)	1975 Town Center Blvd.	25.1 miles	Southwest	16.0 miles
Covenant Health ODC	210 Ft. Sanders W. Blvd.	21.6 miles	West	14.3 miles
E. Tenn. Community Open ODC	1415 Old Weisgarber Rd., St. 150	13.1 miles	West/Central	7.0 miles
E. Tenn. Diagnostic Center	1415 Old Weisgarber Rd., St. 120	13.1 miles	West/Central	7.0 miles
Outpatient ODC of Knoxville	800 Cresent Center Dr.	9.1 miles	Central	0.7 miles

On the other hand, the UTMC on-campus imaging center and the ODC-K are both located in central Knox County, just a few miles apart. This proposed ODC will decompress both those imaging centers, and also bring services the relatively underserved area of North Knox County.

- Quality Standards

RESPONSE: The ODC will be licensed by the Tennessee Department of Health and will be accredited by the American College of Radiology. The owners of the applicant entity are affiliates of UTMC (hospital-based imaging provider), OIA (leader in the field of freestanding outpatient imaging centers), and AUR (Radiologists). This collaborative ownership of experienced and professionals further assures all quality standards will be met and maintained.

- Consumer Advantage
  - Choice
  - Improved access/availability to health care service(s)
  - Affordability

RESPONSE: This will give patients a choice of a quality provider of imaging services in a location closer to their homes. It will also result in faster scheduling and shorter waiting times for services. Closer and faster services is a mark of increased and improved access for patients. In addition, those patients who re-locate their imaging services from the hospital-affiliated imaging centers to the new ODC will see a reduction in charges. The patients who re-locating from the ODC-K center to this proposed center will experience the same or comparable charges.

3E. Consent Calendar Justification

☐ Consent Calendar Requested (Attach rationale)

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.

X Consent Calendar **NOT** Requested

4E. PROJECT COST CHART

	PROJECT COST CHART		
A.	Construction and equipment acquired by purchase:		
	1. Architectural and Engineering Fees	$	64,134.00
	2. Legal, Administrative, Consultant Fees	$	50,000.00
	3. Acquisition of Site		
	4. Preparation of Site		
	5. Total Construction Costs	$	2,117,119.00
	6. Contingency Fund		
	7. Fixed Equipment (Not included in Construction Contract)	$	2,245,659.00
	8. Moveable Equipment (List all equipment over $50,000.00)	$	179,503.00
	9. Other (Specify) Maintance fees on imaging equipment	$	740,020
B.	Acquisition by gift donation, or lease:		
	1. Facility (Inclusive of building and land)	$	615,496.00
	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)	$	6,011,931.00
E.	CON Filing Fee	$	13,526.84
F.	Total Estimated Project Cost (D + E) **TOTAL**	$	6,025,457.84

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: The responses to the Criteria and Standards for ODCs is attached as Attachment 1N(1). The responses to the Criteria and Standards for MRIs is attached as Attachment 1N(2).

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: The primary service area (PSA) consists of Knox, Anderson, and Union Counties. These counties are expected to account for 100% of the Year 1 patients. The location of the ODC in Northern Knox County makes it extremely unlikely patients would travel there from other counties at least to any appreciable extent. The fact that other ODCs are geographically disbursed throughout most of Western Knox County makes it unlikely patients would travel past those providers to come to the proposed ODC. A map of the service area is attached as Attachment 2N.

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

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Service Area Counties	Projected Utilization- County Residents – Year 1	% of Total Patients
Knox	6,003	91.5%
Anderson	373	5.7%
Union	186	2.8%
Total	6,562	100%

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

RESPONSE: A table reflecting the selected demographic characteristics and population projections for the PSA is included below.

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).

Demographic Variable/ Geographic Area	Department of Health/Health Statistics							Bureau of the Census				TennCare	
	Total Population-Current Year (2022)	Total Population-Projected Year (2026)	Total Population-% Change	*Target Population-(18+) Current Year	*Target Population- (18+) Project Year	*Target Population-% Change	Target Population Projected Year as % 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	482,417	498,375	3.31%	379,006	391,666	3.34%	79%	N/A	$59,250	52,583	10.9%	91,763	19.0%
Anderson County	77,746	78,715	1.25%	61,923	62,904	1.58%	80%	N/A	$52,338	10,340	13.3%	19,381	24.9%
Union County	19,900	19,998	0.49%	15,828	16,059	1.46%	80%	N/A	$45,143	3,363	16.9%	6,054	30.4%
PSA Total	580,063	597,088	2.94%	456,757	470,629	3.04%	79%	N/A	$52,244	79,469	13.7%	117,198	20.2%
State of TN Total	6,997,493	7,203,404	2.94%	5,455,516	5,629,600	3.19%	78%	N/A	$54,833	951,659	13.6%	1,687,438	24.1%

* The target population is adults age 18+.
**The Census Bureau website no longer provides the median age for counties.
***The Census Bureau website does not provide the number of persons below poverty level. The totals in this column are calculated by multiplying the poverty level percentage, which is which is provided by the Census Bureau, by the total population.

** Target Population is population that project will primarily serve. For example, nursing home, home health agency, and hospice agency projects typically primarily serve the Age 65+ population. Projected Year is defined in select service-specific criteria and standards. If Projected Year is not defined, default should be four years from current year, e.g., if Current Year is 2022, then default Projected Year is 2026.*

Be sure to identify the target population, e.g. Age 65+, the current year and projected year being used.

RESPONSE: The target population is ages 18+. Although the applicant is technically "initiating" MRI because the ODC might serve 5 or more patients ages 14 and under, as a practical matter it is expected the numbers of pediatric MRI scans will be very low.

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

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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: Although the economic indicators for Union County are below the state averages, as a whole the PSA has only one notable difference from the state-wide averages. The PSA percentage TennCare enrollees (19.4%) is lower than the state average (23.6%).

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

RESPONSE: There are 4 ODCs operational in the PSA (all in Knox County), and there is one certified but not yet operational ODC, which is also owned by University Diagnostics, LLC (CN2109-028) ("UD ODC #1). That ODC is located approximately 25 miles West/Southwest of the site of the proposed ODC (UD ODC #2). UD ODC #1 does not offer MRI services, whereas the proposed UD ODC #2 will have MRI services.

The following is the utilization data for the ODCs which were operational and reported on the 2020 Joint Annual Reports, which is the most recent reporting year publicly available. Data for 2021 is from the HFC Equipment Registry and includes Covenant Health Diagnostic Center, which was converted form an HOPD to an ODC in 2021.

UTILIZATION OF OUTPATENT DIAGNOSTIC CENTERS IN THE SERVICE AREA

		2018					2019					2020					2021*					
Facility	County	Patients	Total Procedures	CT	# MRI Units	MRI	Patients	Total Procedures	CT	# MRI Units	MRI	Patients	Total Procedures	CT	# MRI Units	MRI	Patients	Total Procedures	CT	# MRI Units	MRI	Scans per Unit
East Tennessee Community Open MRI	Knox	4844	5260	0	2	3,375	6380	6789	0	2	4,126	4991	5310	0	2	3,801	N/A	N/A	0	2	4,118	2,059
East Tennessee Diagnostic Center	Knox	3463	4197	3,053	N/A	N/A	4312	5328	4,030	N/A	N/A	4561	5510	4,158	N/A	N/A	N/A	N/A	3,956	0	N/A	N/A
Outpatient Diagnostic Center of Knoxville	Knox	15,263	21,731	2,148	2	9,188	17,816	24,720	2,265	2	7,420	17,998	24,682	3,155	2	8,909	N/A	N/A	4,057	2	11,254	5,627
Covenant Health Diagnostic Center f/k/a Ft. Sanders West Diagnostic Center (HOPD)	Knox	N/A	N/A	1,220	1	769	N/A	N/A	1,268	1	762	N/A	N/A	1,095	1	576	N/A	N/A	1,141	1	486	486
2021 JARs were not avaiable as of the date of filing this application. MRI and CT utilization is from the HFC Equipment Registry.																						
Covenent Health Diagnostic Cetnerws convertedfrmn anHOPD to an ODC in 2021. Therefore, no JARs are on file for that facility																						

Utilization of all MRI units in the PSA reporting to the HFC Equipment Registry is reflected in Attachment 5N. In 2021 MRI units in the PSA average 3,281 scans per unit. This exceeds the SHP benchmark of 2,880 scans per unit. The applicant expects very few, if any, pediatric patients will be scanned, but since the threshold for "initiation of MRI" is only 5 pediatric patients s per year, authorization for pediatric patients is also sought.

UTILIZATION OF SELECTED SERVICES AT ODCs IN THE PSA

Year: 2020	State ID #	Utilization of Services											
Name of ODC		MRI (Patients)	(Procedures)	MRI Type	# MRI Units	CT (Patients)	(Procedures)	CT Type	# CT Units	Ultrasound (Patients)	(Procedures)	X-Ray (Patients)	(Procedures) *
East Tenn. Community Open MRI	47034	3628	3887	Hi Field and Open	2	N/A	N/A	N/A	0	955	1011	18	22
East Tenn. Diagnostic Center	47014	0	0	N/A	0	3159	4108	Fixed	1	N/A	N/A	0	0
Outpatient Diagnostic Center of Knoxville	47024	7030	8909	Hi Field and Open	2	2702	3155	Fixed	1	2439	2732	4289	7278
Year: 2019	**State ID #**	**Utilization of Services**											
Name of ODC		**MRI (Patients)**	**(Procedures)**	**MRI Type**	**# MRI Units**	**CT (Patients)**	**(Procedures)**	**CT Type**	**# CT Units**	**Ultrasound (Patients)**	**(Procedures)**	**X-Ray (Patients)**	**(Procedures)**
East Tenn. Community Open MRI	47034	3886	4167	Hi Field and Open	2	N/A	N/A	N/A	0	1164	1209	947	1030
East Tenn. Diagnostic Center	47014	0	0	N/A	0	3015	4031	Fixed	1	N/A	N/A	0	0
Outpatient Diagnostic Center of Knoxville	47024	7624	9895	Hi Field and Open	2	2553	3007	Fixed	1	2463	2978	3886	6222
Year: 2018	**State ID #**	**Utilization of Services**											
Name of ODC		**MRI (Patients)**	**(Procedures)**	**MRI Type**	**# MRI Units**	**CT (Patients)**	**(Procedures)**	**CT Type**	**# CT Units**	**Ultrasound (Patients)**	**(Procedures)**	**X-Ray (Patients)**	**(Procedures)**
East Tenn. Community Open MRI	47034	3120	3375	Hi Field and Open	2	N/A	N/A	N/A	0	626	661	850	976
East Tenn. Diagnostic Center	47014	0	0	N/A	0	2099	2833	Fixed	1	N/A	N/A	0	0
Outpatient Diagnostic Center of Knoxville	47024	6661	8635	Hi Field and Open	2	1774	2113	Fixed	1	1710	1947	2986	5124

Source: Joint Annual Reports

* X Ray numbers are from the field described as "Radiography (Diagnostic and Special)" on the Joint Annual Reports Master File


Proposed ODC Site
7326 Maynardville Pk
Outpatient Diagnostic Center of Knoxville
East Tenn. Comm. Open Diagnostic Center
1415 Old Weisgarber Road #150
Covenant Health Diagnostic Center
University Diagnostics, CN2109-028A
1975 Town Center Boulevard
Fort Sanders West Boulevard
Skaggston
Mascot
Eastwood
Midway
French Broad River
Kimberlin Heights
New Hopewell
Asbury
Seymour
Dupont
Wildwood
Eagleton Village
Rockford
Alcoa
Louisville
Concord
Farragut
Fountain City
North Knoxville
East Knoxville
Powell
Claxton
Clinton
Helskell
Kans

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: This is a proposed new ODC, so there is no historic data to report or analyze.

The projected utilization broken down by patients and procedures, and further classifying the procedures by imaging modality, is reflected in the table below.

	Procedure Volumes			Patient Volumes	
	Year 1	Year 2		Year 1	Year 2
CT	3,830	4,007		2,347	2,455
ULTRASOUND	1,260	1,285		772	787
XRAY	3,024	3,074		1,853	1,884
MRI	2,596	3,326		1,590	2,038
Grand Total	10,710	11,693		6,562	7,164
	Procedure Volumes			**Patient Volumes**	
	Year 1	Year 2		Year 1	Year 2
Knox	9,798	10,697		6,003	6,554
Anderson	609	665		373	408
Union	303	331		186	203
Grand Total	10,710	11,693		6,562	7,164

The projected utilization was taken from the combined volume of the UTMC HOPD Imaging Center and ODC-Knoxville, by patients residing in the PSA. Some of the volume was estimated due to different record keeping systems the two organizations. However, it is believed this is if anything a conservative estimate.

7N.

CON Number	Project Name	Date Approved	Expiration Date
CN2103-010A	The University of Tennessee Medical Center, Off-Campus Radiation Therapy Service	June 2021	August 1, 2024
CN2106-020A	The University of Tennessee Medical Center, FSED in Fentress County	August 2021	October 1, 2024
CN2109-028A	University Diagnostics, LLC	December 15, 2021	February 1, 2024

- Complete the above chart by entering information for each applicable outstanding CON by applicant or share common ownership; and
- Describe the current progress and status of each applicable outstanding CON and how the project relates to them.

RESPONSE: A brief status summary for each of the projects appears below.

CN2103-010A: Construction has not yet begun, and it is still in late design stages.

CN2106-020A: This project is in the early stages of construction. Significant price increases have caused some delays. UTMC anticipates filing a cost increase request with the Commission shortly.

CN2109-028A: Conversion of the UTMC HOPD to an ODC is underway with a targeted opening date in the 4th quarter of 2022.

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: The ODC will have a Transfer Agreement with UTMC. A copy of the transfer agreement between UTMC and University Diagnostics for a different University Diagnostics ODC is attached as Attachment 1C. A similar agreement will be in place with this University Diagnostics ODC.

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

RESPONSE:

COMMERCIAL MANAGED CARE:
Aetna Health Care
Beech Street
Blue Cross and Blue Shield of TN
Bright Health Plan
Cigna
Coventry Health
CTI
Evolutions
Galaxy
Health Smart Payer Organization
Humana
Initial Group
Multiplan
NX Health Network
Optum Transplant Network
PHCS
Preferred Health Care Ltd
Prime Health
TriWest Healthcare Alliance
United Healthcare
United Healthcare/Optum Veterans Affairs Community Plan
USA MCO

MEDICARE:
American Health Medicare Advantage Plan
Amerigroup
Blue Cross and Blue Shield of TN
Cigna HealthSpring Medicare Advantage
Humana
NHC Medicare Advantage Tennessee
Optum Medicare Transplant Network
USA Senior Care
UHC Community Health
United HealthCare Medicare Advantage & AARP Medicare Advantage
Sterling Health
WellCare Health Plans

TENNCARE:
Amerigroup Community Care
Blue Cross Blue Shield of Tennessee
Optum Transplant Network
United HealthCare Community Plan

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: This ODC is intended to primarily serve the patients of the partners/members of University Diagnostics: UTMC and OIA. Both providers' Imaging Center has a large patient base in the PSA. Many of those will choose this new ODC because it will be closer to their homes. This proposed new ODC will not significantly affect any other existing ODC.

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

RESPONSE: The proposed new ODC will be licensed by the Department of Health, certified for Medicare and TennCare, and will be accredited by the American College of Radiology. It will meet or exceed all licensing, certification, and accreditation standards, including those relating to staffing.

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: The proposed new ODC will be licensed by the Department of Health, certified for Medicare and TennCare, and accredited by the American College of Radiology. It will meet or exceed all licensing, certification, and accreditation standards, including those relating to the referenced items.

6C. See INSTRUCTIONS to assist in completing the following tables.

□ Project Only
□ Total Facility

HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available for the facility or agency.

		Year_____	Year_____	Year_____
A.	Utilization Data			
	Specify Unit of Measure _____	_____	_____	_____
B.	Revenue from Services to Patients			
	1. Inpatient Services	$_____	$_____	$_____
	2. Outpatient Services	_____	_____	_____
	3. Emergency Services	_____	_____	_____
	4. Other Operating Revenue (Specify)_____	_____	_____	_____
	Gross Operating Revenue	$_____	$_____	$_____
C.	Deductions from Gross Operating Revenue			
	1. Contractual Adjustments	$_____	$_____	$_____
	2. Provision for Charity Care	_____	_____	_____
	3. Provisions for Bad Debt	_____	_____	_____
	Total Deductions	$_____	$_____	$_____
NET OPERATING REVENUE		$_____	$_____	$_____

PROJECTED DATA CHART

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

			Year 1	Year 2
A.	Utilization Data			
	Specify Unit of Measure:	Patients	6,562	7,164
		Procedures	10,710	11,693
B.	Revenue from Services to Patients			
	1	Inpatient Services		
	2	Outpatient Services	$ 8,827,181	$ 10,165,539
	3	Emergency Services		
	4	Other Operating Revenue (Specify)_____		
		Gross Operating Revenue	**$ 8,827,181**	**$ 10,165,539**
C.	Deductions from Gross Operating Revenue			
	1	Contractual Adjustments	$ 7,104,517	$ 8,181,768
	2	Provision for Charity Care	$ 78,722	$ 90,659
	3	Provisions for Bad Debt	$ 39,000	$ 44,914
		Total Deductions	$ 7,222,239	$ 8,317,341
NET OPERATING REVENUE			$ 1,604,942	$ 1,848,298

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 -- Per Procedure

	Previous Year to Most Recent Year Year:	Most Recent Year Year:	Year One Year: 2023	Year Two Year: 2024	% Change (Year 1 to Year 2)
Gross Charge *(Gross Operating Revenue/Utilization Data)*	N/A	N/A	$824.20	$869.37	5.2%
Deduction from Revenue *(Total Deductions/Utilization Data)*	N/A	N/A	$674.35	$711.31	5.2%
Average Net Charge *(Net Operating Revenue/Utilization Data)*	N/A	N/A	$149.85	$158.07	5.2%

Project Only Chart -- Per Patient

	Previous Year to Most Recent Year Year:	Most Recent Year Year:	Year One Year: 2023	Year Two Year: 2024	% Change (Year 1 to Year 2)
Gross Charge *(Gross Operating Revenue/Utilization Data)*	N/A	N/A	$1,345.20	$1,418.98	5.2%
Deduction from Revenue *(Total Deductions/Utilization Data)*	N/A	N/A	$1,100.62	$1,160.99	5.2%
Average Net Charge *(Net Operating Revenue/Utilization Data)*	N/A	N/A	$244.58	$258.00	5.2%

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: There are hundreds of charges in the chargemaster for the ODC. A random sample of charges and Medicare reimbursement for each of the various modalities is reflected below.

CPT Code	Chargemaster	2021 Medicare	Procedure Description
70030	$163	$29.66	X-ray eye for foreign body
70100	$194	$35.26	X-ray mandible, less than 4 views
70110	$221	$40.19	X-ray exam of jaw
70140	$163	$29.69	X-ray facial bones, less than 3 vws
70150	$240	$43.65	X-ray facial bones, minimum of 3 vws
70160	$192	$34.91	X-ray nasal bones
70200	$246	$44.66	X-ray orbits
70450	$584	$106.15	CT head/brain w/o dye
70460	$820	$149.08	CT head/brain w/dye
70470	$963	$175.13	CT head/brain w/o & w/dye
70480	$874	$158.99	CT orbit/ear/fossa w/o dye
70481	$1,003	$182.39	CT orbit/ear/fossa w/dye
70482	$1,178	$214.21	CT orbit/ear/fossa w/o&w/dye
70486	$704	$127.94	CT maxillofacial w/o dye
70487	$842	$153.13	CT maxillofacial w/dye
76536	$593	$107.86	Us exam of head and neck
76604	$344	$62.53	Us exam chest
76641	$545	$99.16	Ultrasound breast complete
76642	$450	$81.86	Ultrasound breast limited
72148	$1,041	$189.36	Mri lumbar spine w/o dye
73721	$1,095	$199.06	Mri jnt of lwr extre w/o dye
72141	$1,040	$189.05	Mri neck spine w/o dye
73221	$1,095	$199.06	Mri upper ext joint w/o
70551	$1,064	$193.37	Mri brain stem w/o dye
70553	$1,735	$315.48	Mri brain stem w/o & w/dye
72146	$1,038	$188.74	Mri thoracic w/o
73718	$1,218	$221.42	Mri lower ext w/o
72158	$1,742	$316.68	Mri lumbar w & w/o
73222	$1,718	$312.29	Mri Upper ext w contrast

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: The average charge per procedure for each of the 3 ODCs in the service area are shown below. The Medicare fee schedule for selected charges on the ODC's chargemaster is reflected in the preceding table.

AVERAGE CHARGE PER PROCEDURE – ODCS IN THE SERVICE AREA –2020*	
Facility	**Average Net Charge**
East Tennessee Community Open MRI	$235.67
East Tennessee Diagnostic Center	$707.11
Diagnostic Centers of Tennessee	$221.56

*Covenant Health ODC was not operational as an ODC in 2020.

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

Applicant's Projected Payor Mix
Project Only Chart

Payor Source	Year 1		Year 2	
	Gross Operating Revenue	% of Total	Gross Operating Revenue	% of Total
Medicare/Medicare Managed Care	$3,628,854	41.11%	$4,179,053	41.11%
TennCare/Medicaid	$1,219,916	13.82%	$1,404,877	13.82%
Commercial/Other Managed Care	$3,562,650	40.36%	$4,102,812	40.36%
Self-Pay	$415,760	4.71%	$478,797	4.71%
Other (Specify)_____	$0		$0	
Total*	$8,827,181	100.00%	$10,165,539	100.00%
Charity Care	$78,722		$90,659	

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

RESPONSE: The ODC will participate in Medicare and TennCare. The anticipated payor mix for each of the first two years is shown in the table above.

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.

RESPONSE: The applicant will do so.

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?
- Does the applicant commit to obtaining and maintaining all applicable state licenses in good 3tanding?
- Does the applicant commit to obtaining and maintaining TennCare and Medicare certification(s), if participation in such programs are indicated in the application?

RESPONSE: The applicant's response to each of the questions above is "yes."

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	x Health ○ Intellectual & Developmental Disabilities ○ Mental Health & Substance Abuse Services	Will apply	N/A
Certification	x Medicare x TennCare/Medicaid ○ Other: _____	Will apply	N/A
Accreditation(s)	American College of Radiology	Will apply	N/A

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

RESPONSE: The applicant intends to contract with all of the TennCare MCOs operating in the region.

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?

X 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.

  RESPONSE: N/A; this is a proposed new ODC.

- 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.)

  RESPONSE: No.

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;
- Criminal fines in cases involving a Federal or State health care offense;
- Civil monetary penalties in cases involving a Federal or State health care offense;
- Administrative monetary penalties in cases involving a Federal or State health care offense;
- 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;
- Suspension or termination of participation in Medicare or TennCare/Medicaid programs; and/or
- Is presently subject of/to an investigation, or party in any regulatory or criminal action of which you are aware.

RESPONSE: The applicant's response to each of the above questions is "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.

RESPONSE: A staffing table is on the following page.

	Position Classification	Existing FTEs (enter year)	Projected FTEs Year 1
A.	**Direct Patient Care Positions**		
	Multi-Modality Imaging Technologists	N/A	4.1
	Clinical Manager	N/A	1
	Total Direct Patient Care Positions	N/A	5.1
B.	**Non-Patient Care Positions**		
	Business Office Specialists	N/A	3.5
	Marketer/Sales Representative	N/A	1
	Administrator	N/A	0.33
	Total Non-Patient Care Positions	N/A	4.83
	Total Employees *(A+B)*	N/A	9.93
C.	**Contractual Staff**	N/A	0
	Total Staff *(A+B+C)*	N/A	9.93

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 Agency, 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 HSDA action on the date listed in Item 1 below, indicate the number of days from the HSDA decision date to each phase of the completion forecast.

Phase	Days Required	Anticipated Date (Month/Year)
1. Initial HSDA Decision Date		September 2022
2. Building Construction Commenced	30	October 2022
3. Construction 100% Complete (Approval for Occupancy)	90	December 2022
4. Issuance of License	90	December 2022
5. Issuance of Service	90	December 2022
6. Final Project Report Form Submitted (Form HR0055)	150	February 2022

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

LIST OF ATTACHMENTS

Knoxville NEWS SENTINEL
PART OF THE USA TODAY NETWORK

UNIVERSITY HEALTH SY STEM INC.
PO BOX 32849

KNOXVILLE, TN 37930-2849

State of Wisconsin)

County of Brown)

Before me, the undersigned, a Notary Public in and for said county,this day personally came said legal clerk first duly sworn, according to law, says that he/she is a duly authorized representative of *The Knoxville News-Sentinel*, a daily newspaper published at Knoxville, in said county and state, and that the advertisement of

(The Above-Referenced)

of which the annexed is a copy, was published in said paper in the issues dated:

07/15/2022

and that the statement of account herewith is correct to the best of his/her knowledge, information, and belief

Legal Clerk

Subscribed and sworn to before me this July 20 2022

Notary Public

9.19.25

My commission expires

VICKY FELTY
Notary Public
State of Wisconsin

Publication Cost: $198.70
Ad No: 0005331300
Customer No: 1319080

# of Affidavits: 1
This is not an invoice

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 University Diagnostics, LLC, owned by University Diagnostics, LLC, a Delaware limited liability company authorized to do business in Tennessee, to be managed by Outpatient Imaging Affiliates, LLC intends to file an application for a Certificate of Need for the establishment of an Outpatient Diagnostic Center (ODC), and the initiation of MRI services to persons age 14 and younger. Imaging services to be provided are MRI (adults and peds) , CT, X-ray, and Ultrasound. The ODC will be located at 7326 Maynardville Pike, Knoxville, Knox County, Tennessee 37938. It will be licensed as an Outpatient Diagnostic Center by the Tennessee Board for Licensing Health Care Facilities. The estimated project cost is $6,025,458.

The anticipated date of filing the application is on or before August 1, 2022.

The contact person for this project is Jerry W. Taylor, Attorney, who may be reached at Thompson Burton, PLLC, One Franklin Park, 6100 Tower Circle, Suite 200, Franklin, Tennessee 37067, Telephone number (615) 716-2297.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for a hearing should be sent to:

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

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.

Attachment 3A

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF FORMATION OF "UNIVERSITY DIAGNOSTICS, LLC", FILED IN THIS OFFICE ON THE SEVENTH DAY OF SEPTEMBER, A.D. 2021, AT 4:42 O`CLOCK P.M.

Jeffrey W. Bullock, Secretary of State

6218922 8100
SR# 20213181256

Authentication: 204108762
Date: 09-08-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment 7A

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:42 PM 09/07/2021
FILED 04:42 PM 09/07/2021
SR 20213181256 - File Number 6218922

STATE OF DELAWARE
CERTIFICATE OF FORMATION
OF LIMITED LIABILITY COMPANY

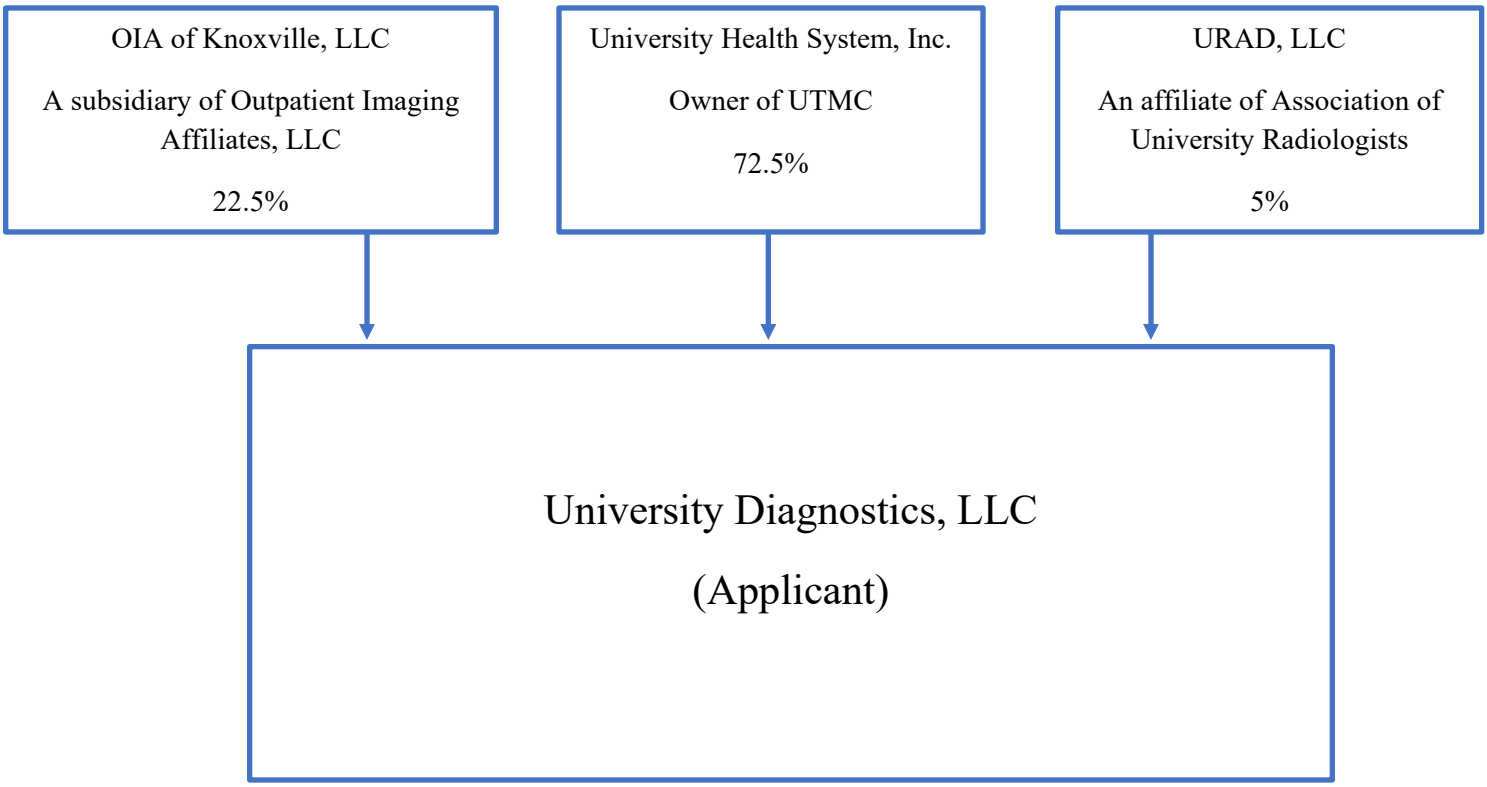
The undersigned authorized person, desiring to form a limited liability company pursuant to the Limited Liability Company Act of the State of Delaware, hereby certifies as follows:

1. The name of the limited liability company is University Diagnostics, LLC.

2. The Registered Office of the limited liability company in the State of Delaware is located at 1209 Orange Street (street), in the City of Wilmington, Zip Code 19801. The name of the Registered Agent at such address upon whom process against this limited liability company may be served is National Registered Agents, Inc.

By: Michaela D. Poizner
Authorized Person

Name: Michaela D. Poizner
Print or Type



Attachment 7A

MANAGEMENT AND BILLING AND COLLECTION SERVICES AGREEMENT

This Management and Billing and Collection Services Agreement (the "Agreement") is made effective as of _____ __, 2021, by and between University Diagnostics, LLC, a Tennessee limited liability company ("Client" or "Company"), and Outpatient Imaging Affiliates, LLC, a Tennessee limited liability company ("OIA" or "Manager").

NOW, THEREFORE, in consideration of the promises and agreements set forth below, THE PARTIES AGREE:

1. RECITALS

1.1. OIA. OIA is a limited liability company organized under the laws of the State of Tennessee, with its principal offices located at Outpatient Imaging Affiliates, LLC, 840 Crescent Centre Drive, Suite 200, Franklin, Tennessee 37067. OIA is primarily engaged in the management of outpatient diagnostic imaging facilities.

1.2. Client. Client is a limited liability company organized under the laws of the State of Tennessee.

1.3. Purpose. Client wishes to retain OIA to provide the management and billing and collection services stated herein for diagnostic imaging centers to be owned by Client from time to time (the "Centers").

1.4. Effective Date. The effective date of this Agreement ("Effective Date") shall be the first date stated above.

2. MANAGEMENT AND BILLING AND COLLECTION SERVICES. OIA shall perform the following management and billing and collection services pursuant to this Agreement, in all cases operating under the direction of Client:

2.1. Management. OIA shall have the authority and responsibility to supervise and manage the pre-opening and the day-to-day operations of the Centers according to the terms of this Agreement, including providing the services outlined on Exhibits A and B, attached hereto, and in accordance with the applicable Operating Plan and Budget (defined below) approved by Client. If OIA requires, but following exercise of its reasonable best efforts cannot obtain, Client's direction concerning a matter involving the Centers, OIA shall exercise its reasonable judgment in addressing such matter until OIA can obtain Client's direction regarding such matter.

2.2. Annual Operating Plan and Budget. As soon as reasonably practical following execution of this Agreement, and at least forty-five (45) days prior to the commencement of each fiscal year thereafter (which fiscal year shall begin [_____] unless otherwise directed by Client), OIA shall submit for Client's approval a management plan and operating budget for the Centers (each such budget being referred to herein as an "Operating Plan and Budget"). Client shall have the right to approve, modify or reject each proposed Operating Plan and Budget or amendment thereto proposed by OIA. Each Operating Plan and Budget and proposed amendment thereto proposed by OIA shall be prepared in reasonable detail, based in part on assumptions and input from Client, and shall include a schedule of projected revenues, a schedule of operating

expenses, a schedule of expected repairs and maintenance expenses, a schedule of proposed capital items, if any, to be acquired by Client, a proposed marketing plan for the period, and other matters reasonably identified by Client for inclusion in the Operating Plan and Budget or amendment thereto. Notwithstanding any other provision of this Agreement, OIA is authorized to make expenditures in accordance with each Operating Plan and Budget approved by Client. Any decision which may result in an unbudgeted expenditure of more than $50,000 shall require the approval of Client. Client may amend the Operating Plan and Budget from time to time upon reasonable notice to OIA. If the applicable Operating Plan and Budget is not approved, OIA shall follow the Operating Plan and Budget from the preceding three months until the applicable Operating Plan and Budget is approved.

2.3. No Guarantee by OIA Regarding Operating Plans and Budgets. OIA makes no guarantee, warranty or representation in connection with any Operating Plan and Budget, or schedule thereto.

2.4. Personnel.

2.4.1. Administrator: OIA shall provide an "Administrator" for the Centers who shall work on a full-time basis in Knoxville, Tennessee. The Administrator will be an employee or leased employee of OIA, and will not be an employee of the Client. Any person proposed by OIA to serve as the Administrator shall be subject to Client's prior approval, which may not be unreasonably withheld. The Administrator, acting in accordance with the then-current Operating Plan and Budget, shall be directly responsible for the day-to-day operations of the Centers. OIA shall supervise, manage and direct the Administrator to assure compliance with the then-current Operating Plan and Budget. OIA shall be responsible for paying (or arranging for the Administrator's employer to pay) the Administrator's salary and benefits, all withholding in accordance with applicable legal requirements, and all required employer contributions. The expense of the Administrator (including any severance benefits in the event of termination of employment of the Administrator) shall be reimbursed as provided in Section 3.1. In the event that Client becomes dissatisfied with the performance of the Administrator, Client shall provide OIA with written notice setting forth with specificity the alleged deficiency in the Administrator's performance. If OIA fails to cure such deficiency within thirty (30) days from the date of receipt of such notice, OIA shall, unless otherwise requested by Client, remove the Administrator from the Centers within five (5) business days thereafter. If Client notifies OIA in writing that the Administrator has taken any action that would constitute grounds for immediate termination of employment under OIA's employee handbook or, would constitute grounds for immediate termination of employment under Client's employee handbook if administrator were employed directly by Client, then OIA shall promptly remove Administrator from service at the Centers. If the Administrator leaves or is removed from the Centers for any reason, OIA shall use its commercially reasonable efforts to provide a replacement Administrator for Client's approval as soon as possible.

2.4.2. Other Center Personnel: OIA shall oversee the hiring of all non-physician personnel necessary to provide the requisite administrative and clinical services for the Centers. All Center personnel will work on site at the applicable Center, unless otherwise approved in advance by Client. All such personnel shall be employees of an affiliate of OIA or a related employee leasing company. OIA or its affiliates shall provide administrative and payroll services

for the Center personnel leased from such company. Client shall reimburse OIA or its affiliate for all wages, fringe benefits or other forms of compensation, including, without limitation, the employer's contribution of FICA, unemployment compensation and other employment taxes, worker's compensation, group life and accident and health insurance premiums and other similar benefits which may be payable with respect to such employees.

2.5. Operating Supplies. OIA shall arrange for the purchase of all necessary medical and administrative supplies and materials in the name of and for the account of Client, all subject to the then-current Operating Plan and Budget.

2.6. Maintenance and Repairs. OIA shall arrange for all purchase or lease arrangements, maintenance contracts, repairs, renovations and replacements to or for Center equipment and furnishings.

2.7. Licenses and Permits. OIA shall use commercially reasonable efforts to notify Client regarding all licenses, permits, provider numbers and regulatory approvals necessary to operate the Centers, and timely prepare and submit on Client's behalf all applications and documentation necessary for Client to obtain and maintain such licenses, permits, provider numbers and regulatory approvals.

2.8. Bank Account. OIA shall arrange for all payments from third party payors for any services provided by Client to be deposited by the applicable payor directly into an account in Client's name at a bank or other financial institution. OIA shall take all steps necessary to establish such account, to notify all applicable payors concerning such account and to take all steps necessary to provide for payor deposits directly into such account. OIA also shall arrange for all patient payments and any other payments for any services provided by Client to be deposited directly into such account. OIA will have no ownership rights in the bank account or funds in such account, and will have no right to negotiate or assert ownership rights in or to checks made payable to Client or any amount paid or payable for services furnished by Client. Client will be responsible for all bank fees associated with such bank account. OIA shall have authority to write checks on such Client account for items identified in the then-current Operating Budget or otherwise approved by Client. There shall be no commingling of OIA's funds with Client's funds.

2.9. Disbursements. OIA shall disburse and pay on behalf of Client, in such amounts and at such times as the same are required in connection with the operation of the Center, the items set forth below in accordance with the then-current Operating Plan and Budget. In making such disbursements, OIA shall at all times exercise the same care that an ordinarily prudent businessperson with experience in health care management would exercise with regard to the funds of the Client.

2.9.1. Taxes: All taxes, assessments, and impositions of every kind imposed by any governmental authority having jurisdiction, unless the payment thereof is contested by Client;

2.9.2. Center Operating Costs: All costs and expenses of operating the Centers, including without limitation:

2.9.2.1. Equipment Lease Costs: Equipment lease and debt service obligations;

2.9.2.2. Rent: Facility rent;

2.9.2.3. Loan Payments: Principal and interest payments on approved loans;

2.9.2.4. Operating Supplies: The cost of all operating supplies necessary for the operation of the Centers;

2.9.2.5. Equipment Maintenance: Center equipment maintenance and service contracts;

2.9.2.6. Advertising/Promotion Costs: The cost of advertising and promotion of the Centers;

2.9.2.7. Insurance Premiums: Premiums for insurance maintained with respect to the Centers;

2.9.2.8. Utilities: The cost of utilities, services and concessions at the Centers;

2.9.2.9. License/Permit Fees: Application fees and any other expenses associated with obtaining or maintaining numbers or regulatory approvals required in connection with the Centers;

2.9.2.10. Management and Billing Fees: Those amounts due to OIA or any affiliate as out-of-pocket expense reimbursements and the Management Fee as set forth in Section 3 hereto; provided that OIA agrees not to make any such payment if Client notifies OIA in writing that such amount is in dispute; and further provided that in such case Client shall turn over to a mutually approved escrow agent the amount in dispute, which shall be held in escrow until resolution of the dispute;

2.9.2.11. Personnel Expenses: Reimbursement for salaries, fringe benefits, payroll processing fees and costs, HR/recruitment fees, withholding costs, and other expenses of the Administrator and other personnel working on-site for the Centers pursuant to this Agreement;

2.9.2.12. Printing Costs: Third party printing costs for materials prepared for the Centers;

2.9.2.13. Membership Fees: The fees and expenses of Client's membership in any professional or trade associations; and

2.9.2.14. Other Expenses: All other expenditures which have been provided for in the then-current Operating Budget or which have been approved by Client.

2.10. Insurance. Unless Client elects other arrangements and notifies OIA to such effect, OIA shall obtain and maintain during the term of this Agreement, at Client's expense, appropriate insurance coverage for the Centers in accordance with the description of insurance coverage set

forth on Exhibit 2.10, provided that if such insurance coverage cannot be obtained at a reasonable expense, OIA and Client shall determine such other coverages as may be reasonably obtained, and shall modify Exhibit 2.10 accordingly. All such polices, except workers compensation insurance policies, shall be written or amended to include OIA, its agents, servant, employees, officers, and directors as additional name insureds.

2.11. Accounting. OIA shall perform or shall arrange for an outside accounting firm to provide all accounting functions necessary in the operation of the Centers, including management of accounts payable, payroll and preparation of income and cash flow statements and balance sheets. OIA shall supervise the performance of such outside accounting services. An outside accounting firm shall be engaged, at Clients expense, to prepare Client's tax returns. The expense of an independent auditor to conduct an annual audit shall be Client's obligation if Client elects to have such an audit performed.

2.12. Financial Reports. OIA shall deliver or cause to be delivered to Client financial statements as follows:

2.12.1. Monthly Report: On or before the thirtieth (30th) day of each month, a statement showing the results of operations of the Centers for the preceding month and year-to-date;

2.12.2. Year-End Statements: Within forty five (45) days after the end of each fiscal year of the Centers, an unaudited balance sheet and related statements of profit and loss; and

2.12.3. Other Reports: Such other monthly, quarterly and annual reports as Client reasonably requests from time to time.

2.13. Agency. In the performance of its duties pursuant to this Agreement, OIA shall act solely as the agent of Client. Except as otherwise expressly stated in this Agreement, OIA shall not be responsible for any debts or liabilities of Client to third parties. Likewise, Client shall not be liable for any debts or liabilities of OIA, except as expressly stated herein. Nothing contained in this Agreement shall be construed to create a joint venture or partnership between Client and OIA.

2.14. Quality Control. OIA shall develop, recommend and assist Client in the evaluation, implementation and supervision of all quality control aspects of the Centers and their operations designed to bring about a high standard of health care in accordance with Client's policies and resources available to the Centers.

2.15. Medical and Professional Matters OIA shall have no responsibility hereunder for the practice of medicine by any physician providing services for the Centers, or the delivery of health care services as appropriately directed by any such physician.

2.16. Coding, Billing and Collection Services. OIA is responsible for performing, or arranging for a third party to perform, all coding, billing and collection services in connection with, and based on documentation provided by, Client regarding services provided by Client, as more fully set forth on Exhibit C and D attached hereto,

2.17. Compliance Program. Client will develop and submit to Client for approval a compliance program that is intended to comply with any guidance provided by the Department of Health and Human Service Office of Inspector General and with the requirements of the Federal Sentencing Guidelines to qualify as an "effective" compliance program. Following Client's approval of the compliance program, OIA will use commercially reasonable efforts to implement and monitor the compliance program.

2.18. Insurance. OIA must maintain during the term of this Agreement the following insurance coverage on itself: management liability (errors and omissions), $1 million per incident/$3 million aggregate; general liability, $2 million per incident/$3 million aggregate; umbrella coverage, $3 million. OIA shall provide Client with evidence of such insurance coverage upon execution of this Agreement and annually thereafter (or at such other times as Client requests). OIA will ensure that the Administrator and any leased employees are covered by workers compensation insurance at the statutory limits.

2.19. Health Law Compliance.

2.19.1. No Violations: OIA hereby represents to Client that (i) neither OIA nor any of its employees who provide services hereunder or at the Centers has been convicted of a criminal offense related to health care or is excluded from participating in any federal or state procurement or health care program, and (ii) there is no pending investigation or proceeding which may result in any such conviction or exclusion with respect to any such person or entity.

2.19.2. Background Checks: Prior to engaging or providing any person to provide services hereunder or at the Centers, OIA may (at its own expense as to OIA employees, and at Client's expense as to persons performing services at the Centers) perform or arrange for a background check, in accordance with all applicable local, state and federal requirements, on such person to confirm that such person is qualified to perform the duties of his or her position, and to confirm that the person has never been convicted of a criminal offense related to health care or excluded from participating in any federal or state procurement or health care program.

2.20. Ownership of Operating Documents of Centers. All development and operating documents, including all policies and procedures, developed and/or implemented by OIA for the Centers and Client are the property of Client. Such documents shall remain the property of Client notwithstanding any termination of the Agreement.

2.21. Information Technology. Each party will work collectively to determine a mutually agreed upon RIS/PACS platform that will ensure continuity of care for Center patients and healthcare providers through the sharing of patient demographics, exam history, diagnostic images and transcribed reports throughout the enterprise. The clinical systems will also be capable of being interfaced with the OIA Management and Billing platform and Center's Electronic Health Records system. The chosen information technology platform(s) will be interoperable with Centers, OIA, Association of University Radiologists, PC and referring physicians according to commercially reasonable and industry best practices, and compliant with any regulations applicable to the Centers.

2.23. Negotiation of Contracts and Enrollment as a Medicare and Medicaid Provider. Each party shall work together to enroll the Centers as Medicare and Medicaid suppliers and to negotiate new ambulatory imaging payment contracts with third party managed care payors.

3. COMPENSATION FOR MANAGEMENT AND BILLING AND COLLECTION SERVICES

3.1. Reimbursement for Out-of-Pocket Expenses. The actual salary, bonus (if any), benefits and withholding costs paid by OIA, or actual employee leasing cost paid by OIA to a third party unrelated to OIA or to any of OIA's affiliates, whichever is applicable, for the Administrator, and any other personnel, if any, who perform services at the Centers in accordance with the terms of this Agreement will be reimbursed by Client on the same business day that such expenses are paid by OIA. With respect to other expenses incurred by OIA, within thirty (30) days of incurring such and such not being disputed by Client, OIA shall receive reimbursement for all direct out-of-pocket expenses reasonably incurred by OIA to provide the pre-opening, management, billing and collection services for the Centers in accordance with this Agreement.

3.2. Compensation for Management and Billing and Collection Services. For all services rendered by OIA pursuant to this Agreement, OIA shall receive a monthly fee (the "Management Fee") in an amount equal to the sum of (i) $25,000.00 plus $8,333.33 for each additional Center acquired or developed by the Client after the date hereof that provides MRI services and 4,166.67 for each additional Center acquired or developed by the Client after the date hereof that does not provide MRI services; plus (ii) five and 5/10 percent (5.5%) of Net Collected Revenue for the previous month; plus (iii) an incentive fee of up to two percent (2%) of Net Collected Revenue for the previous month based on performance metrics as set forth on Exhibit E ("Incentive Pay"). For the purposes of this Agreement the term "Net Collected Revenues" means for any calendar month or portion thereof that this Agreement is in effect the revenues actually collected by the Centers for diagnostic procedures, less patient refunds and adjustments as may be required by third party payors retroactively for contractual allowances and other adjustments. The Management Fee for each calendar month or portion thereof that this Agreement is in effect shall be paid to OIA within five (5) business days after the end of each calendar month.

4. OBLIGATIONS OF CLIENT

4.1. Reasonable Institutional Support. In addition to any other obligations set forth herein, Client and its owners agree to provide such assistance to OIA as may be reasonably necessary to allow OIA to fulfill its obligations under this Agreement, including responding in a timely manner to requests for information and direction from Client.

4.2. Covenant Not to Hire Administrator. Neither Client nor University Health System, Inc nor Association of University Radiologists, PC nor any of their respective Affiliates shall hire or otherwise engage the Administrator during the term of this Agreement or for two (2) years after termination of this Agreement unless otherwise agreed to by OIA.

5. CONFIDENTIALITY

5.1. Confidentiality.

5.1.1. OIA Confidential Information: The term "OIA Confidential Information" shall mean all confidential and proprietary information shared by OIA with the Client. Notwithstanding the foregoing, the term "OIA Confidential Information" does not include any information in the public domain, now or in the future, other than information in the public domain solely due to public disclosure by Client without authorization pursuant to this Agreement or other authorization by OIA. Client recognizes and acknowledges that Client's public dissemination, release or use of any OIA Confidential Information other than pursuant to this Agreement could be injurious to the business and operations of OIA. Therefore Client explicitly agrees to maintain the confidentiality of the OIA Confidential Information. Client also agrees not to use, appropriate or disseminate any OIA Confidential Information for its own benefit or the benefit of others, except as permitted under this Agreement. OIA hereby authorizes Client to use any OIA Confidential Information in connection with the operation of the Center, and authorizes Client to disclose any OIA Confidential Information as required by applicable law or as Client reasonably deems necessary to respond to any request or order by a court or regulatory entity. OIA acknowledges that Client is not responsible for any disclosure of OIA Confidential Information by: (i) the Administrator and any personnel provided or engaged by OIA to work at the Centers (the Administrator and such personnel are referred to as the "Center Personnel"); or (ii) any other personnel not employed by Client.

5.1.2. Client Confidential Information: OIA acknowledges that all documents, materials and information concerning the development or operation of the Centers, including policies and procedures developed by OIA for Client but not including any OIA Confidential Information, constitute Client's confidential information (the "Client Confidential Information"). Notwithstanding the foregoing, the term "Client Confidential Information" does not include any information in the public domain, now or in the future, other than information in the public domain solely due to disclosure by OIA or any Center Personnel without authorization pursuant to this Agreement or other authorization by Client. OIA recognizes and acknowledges that OIA's or any Center Personnel's public dissemination, release or use of any Client Confidential Information other than pursuant to this Agreement could be injurious to the business and operations of Client. Therefore OIA explicitly agrees to maintain, and arrange for all the Center Personnel to maintain, the confidentiality of the Client Confidential Information. OIA also agrees not to use, appropriate or disseminate any Client Confidential Information for its own benefit or the benefit of others, except as permitted under this Agreement. OIA shall take commercially reasonable efforts to arrange for each person provided by it pursuant to this Agreement to execute a confidentiality agreement binding such person to confidentiality restrictions in such form and in such manner as may be required by Client. Client hereby authorizes OIA and the Center Personnel to use any Client Confidential Information in connection with the operation of the Center, and authorizes OIA and the Center Personnel to disclose any Client Confidential Information as required by applicable law or as OIA reasonably deems necessary to respond to any request or order by a court or regulatory entity.

5.1.3. Injunctive Relief: The parties acknowledge that the obligations contained in this Section 5 are an essential element of this Agreement, without which this Agreement would

not exist, and that any breach of this Section 5 may cause irreparable harm to the non-breaching party. For those reasons the parties agree that any breach of this Section 5 will entitle the non-breaching party to seek injunctive relief, along with any other remedies available to such non-breaching party at law or in equity.

5.1.4. Survival of Obligations: The obligations in this Section 5 will survive termination or expiration of this Agreement for any reason, including expiration.

6. DEFAULT; REMEDIES

6.1. Default by Client. It shall constitute an event of default under this Agreement (an "Event of Default") by Client if Client:

6.1.1. Unpaid Fee or Failure to Reimburse Expenses: Fails to authorize or permit payment of any fee owed to OIA pursuant to this Agreement or any expense incurred by OIA for which Client is required to reimburse OIA hereunder within ten (10) business days following the date such payment is due pursuant to Section 3.1 or 3.2; or

6.1.2. Breach: Fails to perform any other material obligation under this Agreement, unless such failure to perform is due to any act or omission by OIA.

6.2. Client's Right to Cure; OIA's Remedies. With respect to an Event of Default under Section 6.1.2, Client shall have sixty (60) days (five (5) days in the case of a payment default) from the receipt of written notice of an Event of Default from OIA to remedy such Event of Default. Such notice shall state with particularity the Event of Default, and the action(s) required by Client to cure such Event of Default. If Client fails to cure such Event of Default by the close of such sixty (60) day (five (5) day in the case of a payment default) period, OIA may terminate this Agreement on notice to Client and exercise any remedies available to OIA at law or in equity. Further, any amounts due and owing to OIA by Client pursuant to this Agreement shall bear interest at the lesser of ten percent (10%) or the highest rate of interest permitted by law.

6.3. Default by OIA. It shall constitute an Event of Default by OIA under this Agreement if:

6.3.1. Fraud: OIA commits fraud, misappropriation, embezzlement, or the like, of Client's assets or property ("Monetary Fraud");

6.3.2. Gross Negligence: OIA commits or engages in gross negligence, willful misconduct or any intentional breach of its contractual duty to Client pursuant to this Agreement; or

6.3.3. Breach: OIA fails to perform any other material obligation under this Agreement, unless such failure to perform is due to any act or omission by Client, provided, however, that any such Monetary Fraud, gross negligence, willful misconduct or intentional breach by the Administrator or any third party engaged by OIA shall not constitute an Event of Default by OIA if OIA, upon discovery of such action, promptly and permanently terminates such Administrator or third party's work at the Centers.

6.4. OIA's Right to Cure; Client's Remedies. In the event Client determines that an Event of Default has occurred, Client shall provide OIA written notice of the event or events constituting default, and shall specify with reasonable particularity such actions as would be required to remedy such default. OIA shall then have sixty (60) days from the receipt of written notice of an Event of Default from Client to remedy such Event of Default. If the Event of Default may not reasonably be remedied within such Cure Period, OIA will submit to Client, within sixty (60) days from the receipt of written notice from Client of an Event of Default, a written plan describing the manner and the time period in which OIA will remedy the Event of Default (the "Cure Plan"). Client may terminate this Agreement upon written notice to OIA and exercise any remedies available to Client under this Agreement, if OIA fails to cure an Event of Default within the Cure Period. If the Event of Default may not reasonably be remedied within the Cure Period, Client may terminate this Agreement upon written notice to OIA and exercise any remedies available to Client under this Agreement, if OIA fails to: (i) submit a Cure Plan to Client within sixty (60) days from the receipt of written notice from Client of an Event of Default; or (ii) fails to cure the Event of Default within the time period allowed for such in the Cure Plan.

6.5. Limitation of Liability. In the event of error or omission in the performance of the services rendered by OIA hereunder due solely to the actions or failure to act of OIA, OIA will re-perform the services at no additional cost to Client. Notwithstanding the foregoing, it is expressly understood and agreed that (1) OIA shall have no liability for the (a) inability of third parties or systems beyond the control of OIA to accurately process data, or (b) transmission to OIA of inaccurate, incomplete or duplicate data provided by third parties; and (2) OIA's liability cap for any negligent or intentional acts shall be equal to the amount of liability coverage required in the Section of this Agreement entitled "Insurance." Neither party shall in any event be liable to the other for any indirect, special, or consequential losses or damages suffered by such party or any third party.

6.6. Other Termination Rights.

6.6.1. Bankruptcy: Either party may terminate this Agreement upon written notice to the other party if the other party applies for or consents to the appointment of a receiver, trustee or liquidator or all or a substantial portion of its assets, files a voluntary petition in bankruptcy or is the subject of an involuntary bankruptcy filing, makes a general assignment for the benefit of creditors, or files a petition or an answer seeking reorganization or arrangement with creditors or to take advantage of any insolvency law, or if an order, judgment or decree shall be entered by any court of competent jurisdiction, on the application of a creditor, adjudicating the other party bankrupt or insolvent or approving a petition seeking reorganization of such other party or appointing a receiver, trustee or liquidator for such other party of all or a substantial portion of its assets, and such order, judgment or decree shall continue unstayed and in effect for any period of sixty (60) consecutive days.

6.6.2. Violation of Health Care Law: Notwithstanding any other provision of this Agreement, either party may terminate this Agreement immediately on notice to the other party if the other party is (i) convicted of violating any law or regulation concerning the provision of health care services, or (ii) excluded from participating in any federal or state procurement or health care program.

6.6.3. Change in Law: Either party may provide written notice to the other party if counsel for such party reasonably determines that continuation of this Agreement may subject such party to sanctions under applicable legal requirements or may jeopardize such party's participation in or material payments under Medicare, Medicaid, any successor to either such program, or any other governmental payor arrangement or may subject the party to sanctions or penalties under the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b), the Federal Physician Self-Referral (Stark) Law (42 U.S.C. § 1395nn), the Federal Civil Monetary Penalties Law (42 § 1320a-7a) or any similar state health regulatory compliance law. The parties agree to use reasonable best efforts and negotiate in good faith following such notice to determine whether they can reach mutual agreement concerning how to modify this Agreement to comply with applicable legal requirements. To the maximum extent possible, any such amendment shall preserve the underlying economic and financial arrangement between the parties. In the event the parties are unable to reach agreement as to the terms of the amendment within sixty (60) days following the date of written notice, then either party may terminate this Agreement. No party shall assert illegality as a defense to enforcement of this Agreement or any provision hereof.

6.6.4. Failure to Enroll in Medicare or Medicaid or Secure Sufficient Third Party Payor Contracts: In the event that (i) the Centers are not enrolled as providers under the Medicare and Medicaid programs and a reasonable number of third party payor contracts within six (6) month after opening, in each case, despite the exercise of commercially reasonable efforts by both OIA and the Client, and (ii) the Client elects to permanently close and cease to conduct operations of the Centers, then the Client may terminate this Agreement by providing OIA with at least twenty (20) business days advance notice.

6.7. Effect of Termination. Termination of this Agreement for any reason will not relieve either party of any obligation which arose under this Agreement prior to such termination, or any obligation expressly stated herein as surviving termination of this Agreement and shall not adversely effect, directly or indirectly, any rights or obligations of the parties set forth on the operating agreement of the Client.

6.8. Termination Procedures for Billing and Collection Services. In the event of termination of this Agreement for any reason, Client shall choose one of the following two (2) options as a means of transferring its accounts receivable from OIA to another provider of coding, billing and collection services. Client shall notify OIA in writing as to which option it has chosen:

(a) Upon the effective date of termination, OIA shall cease to enter new patient and charge data into its computer system on behalf of Client, but will (a) continue to perform the coding, billing and collection services hereunder for a period of ninety (90) days after termination with respect to all of Client's accounts receivable relating to Client's charges for clinical procedures rendered prior to the termination date, and Client shall continue to pay OIA for such services in accordance with Section 3 during such ninety (90) day period, (b) thereafter discontinue processing Client's existing accounts receivable, (c) deliver to Client, after full payment of all fees owed, a final list of accounts receivable, (d) provide transitional services as mutually agreed, and (e) have no further obligations to Client thereafter with respect to the provision of services in this Agreement; or

(b) On or before the effective date of termination, Client shall pay OIA the "Services Rendered Fee" as defined below. Upon payment of the Services Rendered Fee, OIA shall (a) be immediately relieved of the obligation to provide any further services on behalf of Client with respect to the provision of services set forth in this Agreement, (b) deliver to Client, after full payment of all fees owed, a final list of accounts receivable, (c) provide transitional services as mutually agreed, and (d) have no further obligations to Client with respect to the provision of services set forth in this Agreement. Client may negotiate with OIA for additional transitional services to be provided by OIA to Client after the date of termination at Client's additional expense. The parties understand and acknowledge that the Services Rendered Fee is in addition to any other legal or equitable remedy OIA may have against Client, if any, and in no way is intended to limit the rights and remedies OIA may have against Client arising out of any breach of this Agreement. The "Services Rendered Fee" shall be equal to the percentage set forth in Section 3.2 for determining the monthly Management Fee, multiplied by the aggregate outstanding accounts receivable incurred in the past 180 days (not including accounts receivable held with or transferred to early-out agencies, collection agencies or any other third party billing/collection organization) as of the effective date of termination, multiplied by the historical gross collection percentage (gross collections divided by gross charges) for the six (6) months immediately preceding the effective date of termination and meet industry standards of being commercially reasonable

7. TERM OF THE AGREEMENT

7.1. Term. Subject to the conditions precedent set forth below, the term of the Agreement will continue for so long as OIA or any of its Affiliates (including Diagnostic Health Centers of Tennessee, LLC) continues to own a membership interest in the Client, subject to any express rights of early termination as set forth elsewhere in this Agreement.

7.2. Payment of Fees; Delivery of Property.

7.2.1. Payment of Fees: Subject to Section 6.8, upon the termination of this Agreement for any reason, all undisputed amounts due OIA hereunder as of the date of termination (minus any undisputed amounts owed by OIA to Client) shall be paid to OIA by Client within thirty (30) calendar days after the date of termination.

7.2.2. Delivery of Property: Upon termination of this Agreement for any reason, each party hereto shall promptly deliver to the other party all of the other party's property in such party's possession. Each party shall cooperate with the other party to effect the termination and transition to another management company if one is appointed. Upon termination, OIA shall deliver to Client all funds, without any set offs, hold backs, or deductions, controlled by or in the possession of OIA as agent for Client.

8. MISCELLANEOUS

8.1. Indemnification. Except as otherwise provided herein, each party shall indemnify the other party, and hold it harmless from any and all liability, including reasonable attorney's fees and costs, caused by or resulting from any gross negligence or willful misconduct of the indemnifying party, that party's officer, director, agent, employee, leased employee, or any Center

Personnel employed or otherwise engaged by such party to provide services in conjunction with the Centers. In addition, OIA shall indemnify and hold harmless Client, its officers, directors, agents and employees, from and against all liability, claims, damages, suits, demands, expenses and costs, of every kind arising out of OIA's execution of this Agreement, specially to include any breach of any applicable restrictive covenant or exclusivity provision applicable to OIA.

8.2. Disclaimer of Employment of Medical Employees. No person employed by Client as a physician shall be or be deemed to be an employee of OIA, and OIA shall have no liability for payment of any wages, payroll taxes and other expenses of employment for any such person employed by Client, except that OIA shall have the obligation to exercise reasonable care in the management of the Centers and to apply available Client funds to the payment of such wages, benefits, and payroll taxes in accordance with this Agreement.

8.3. Non-Assumption of Liabilities. OIA shall not, solely by virtue of entering into and performing this Agreement, become liable for any of the existing or future obligations, liabilities or debts of Client. Client shall not, solely by virtue of entering into and performing this Agreement, become liable for any of the existing or future obligations, liabilities or debts of OIA.

8.4. Access to, Maintenance and Confidentiality of Records.

8.4.1. Access to Records; Confidentiality: OIA shall, during the term hereof be given complete access to the Centers' records, offices and facilities as necessary for OIA to carry out its obligations hereunder, subject to all applicable legal requirements and Client's policies concerning the confidentiality of patient information and medical records. OIA shall maintain the confidentiality of all files and records, including patient records, of Client, disclosing the same only as required by law, or in accordance with Client's policies in circumstances when disclosure is permitted by law.

8.4.2. Records to be Maintained: Client will maintain all records related to the Centers for at least: (i) the maximum applicable statute of limitations period; (ii) the period of time as is otherwise required by state or federal law with respect to the retention of medical records; (iii) six (6) years after the last date of services rendered; and (iv) five (5) years from termination of this Agreement. If records are under review or audit by any third party payor or governmental agency, Client shall maintain such records until the review or audit is complete. Said records shall be made available and furnished immediately upon request for fiscal audit, medical audit, medical review, utilization review, and other periodic monitoring upon request of authorized representative of authorized federal or state personnel.

8.5. HIPAA Compliance. The parties acknowledge that the relationship between them will involve the transmission and sharing of information that is or may become subject to the provisions of HIPAA. Accordingly, the parties adopt and incorporate by reference herein the provisions of the "Business Associate Addendum" attached hereto as Exhibit 9.5.

8.6. Assignment; Permitted Assignment. Neither party may assign or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the other party, and any attempt to assign or otherwise transfer any rights or obligations hereunder in

violation of this Section is void; provided, however, that OIA may assign this Agreement to an entity that purchases all or substantially all of the assets of OIA.

8.7. Rights Cumulative; No Waiver. No right or remedy herein conferred upon or reserved to either of the parties hereto is intended to be exclusive of any other right or remedy, and each and every right and remedy shall be cumulative and in addition to any other right or remedy given hereunder, or now or hereafter legally existing upon the occurrence of an Event of Default hereunder. Every right and remedy given by this Agreement to the parties hereto may be exercised from time to time and as often as may be deemed expedient by the parties, as the case may be.

8.8. Headings. The section and paragraph captions and headings contained in this Agreement are included for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

8.9. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original document and all of which, taken together, shall be deemed to constitute but a single original document.

8.10. Notices. All notices, offers, requests, demands, and other communications pursuant to this Agreement shall be given in writing by personal delivery, by prepaid first class registered or certified mail properly addressed with appropriate postage paid thereon, or by nationally recognized overnight express courier service for next business day delivery. Any such notice, offers, requests, demand, or other communications shall be deemed to be duly given and received on the date of delivery or the next business day following sender's delivery to a nationally recognized overnight express courier service, or five (5) business days following the mailing of notice by registered or certified mail. Notices shall be sent to the parties at the following addresses or at such other address as any party may have furnished to the other in writing in accordance herewith, except that notices of change of address shall only be effective upon receipt.

Address for Notices:	Address for Notices:
Outpatient Imaging Affiliates, LLC	_____
Attn: Chief Executive Officer	_____
800 Crescent Centre Drive, Suite 400	_____
Franklin, TN 37067	_____

8.11. Entire Agreement. This Agreement, including the exhibits attached hereto, contains the entire understanding of the parties with respect to its subject matter. This Agreement merges and supersedes all prior agreements and understandings between the parties, written or oral, with respect to its subject matter, and there are no restrictions, agreements, promises, warranties, covenants or undertakings between the parties with respect to the subject matter hereof other than those expressly set forth herein.

8.12. Severability. In the event that any provision of this Agreement, or the application thereof to any person or circumstance is held by a court of competent jurisdiction to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement, or the application of the invalid, illegal or

unenforceable provision to any other person or circumstance, and this Agreement shall then be construed as if such invalid, illegal or unenforceable provision had not been contained in this Agreement, but only to the extent of such invalidity, illegality or unenforceability.

8.13. Amendment. This Agreement may be amended by mutual written consent of duly authorized representatives of the parties.

8.14. Force Majeure. Neither party shall be liable for any failure or delay in performing its obligations under this Agreement due in whole or in material part to any cause beyond its reasonable control, including but not limited to fire, accident, labor dispute or unrest, flood, riot, war, rebellion, insurrection, sabotage, terrorism, transportation delays, shortage of raw materials, energy or machinery, acts of God or of the civil or military authorities of a state or nation, or the inability, due to the aforementioned causes, to obtain necessary labor or facilities.

8.15. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Tennessee, without regard to the State's cases and statutes concerning conflict of laws. Exclusive venue for any legal proceeding in respect of or arising out of this Agreement shall lie in any court of competent jurisdiction sitting in Knoxville, Tennessee.

8.16. Arbitration. In the event the parties to this Agreement disagree on the interpretation, construction, performance or enforcement of this Agreement ("Dispute"), the parties hereby agree, to the extent permitted by law, to resolve the Dispute by binding arbitration in accordance with the following procedures. First, any party with a Dispute may demand in writing that the Dispute be submitted to arbitration. A period of twenty (20) business days shall pass from the date of the demand during which the parties shall exercise good faith to reach a common understanding and resolution of the Dispute. In the event that the parties shall not be able to resolve the Dispute within the twenty (20) business day period, the Dispute shall be referred to binding arbitration in Knoxville, Tennessee, before a single arbitrator agreeable to both parties under the then-existing rules of the American Arbitration Association. Judgment on the arbitration award may be entered in any court of competent jurisdiction. The prevailing party shall have the costs of the arbitrator and its reasonable attorney's fees paid by the losing party. In the event that the arbitrator determines that neither party has substantially prevailed in its claim, each party shall share the costs of the arbitrator equally and shall pay their own attorney's fees.

8.17. Affiliate. The term "affiliate" as used in this Agreement with respect to any person or entity shall mean, any other person or entity that controls, is controlled by, or is under common control with such first person or entity. For purposes of the foregoing, "control" means the power to direct or cause the direction of the management and policies of an entity, directly or indirectly, whether through ownership of voting securities, by contract, as trustee or executor, or otherwise.

IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized representatives as of the day and year first above written.

OUTPATIENT IMAGING AFFILIATES, LLC	UNIVERSITY DIAGNOSTICS, LLC
By:_____	By:_____
Title:_____	Title:_____
Print Name:_____	Print Name:_____

EXHIBIT 2.11

INSURANCE COVERAGE

OIA shall obtain and maintain during the term of this Agreement, at Client's expense, appropriate insurance coverage for the Centers, including Property, General Liability and Professional Liability. Workers compensation insurance, in addition to the coverage provided by the Client's Professional Employment Organization ("PEO"), shall be obtained to cover any independent or subcontractors not covered by the PEO. D&O coverage will be applied for and purchased if available, and can be provided at a reasonable cost. In the event that any of the insurance coverage cannot be obtained at a reasonable expense, OIA and Client shall determine such other coverages as may be reasonably obtained, and shall modify this Exhibit 3.11 accordingly. All such policies, except workers compensation insurance policies shall be written or amended, at OIA's expense (if any), to include OIA, its agents, servants, employees, officers, and directors as additional insureds.

Coverage

Property	- All medical equipment, furniture & fixtures, IT & other equipment, building and tenant improvements
	Includes Business income.
Liability	- Includes general and professional coverage of $1.0 million per occurrence / $3.0 million aggregate.
W/C	- Statute coverage

Exhibit A

Pre-Opening Services

OIA will provide Centers with certain planning, financial projection, equipment, real estate, project financing, payer contracting assistance, billing and collections, physician education and other services reasonably necessary in anticipation of opening of the Centers. Such services may include, for example, the following:

- **Project Assessment and Definition** – OIA will perform any market analysis required, including demographic, competitive, payor, legislative analysis, and physician interviews – all of which help to define the scope and need for services. All are funneled into a business plan detailing the opportunity under consideration. Centers may be asked to aid in OIA's research if its assistance would prove to be beneficial.
- **Preparation of Financial Forecasts** – OIA will prepare pro forma financial statements (using commercially reasonable efforts with regard to assumptions therein) prior to the opening of the Centers and in connection with the financing needs.
- **Equipment Selection** – OIA, along with Centers, will evaluate vendors and select the appropriate imaging equipment, with ultimate approval by Client's CEO. Additionally, where required, OIA will manage the negotiation of any purchase or finance terms including price, term, associated discounts, and maintenance agreements, all subject to Centers' approval.
- **Information Systems** – OIA will assist with the selection, procurement and integration of all information systems, including RIS, PACS, transcription, workstations and network connectivity, to support the parties' mutually agreed to information systems and technology plan.
- **Staffing** – OIA will oversee the hiring of technologists and administrative personnel necessary to staff the Centers, all subject to Client's approval. OIA and Client will mutually agree to the employment platform of the staff in the Agreement.
- **Space** - Where necessary, OIA will locate a suitable physical location for the Centers.
- **Financing** – OIA will assist Client in securing leasehold and equipment financing of the Centers, all subject to Client's approval.
- **Project Planning and Development** - Once the type of services to be included are approved, OIA will assist in the development of an appropriate architectural design for the Centers (subject to Client's approval, not to be unreasonably withheld) and assist in overseeing construction and the interior design including furnishings, office equipment, and all supplies for the Centers.
- **Regulations** – OIA will assist Client to obtain all necessary certificates, licenses and permits from regulatory agencies necessary to develop, open and operate the Centers.
- **Managed Care Contracting** –OIA will secure provider numbers from governmental payors and their agents, as well as commercial payors, on behalf of and in the name of the Centers, as necessary to develop, open and operate the Centers.
- **Pre-Opening Physician Education** – OIA will oversee the implementation of a pre-opening referring physician education plan, including the development of physician education materials, face to face education to physicians, press releases, and market awareness campaigns.

- **Pre-Opening Operating Protocols** – OIA will ensure the technical, and administrative staff is properly trained and ready for service to commence.
- **Other Items** – OIA and Client may mutually agree from time to time with respect to other pre-opening services in connection with the Center.

Exhibit B

Management Services

Working under the direction of the Client, OIA's principal responsibility will be to manage, supervise and direct all aspects of the Centers on a day-to-day basis.

1. **Management Plan and Budget** - The roadmap for Center operations is an annual management plan and corresponding budget that is presented to and approved by Client. OIA will take responsibility for directing the effort to develop these documents on an annual basis. Areas addressed will be projected exam volume by modality, expected billings, contractual adjustments and collections per procedure, detailed physician education plan, capital expenditure needs, staffing requirements, a detailed categorization of Center expenses for each year and any other information deemed reasonably necessary.

2. **Physician Education** - Central to the Centers' success is a dedicated, sustained effort to educate referring physicians on the services provided by Centers and the benefits of using Centers. OIA will take responsibility for recruiting and training staff and implementing a detailed physician education plan for this purpose. This will also entail working closely with the radiologists covering the Centers as their involvement is fundamental to delivering services promised by the Centers to the referral base.

Fundamentals of this program include:

- Actively making known the Centers' services through the development of personal relationships with the referring physician and their office staff and through the implementation of a pre-determined promotional and advertising plan.
- Monitoring actual services performed against original expectations and promptly handling any service deficiencies or shortfalls.
- Representing the Centers at all medical symposiums, trade shows and relevant community functions.
- Serving as a communications liaison with the referral community and the Centers' staff with respect to opportunities to improve customer service.
- Conducting regularly scheduled staff in-service programs to elevate the staff's patient satisfaction skills and sensitivities.
- Develop and constantly update the Centers' promotional, patient information and procedure ordering materials; make sure, at all times, referring physician offices are well-stocked with this information.
- Monitoring physician office referral patterns to be on the alert for new physician inquiries or adverse referral trends that will lead to positive reinforcement measures or corrective action steps.

3. **Financial Statements -** On a monthly basis, OIA will prepare and distribute financial statements and accompanying operational reports that will summarize actual performance for "key result" areas against budgeted expectations. OIA will assume responsibility for

the accounts payable function at its corporate office and will coordinate with outside accountants the annual preparation of financial statements and tax returns to the extent required to be filed by the Centers individually. Expected due dates for monthly and annual financial statements will be mutually agreed upon and stipulated in the Agreement.

4. **Center Staffing** – Subject to the parties' ultimate determination of staffing for the Centers, OIA will oversee the recruitment, hiring, training and supervising all Center technical, physician education and administrative staff. Included in this area is responsibility for payroll administration, employee benefit issues, and development and implementation of an annual incentive program for all staff.

5. **Operations Policies and Procedures**- OIA will work with Client's staff to develop and implement operations and compliance policies and procedures regarding every Center "key result" area. These will include patient scheduling, reception and average wait time parameters, report transcription and turnaround, monitoring of referring physician and patient satisfaction, quality assurance, oversight of billing and collections activities, and internal and external information management processes.

6. **Information Systems** - Working in concert with Client's information technology associates, and in accordance with the mutually agreed plan developed by the parties, OIA will coordinate the installation and networking (as required) of radiology information management, billing, digital archiving, tele-radiology, transcription and related systems to assure a smooth and efficient flow of information both within the Centers and to and from relevant third parties.

7. **Quality Assurance** - OIA will assume responsibility for the development, implementation, and perpetual monitoring of all Center quality assurance, credentialing, accreditation, and licensing requirements. These programs will be managed in concert with federal and state requirements related to these types of outpatient services, and in coordination with Center policies and procedures.

8. **Equipment and facility management** - Working with Client staff, OIA will take overall responsibility for negotiating all future equipment procurement, service contracts and any modifications or renovations to the Centers' facilities. OIA will perform a feasibility and breakeven analysis for any equipment replacement or upgrades and negotiate the associated financing of all capital expenditures, both at the outset and on an ongoing basis.

9. **Communications** – OIA will provide regular written and verbal communications to Client as to the Centers' mission, annual goals and progress against these goals as such communication is fundamental to the management process.

Exhibit C

Billing and Collection Services

OIA shall perform all coding, billing and collection services for the Centers, subject to ongoing approval and direction from Client. Such services may include, for example, the following:

1. Entry of appropriate fee schedule into OIA's billing system prior to the Billing Start Date. OIA will continue to update such fee schedule on OIA's billing system as such fee schedule may be revised from time to time
2. Enter all necessary demographic information and coding information onto the OIA billing system.
3. Handle accounts in accordance with standard accounting principles and applicable laws.
4. Bill each payor account and patient covered by such payor in accordance with the terms of the agreement with such payor. For accounts for which no payor agreement exists, OIA will bill in accordance with applicable legal requirements and community standards.
5. Receive copies of the patient charts, check for completeness, and maintain a daily log of charts received.
6. Conduct electronic transfer of demographic data to or from other providers, where available (may require physician involvement).
7. Code each patient chart, including ICD-10 and CPT coding, and enter demographic information and coding information onto the OIA billing system.
8. Conduct electronic filing with Medicare, Medicaid and all other third-party payors whenever reasonably possible.
9. Conduct electronic remittance from Medicare and all other payors whenever possible.
10. Mail patient/payor statements, notices and pre-collection letters.
11. Provide and man a toll-free "800" phone number to answer phone inquiries concerning patient account information.
12. Respond to inquiries received from patients and/or third-party payors.
13. Receive all payment and reimbursement notices from bank and post payments to the appropriate patient account.
14. Post all contract discounts and adjustments that are required by law or previously authorized.
15. Provide fee schedule consultation, evaluation and development.
16. Provide payor contract review via a written synopsis, historical review, and subsequent conversations with onsite associates.
17. Provide third-party payor credentialing for all necessary provider numbers.
18. Provide customized billing statements in Center's name.
19. File primary, secondary and tertiary insurance for patients and resubmit rejections and no action accounts.
20. Back-up data billing system every night and store back-up tapes off-site to ensure data redundancy.
21. Provide monthly, quarterly, annual and special management reporting as directed by Center, to include, for example:

- Monthly/yearly financial comparative trends by payor and procedure
- Charge and payment analysis total and by payor

- Location productivity profile and summary
- Aging payment report
- General accounts receivable summary
- Physician documentation feedback (if applicable)

22. Regularly provide current information concerning governmental regulations, third-party payor activities, competition, economic changes and other outside influences.
23. Follow up on delinquent insurance accounts.
24. Provide annual charge review and analysis/projections.
25. Provide annual impact analysis of Medicare reductions and/or participation evaluation and recommendation.
26. Maintain computer system with system generated operational reports.
27. Provide physician enrollment (and re-enrollment) for third-party payor contracts and healthcare facilities (i.e. hospitals and surgery centers).
28. If it is desired for OIA to forward its unpaid billings to a collection agency, OIA will transmit the information required by the collection agency either by hard copy or electronically, in a mutually acceptable format, as requested by such collection agency, pursuant to instructions provided to OIA.
29. Notify Centers of all refund amounts owed for the previous month. Prepare refund checks for individual patients and payors for signature and release.
30. OIA to follow/apply Center bad debt collection agency referral process.

EXHIBIT D

CODING, BILLING, COLLECTION AND RELATED SERVICES

OIA will commence coding, billing and collection services for Client with respect to the Centers upon commencement of operation of any such Center (the "Billing Start Date"). OIA shall recommend, implement, and monitor such operating policies and procedures as may be necessary from time to time in relation to coding, billing, collections, and related services. Subject to timely receipt of necessary data and information from Client, OIA shall perform all coding, billing and collection services needed for operation of the Center(s) and to facilitate timely submission and collection of all claims.

The parties acknowledge that OIA must have access to certain information, including the following, in order to perform coding, billing and collection services for Client and Client agrees to make such information available in a timely manner:

(1) patient's demographic face sheet (including name, sex, date of birth, and status as single, married, or other);
(2) responsible party's name, address, telephone number, employer;
(3) insured's name (if different from patient), sex, date of birth, address, relationship to patient, insured's employer (if group policy), insured's employer's address;
(4) name of insurance company, address, policy certificate number, group policy number;
(5) copy of radiology report;
(6) copy of release of information and insurance assignment of benefits;
(7) HMO/PPO authorization numbers approvals (if applicable) (referral hard copy, if applicable);
(8) copy of amount paid at time of service receipt (if applicable);
(9) date of service, chief complaint, medical history and exam, treatment, diagnosis, and physicians' notes;
(10) name of performing physician;
(11) name of referring physician; and
(12) a copy of the charge documents completed by Client for each patient for whom OIA is to provide coding, billing and collection services, which documents shall include CPT-4 codes and modifier(s) with appropriate ICD-9 codes assigned by Client.

Client shall (1) work with OIA to establish electronic transmission of patients' demographic, financial and charge information; (2) provide access to one or more members of Client's staff to respond in a timely manner to OIA' s claim inquiries requesting additional required information or special handling authorization; (3) notify OIA of patients who qualify for free or reduced charge services due to financial hardship; (4) provide names and summary information (including copies of required documents) of new physicians for initiation of payor enrollment by OIA and provide one or more members of the Client's staff to coordinate the timely return of completed and signed physician enrollment applications and electronic claim submission authorization forms for all physicians; (5) send copies of workers' compensation notification of compensable injury forms; (6) provide OIA with Client's fee schedule for entry onto OIA's system

prior to the start date of this Agreement; (7) transmit or cause to be transmitted to OIA only accurate external date/time data, in accordance with the requirements, procedures, data element standards, formats, codes, protocols and edits set forth by OIA; (8) provide OIA with an electronic file, if available, of Client's referring physicians, including unique identifying codes (UPIN), and license numbers as of the effective date of this Agreement. Provide OIA with electronic updates, if available, to this file, containing similar required data, on a minimum monthly basis; and (9) provide OIA with copies of contracted agreements with managed care plans, including the negotiated fee schedules.

Exhibit E
Performance Metrics and Incentive Fee

OIA shall be paid an additional fee amounting to up to 2.0% of Net Collected Revenue at the end of each month, based on satisfaction of performance metrics or if a performance metric is not satisfied due to factors outside the control of OIA, including, by way of example, acts of God, electrical outages, failure of a Center to follow advice of OIA, or other similar factors. The performance metrics and potential incentive fee shall be as follows:

- Press Ganey Patient Satisfaction Scores exceeding equivalent UHS scores (0.5%)
- Maintain ACR Accreditation (0.5%)
- Call abandon rate under 5% (0.25%)
- At or above 97% initiating MRI and CT referral per-cert and scheduling effort within 48 hours (0.5%)
- Average third appointment availability not to exceed five (5) days (0.25%)

[*consider what periods these are measured over and how often than will change*]

Exhibit 9.5

BUSINESS ASSOCIATE ADDDENDUM

Business Associate Agreement

This Business Associate Agreement ("Agreement"), is made and entered into by and between [UNIVERSITY DIAGNOSTICS, LLC] LLC ("Company") and Outpatient Imaging Affiliates, LLC ("Service Provider"), and (collectively the "parties"). The Underlying Contract(s) ("Underlying Contract") to which this Agreement applies include one or more agreements, written or oral, which the Parties have entered into, or may in the future enter into, under which Service Provider may be provided with, have access to, and/or create Protected Health Information. This Business Associate Agreement shall supplement and/or amend each of the Underlying Contracts only with respect to Service Provider's receipt, use, and creation of Protected Health Information pursuant to the Underlying Contracts to allow Company to comply with the requirements of the HIPAA Privacy and Security Rules.

NOW, THEREFORE, the parties intending to be legally bound, agree as follows:

1. Current federal law, specifically Sections 1173 and 1175 of the Social Security Act (the Health Insurance Portability and Accountability Act of 1996) and 45 CFR Parts 160, 162, and 164 arising from that Act and commonly referenced as the Privacy & Security Rules (hereinafter referred to as "HIPAA"), and as further modified by the American Recovery and Reinvestment Act of 2009, establish enforceable privacy regulations governing the access, use, and disclosure of certain individually identifiable information. Company stores and transfers patient information in a manner that brings it within the scope of these laws. In accordance with HIPAA, Company is required to enter into an agreement with Service Provider regarding Service Provider's ability to access, use, and disclose information about Company's patients. Accordingly, Service Provider and Company agree to follow the terms and conditions set forth in this Agreement.

2. The parties acknowledge that amendment of this Agreement may be required in order to ensure compliance with changes in the laws and clarifications of meaning provided by the governmental entities charged with enforcing the laws. The parties specifically agree to take such action as is necessary to implement the requirements of HIPAA and other applicable laws relating to the security and confidentiality of protected health information. In the event that counsel for Company determines that any term of this Agreement places Company, as a covered entity, at risk of violating such laws, then the applicable term(s) shall be subject to renegotiation and amendment. Upon request by Company, Service Provider agrees to enter promptly into negotiations regarding the terms of a written amendment to this Agreement to supplement and/or modify language as is required to comply with all applicable laws.

3. Service Provider acknowledges that Company collects confidential and other personal information concerning its patient's medical condition, care and treatment as contemplated in 45 C.F.R. § 160.103 (hereinafter referred to as "Protected Health Information"). Information deemed to be "Protected Health Information" includes information that directly identifies an individual or is of such a type or specificity that there is reasonable basis to believe the

information could be used to identify an individual. Examples of Protected Health Information include, but are not limited to, names, addresses, Social Security numbers, telephone numbers, electronic mail addresses, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers, biometric identifiers, including finger and voice prints, full face photographic images, and any other unique identifying numbers, characteristics, or codes. Service Provider acknowledges that Company has a legal obligation to keep Protected Health Information confidential and that the unauthorized use and/or disclosure of Protected Health Information could irreparably damage Company and/or its patients. Due to its duties under the Underlying Contract, Service Provider and/or Service Provider's employees, agents, sub-contractors or representatives will or may gain access to Protected Health Information. Additionally, Service Provider acknowledges that it meets the definition of a "Business Associate" as defined in 45 CFR §160.103. Accordingly, Service Provider agrees to abide by the following requirements:

4. Service Provider and/or Service Provider's employees, agents, sub-contractors or representatives agree that they will abide by all applicable provisions of Sections 1173 and 1175 of the Social Security Act and any Rules or Regulations promulgated thereunder, including, but not limited to, 45 CFR Parts 160, 162 and 164, and further modified by the American Recovery and Reinvestment Act of 2009. Service Provider and/or Service Provider's employees, agents, sub-contractors or representatives further agree to comply with any amendments, revisions, and/or alterations of Sections 1173 and 1175 of the Social Security Act and 45 CFR Parts 160, 162 and 164. Additionally, Service Provider agrees to execute additional agreements as necessary to accommodate finalization and/or amendment of the above-cited law, rules or regulations.

5. Service Provider agrees that it will not access Protected Health Information other than as necessary to provide diagnostic imaging center management services. Service Provider agrees that it will not otherwise use, disclose, remove, or otherwise alter any Protected Health Information maintained by Company without express written consent to do so.

6. Service Provider agrees that it will not use or disclose Protected Health Information other than as permitted by the Underlying Contract, this Agreement, or as required by law. This shall include holding Protected Health Information in strict confidence and not discussing, transmitting, or disclosing such Protected Health Information for any purposes other than as permitted by the contract and only after securing either proper authorization or consent as required by law, if such authorization or consent is necessary. Service Provider further agrees not to use or disclose Protected Health Information that would violate HIPAA regulations if Service Provider were a covered entity, even if the information was placed into Service Provider's possession through authorized means.

7. Service Provider acknowledges that Company is the rightful owner of all Protected Health Information provided to Service Provider by Company.

8. Service Provider may disclose Protected Health Information for the purposes authorized by this Agreement:

(a) to its employees, subcontractors and agents, in accordance with the remaining terms of this Agreement, or

(b) as directed by Company, or

(c) as otherwise permitted by the terms of this Agreement including for its own proper management and administration, provided such disclosure comports with current laws, rules, regulations and advice and to fulfill any present or future legal responsibilities of Service Provider, provided that such uses are permitted under state and federal laws.

9. Service Provider may disclose the Protected Health Information in its possession to third parties for the purpose of its proper management and administration or to fulfill Service Provider's present or future legal responsibilities, provided that Service Provider represents to Company, in writing, that:

(a) the disclosures are required by law, as provided for in 45 C.F.R. § 164.502, or

(b) Service Provider has received from the third party written assurances regarding its confidential handling of such Protected Health Information as required under 45 C.F.R. § 164.504(e)(4).

10. Service Provider warrants and represents that any Protected Health Information requested pursuant to the Underlying Contract by Service Provider or Service Provider's employees, agents, sub-contractors or representatives shall be only the minimum information necessary to serve the intended purpose(s) of the Underlying Contract.

11. If Service Provider maintains patient information in a designated record set, Service Provider agrees to provide a patient the right to access, inspect, and copy their Protected Health Information in accordance with all provisions of 45 CFR §164.524.

12. If Service Provider maintains patient information in a designated record set, Service Provider agrees to provide a patient the right to amend their Protected Health Information in accordance with all provisions of 45 CFR §164.526.

13. Service Provider agrees to provide Company with an accounting of all disclosures of Protected Health Information in accordance with all provisions of 45 CFR §164.528. To the extent that Service Provider makes disclosures of Protected Health Information through an Electronic Health Record, Service Provider shall also record all disclosures for the purposes of treatment, payment or health care operations, effective upon the compliance date applicable to Company for the recording of such disclosures.

14. Service Provider agrees to use appropriate safeguards to prevent the use or disclosure of Protected Health Information in any manner other than as provided for in this Agreement. Service Provider further agrees to take appropriate actions with each of Service Provider's employees, agents, contractors, sub-contractors and representatives who may have access to Protected Health Information to keep such information confidential and abide by the same

restrictions, conditions and covenants contained in this agreement and further abide by all applicable laws, rules, regulations and advice.

15. Service Provider agrees to make its internal practices, books and records related to Protected Health Information available to the United States Department of Health and Human Services or its agents or designees as necessary for enforcement of the HIPAA regulations.

16. Service Provider agrees to provide Company access to all Protected Health Information in Service Provider's possession that was originally submitted to Service Provider by Company.

17. Service Provider agrees to implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any electronic Protected Health Information that Service Provider creates, receives, maintains, or transmits on behalf of Company.

18. Service Provider agrees to report, in writing, to Company's designated Privacy Officer any use or disclosure of Protected Health Information that is not provided for in this Agreement, or any Security Incident, within five (5) days of the Service Provider's discovery of such unauthorized use and/or disclosure or Security Incident. Service Provider agrees to take all reasonable steps necessary to mitigate, to the greatest extent possible, any deleterious effects from any improper use and/or disclosure of Protected Health Information or any Security Incident.

19. When patient-related information is in its possession, Service Provider agrees to comply with all applicable state laws and regulations relating to the confidentiality of such patient-related information including, without limitation, all such laws and regulations that impose more stringent requirements on Company and/or Service Provider than HIPAA.

20. As provided for under 45 CFR § 164.504(e)(2)(iii), Company may immediately terminate the Underlying Contract and any other agreements existing between Service Provider and Company if Company makes the determination that Service Provider has breached a material term of this Agreement. Alternatively, Company may choose to provide Service Provider with notice of the existence of an alleged material breach and afford Service Provider an opportunity to cure said alleged material breach. In the event Service Provider fails to cure said breach to the satisfaction of Company within five (5) days, Company may immediately thereafter terminate the Underlying Contract any other agreements existing between Service Provider and Company.

21. Upon the termination of the Underlying Contract, Service Provider agrees to return or destroy all Protected Health Information pursuant to 45 C.F.R. § 164.504(e)(2)(ii)(I), if it is feasible to do so. Before doing so, Service Provider further agrees to recover any Protected Health Information in the possession of its subcontractors or agents. If it is not feasible for Service Provider to return or destroy said Protected Health Information, Service Provider will notify Company in writing. Said notification shall include a statement that Service Provider has determined that it is not feasible to return or destroy the Protected Health Information in its possession, and the specific reasons for such determination. Service Provider further agrees to extend any and all protections, limitations and restrictions contained in this Agreement to Service

Provider's use and/or disclosure of any Protected Health Information retained after the termination of the Underlying Contract, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible. If it is infeasible for Service Provider to obtain from a subcontractor or agent any Protected Health Information in the possession of the subcontractor or agent, Service Provider will provide a written explanation to Company and require the subcontractors and agents to agree to extend any and all protections, limitations and restrictions contained in this Agreement to the subcontractors' and/or agents' use and/or disclosure of any Protected Health Information retained after the termination of the Underlying Contract, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible.

22. Service Provider represents and warrants to Company that it will not enter into any agreement the execution and/or performance of which would violate or interfere with this Agreement.

23. This Agreement shall not be construed against the party or parties preparing it. It shall be construed as if all the parties and each of them jointly prepared this Agreement, and resolved in favor of a meaning that permits Company to comply with HIPAA and the regulations promulgated pursuant thereto.

24. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the Parties and the respective successors or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.

****

The signatories below acknowledge and warrant that they are properly authorized by their organizations to execute this agreement.

On behalf of Company:	*On behalf of Service Provider:*
OUTPATIENT IMAGING AFFILIATES, LLC	[UNIVERSITY DIAGNOSTICS, LLC] LLC
By: _____	By: _____
Printed name: _____	Printed name: _____
Title: _____	Title: _____
Date: _____	Date: _____

OPTION TO LEASE

For and inconsideration of $100.00, cash in hand paid, the receipt of which is hereby acknowledged, and other good and valuable consideration, University Health System, Inc. ("UHS") hereby bargains, sells and grants to University Diagnostics, LLC, (University Diagnostics) the right and option to lease certain 5,350 square feet located at 7326 Maynardville Highway, Knoxville, TN 37926. The terms and conditions of the lease of the property to be executed by and between the parties (the "Lease") shall include the following terms, along with others negotiated by the parties:

1. **TERM**. Ten (10) years from effective date of the Lease, with two subsequent five (5) year renewal term options.

2. **ANNUAL BASE RENT:** $23.85/square foot with an annual accelerator of 2.5%.

If there is any conflict between the provisions of the Lease and those set forth here, the provisions of the Lease shall prevail.

University Diagnostics must give written notice to UHS of its election to exercise its option to lease the property not later than ten (10) days after UHS receives approval of a Certificate of Need from the Tennessee Health Services and Development Agency Facilities. If University Diagnostics fails to give such notice, this Option shall terminate and be of no further force and effect. In the event that the Certificate of Need is denied, then this Option shall terminate and be of no further force and effect unless appeal is made by UHS, in which event University Diagnostics must give written notice of its intent to exercise the option within ten (10) days after any favorable decision on appeal. In the event such appeal is denied, this Option shall terminate and be of no further force and effect. In any event, this option will expire on January 1, 2023.

The provisions of this Option shall be binding upon and inure to the benefit of all parties and their respective heirs, successors and assigns.

This Option shall be construed in accordance with and governed by the laws of the State of Tennessee and shall be subject to receipt by UHS and University Diagnostics of all appropriate legal and regulatory approvals as may be required by each party with respect to this Option and the resulting proposed Lease.

IN WITNESS WHEREOF, the parties have signed this Option on this 21st day of July, 2022.

UNIVERSITY HEALTH SYSTEM, INC.

BY: _____

UNIVERSITY DIAGNOSTICS, LLC

BY: _____

LEASE AGREEMENT

THIS LEASE AGREEMENT (this "Lease"), is made and entered as of the date of the last party to execute this Lease (the "Effective Date"), by and between **HALLS CENTRE LLC,** a Tennessee limited liability company and or its assigns ("Landlord") and **UNIVERSITY HEALTH SYSTEM, INC.**, a Tennessee nonprofit corporation ("Tenant").

WITNESSETH:

WHEREAS, Landlord owns certain real property (the "Land") consisting of approximately 6.94 acres located at or about 7326 Maynardville Pike, Knoxville, Tennessee 37938 and having Knox County Tax ID of 038 13502 as shown in Exhibit A attached hereto, together with the building constructed thereon consisting of approximately 52,976 +/- square feet (the "Building"); and

WHEREAS, Landlord has agreed to lease to Tenant and Tenant has agreed to lease from Landlord a portion of the Building consisting of approximately 46,202 +/- square feet together with the non-exclusive use of the Land in common with other tenants of the Building (if any) upon the terms and conditions hereinafter set forth; and

WHEREAS, it is the desire of both parties, Landlord and Tenant, to reduce the terms of their agreement to writing.

NOW, THEREFORE, for and in consideration of the mutual covenants, agreements representations and warranties set forth herein, and for other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. PREMISES AND TERM.

1.1 Premises. Landlord hereby leases to Tenant, and Tenant hereby leases and accepts, subject to the terms and conditions of this Lease, the medical office space containing approximately 46,202 +/- square feet together with the non-exclusive use of the Land and all easements and rights thereto (collectively, the "Premises"). The parties acknowledge and agree that the Tenant shall be performing the Tenant Improvements (as defined herein) to the Premises which may or may not change the actual or rentable number of square feet within the Premises and that the Rent due from and payable by Tenant hereunder shall not be modified (up or down) based on the actual or rentable number of square feet within the Premises.

1.2 Term. Subject to the terms, covenants and conditions herein, the term of this Lease shall commence on the earlier of (the "Commencement Date"): (i) the date that is one (1) year following the date on which Landlord delivers the Premises to Tenant in substantial conformity with Exhibit B or (ii) the date on which Tenant commences operations within the Premises and said term shall continue for a period of Ten (10) years, unless earlier terminated pursuant to the terms of this Lease (herein referred to as the "Initial Term"). Thereafter, provided that there is no Tenant Default (as defined in Section 9.1 below), Tenant may extend the Initial Term for up

to two (2) additional, consecutive terms of five (5) years each (each a "Renewal Term") upon the same terms herein, except for the Base Rent, which shall be determined as set forth in Section 2.1 below. Tenant shall exercise each Renewal Term by providing Landlord written notice of such election not less than one hundred eighty (180) days prior to the end of the Initial Term or the first Renewal Term, whichever is applicable. As used herein, the term "Lease Year" means a period of twelve (12) consecutive calendar months beginning on the Commencement Date. The Initial Term and the Renewal Term(s) are collectively referred to as the "Term".

2. **RENT**.

2.1 Base Rent. During the term of the Lease, from and after the Commencement Date (as defined above) Tenant shall pay Landlord base rent ("Base Rent") as set forth below together with the Additional Rent as defined below herein (collectively, the Base Rent and the Additional Rent are referred to as "Rent" herein) without set off or demand, except as otherwise expressly provided in this Lease.

Initial Term Lease Year	Annual Base Rent	Monthly Base Rent
1	$1,000,000.00	$83,333.33
2	$1,000,000.00	$83,333.33
3	$1,020,000.00	$85,000.00
4	$1,040,400.00	$86,700.00
5	$1,061,208.00	$88,434.00
6	$1,082,432.16	$90,202.68
7	$1,104,080.80	$92,006.73
8	$1,126,162.42	$93,846.87
9	$1,148,685.67	$95,723.81
10	$1,171,659.38	$97,638.28

The Base Rent payable hereunder during each Lease Year of either the First or Second Renewal Term shall be based upon a fair market value opinion of an independent third party, but in no event shall the annual Base Rent be reduced below $1,000,000.00 per Lease Year. The Tenant shall have the right to request a market rate tenant improvement allowance at the time of exercise which may be agreed upon by Landlord and Tenant and used for permanent improvements to the Premises.

2.2 Security Deposit. *Intentionally Omitted.*

2.3 Late Fee. If Rent is not paid by the tenth (10^{th}) day of the month, a late charge of five percent (5%) per month on the outstanding rental amounts may be assessed by the Landlord and payable by Tenant within ten (10) days after Tenant's receipt of a written notice therefor.

2.4 Additional Rent. Landlord shall reasonably estimate for each calendar year during the Term, Tenant's Proportionate Share (defined herein as 87.21%) of the cost of Landlord's

Insurance (as defined in Section 7.1 below), the Taxes (as hereinafter defined), and the Common Area Maintenance Expenses (as hereinafter defined) (the "Tenant's Estimated Share"). Tenant's Estimated Share shall be divided by 12 and paid in equal monthly installments ("Tenant's Monthly Estimated Share") with each monthly installment of Base Rent. Within one hundred twenty (120) days after the expiration of each calendar year, Landlord shall forward to the Tenant an itemized statement showing the actual amount of the costs of the Landlord's Insurance, the Taxes and the Common Area Maintenance Expenses (the "Tenant's Actual Share"). Should the Tenant's Actual Share, differ from the Tenant's Estimated Share, then either Tenant shall remit to Landlord any amount by which the Tenant's Estimated Share was deficient within thirty (30) days after receiving the itemized statement or Landlord shall refund to Tenant any amount paid in excess of the Tenant's Actual Share simultaneously with its submission of the itemized statement, provided if Landlord fails to pay any excess amount within twenty (20) days after Tenant's receipt of the itemized statement, then Tenant may offset such excess amount against the rent due hereunder until Tenant is reimbursed in full. Landlord shall keep good and accurate books and records of the costs of the Landlord's Insurance, the Taxes and the Common Area Maintenance during the Term in accordance with generally accepted accounting principles, and Tenant or its accountants shall have the right to inspect the same upon thirty (30) days' written notice from Tenant. If any statement of the Tenant's Actual Share previously furnished to Tenant is more than the Tenant's Actual Share shown by an audit, Landlord shall promptly pay the reasonable cost of such audit for the period audited upon its receipt of the audit results. Notwithstanding any such dispute, Landlord shall promptly pay Tenant the amount of any costs of the Tenant's Actual Share shown by such audit to be overpaid by Tenant. The provisions of this paragraph shall survive the expiration or earlier termination of this Lease.

2.4.1 For the purposes of this Lease, "Tenant's Proportionate Share" is hereby deemed to be 87.21%.

2.4.2 For the purposes of this Lease, "Taxes" shall mean all real estate taxes and assessments with respect to the Premises during the Term (excluding federal, state and city income, excess profit, gift, estate, succession, inheritance, franchise and transfer taxes, and any other taxes relating to the operation of Landlord's business, all of which are Landlord's responsibility).

2.4.3 For the purposes of this Lease, "Common Area Maintenance" shall mean all utilities provided to the exterior of the Building/parking lot (if there is a single meter to the Building, then Tenant will pay utilities directly to the provider), the cost of removing trash from the Building/parking lot, the cost of re-sealing and repairing the parking lot, the cost of monitoring, testing and maintaining the sprinkler system for the Building, the costs attributed to the maintenance and repair of the Premises, including painting of the exterior of the Building, landscaping the Land together with a reasonable property management fee not to exceed ten percent (10%) of Tenant's Actual Share.

3. **USE OF PREMISES, USE RESTRICTIONS.**

3.1 Tenant's Use. The Premises shall be used and occupied by Tenant as an outpatient department of the hospital as defined by Centers for Medicare & Medicaid Services ("CMS"), as an independent diagnostic testing facility, medical office or clinic, or other uses related to the operation of any of the foregoing, and for no other use without Landlord's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Tenant shall comply with all rules, regulations and laws of any governmental authority with respect to Tenant's particular use and occupancy of the Premises, as well as any reasonable rules and regulations promulgated by Landlord, provided such reasonable rules and regulations (a) do not materially interfere with the lawful conduct of Tenant in the Premises, (b) have a nondiscriminatory effect, (c) are applied equally to all tenants of the Building and (d) do not increase Tenant's obligations under this Lease.

3.2 Compliance and Restrictions.

3.2.1 Tenant shall not (i) use the Premises or any improvements now or hereafter constructed thereon for the treatment, storage, disposal, burial, or placement of any "hazardous substance", as that term is defined under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as the same may now or hereafter by amended ("CERCLA"), pollutants, contaminants or any other substance, the treatment, storage, disposal, burial or placement of which is regulated under any state, federal or local statute, law, rule, regulation or ordinance, except to the extent that such are reasonably required in the normal practice of any Tenant's medical specialty, and then only to the extent permitted by, and in strict compliance with, applicable law, or (ii) knowingly release, as that term is defined in Section 101(22) of CERCLA, or knowingly permit the release of any hazardous substance, pollutants, contaminants or other substances regulated under applicable federal, state or local statute, rule regulation or ordinance onto the Premises or into the subsurface thereof or into any surface or ground waters unless said use or release is in compliance with all applicable statutes, laws, rules, regulations and ordinances or pursuant to a valid and current permit or permits from all governmental authorities having jurisdiction over the Tenant, the Premises or the use and occupancy of the Premises by Tenant.

3.2.2 Any medical waste generated by Tenant on the Premises shall be segregated and packaged by Tenant as required by applicable laws, rules and regulations, and disposed of by Tenant. Tenant shall comply with all laws relating to the disposal of medical waste. For the purpose of this Lease, medical waste means, without limitation, any substance which, because of its quantity, concentration, or its chemical, radioactive, flammable, explosive, infectious, corrosive, reactive or other characteristics, constitutes or may reasonably be expected to constitute or contribute to a danger or hazard to the public health, safety, or welfare or the environment, all as more fully defined in federal, state and local laws, rules and regulations relating to the disposal of medical waste.

3.3 Signs. Tenant shall not place on any exterior door, wall or window of the Premises any sign or advertising matter without first obtaining Landlord's written approval and consent to such sign, which approval and consent shall not be unreasonably withheld, conditioned or

delayed. Landlord, at Tenant's sole cost and expense, shall provide exterior signage at the Building acceptable to Tenant which identifies Tenant in a prominent fashion. In the event that Landlord constructs a monument sign, at its sole cost and expense, then Tenant shall be able to install signage on the monument sign subject to local codes and ordinances. All signs shall comply with applicable ordinances or other governmental restrictions and the determination of such requirements and the prompt compliance therewith shall be the responsibility of Tenant.

3.4 Utilities. Landlord agrees that the utilities to the Premises will be separately metered. Tenant agrees to pay when due and before delinquent, all charges for Tenant's usage of electric current, gas, sewer, heat, water, telephone, building security/monitoring and all other utilities and all taxes or charges on such utility services which are used on or attributable to the Premises. In no event shall Landlord be liable for any interruption or failure in the supply of any utilities to the Premises unless arising from the negligence or intentional misconduct of Landlord or its agents, contractors or employees. Tenant shall at all times keep the Premises at a temperature sufficiently high to prevent freezing of water pipes and fixtures.

4. LANDLORD'S WORK AND TENANT IMPROVEMENTS; MAINTENANCE AND REPAIRS.

4.1 Landlord and Tenant's Work. Landlord shall deliver the Premises to Tenant in its "As-Is" condition as set forth in Exhibit B (the "Landlord's Work"). Tenant shall at Tenant's sole cost and expense (subject to the reimbursement pursuant to the Tenant Improvement Allowance and the Common Area Improvement Allowance) all of the design, material, labor and equipment required to construct all improvements of the Premises as set forth in Exhibit B (collectively, the "Tenant's Work"). Tenant agrees Tenant's Work will be constructed in a good and workmanlike manner, in accordance with all applicable laws, statutes, ordinances and building codes, governmental rules, regulations and orders relating to the construction of Tenant's Work.

4.2 Tenant's Duty to Repair. Except as may be the responsibility of Landlord pursuant to Section 4.5 below, Tenant shall keep and maintain in good order, condition and repair the interior of the Premises and every part thereof, including, without limitation, the interior portion of all doors, interior windows and plate glass, all plumbing and sewage facilities within the Premises including free flow up to the main sewer line, fixtures, interior walls, floor coverings, ceilings, and fixtures applicable to the interior of the Premises, and all installations made by Tenant under the terms of this Lease and any exhibits thereto, as herein provided. Tenant shall keep and maintain the Premises in a clean, sanitary and safe condition and in accordance with all directions, rules and regulations of the proper official of the government agencies having jurisdiction, at the sole cost and expense of Tenant, and Tenant shall comply with all requirements of law, by statute, ordinance or otherwise, affecting the Premises and all appurtenances thereto. If Tenant does not make any repairs required of Tenant in this Lease within thirty (30) days after its receipt of written notice from Landlord specifying the need of such repair, Landlord may, but shall not be required to, make and complete said repairs and Tenant shall reimburse Landlord for the reasonable cost thereof within a reasonable time after Tenant's receipt of reasonably documented invoice therefor. Tenant shall also allow no nuisance to exist with respect to the Premises.

4.3 Mechanic's Liens. Tenant will not permit any mechanic's lien to be placed on the Premises, or improvements thereon by reason of acts or agreement of Tenant. Nothing in this Lease shall be construed in any way as constituting the consent or request of Landlord to Tenant to contract for, or permit the rendering of, any services or the furnishing of any materials that would give rise to any mechanic's or other liens against the interest of Landlord in the Premises. In the event any such lien is filed, Tenant shall cause it to be discharged of record within thirty (30) days after filing, or shall post a bond or arrange conditional payment, provided any such bond or arrangement is approved by Landlord and their mortgagees.

4.4 Surrender of Premises. At the termination of the Initial Term, or any Renewal Term thereof, Tenant shall deliver the Premises to Landlord in the same condition as received by it on the Commencement Date (subject to the removals hereinafter required), reasonable wear and tear and casualty or condemnation excepted. Tenant shall remove all trade fixtures owned by Tenant (defined as those not installed or purchased by Tenant with the proceeds of the Tenant Improvement Allowance or the Common Area Improvement Allowance), and before surrendering the Premises as aforesaid, shall repair any damage to the Premises caused by removal of such items to the reasonable satisfaction of the Landlord.

4.5 Landlord's Duty to Repair. Landlord, at Landlord's sole cost and expense shall keep and maintain the roof of the Building, the structural portions of the Building (i.e. floor slab (excluding floor coverings), load bearing walls (excluding wall coverings, paint and drywall), the exterior walls of the Building (excluding painting) and the parking lot replacement (excluding ordinary maintenance and repairs which are expressly included as Common Area Maintenance). Tenant shall promptly notify Landlord in writing of the need to perform any maintenance or repairs required hereunder. Notwithstanding the foregoing, it is expressly acknowledged that any repairs or replacement of the roof which are caused by Tenant or Tenant's contractor during the construction of the Tenant's Work shall be repaired or replaced by Tenant.

5. SERVICE.

5.1 Exterior Service. Routine exterior maintenance and repairs and maintenance and repairs to the Common Areas shall be performed by Landlord, at Landlord's expense, and passed through to Tenant as Additional Rent in accordance with Sections 2.4 and 2.4.3 herein. Routine exterior maintenance includes lighting, repairing, and maintaining of the exterior of the Premises, specifically including signage, landscaping and gardening, the maintenance and cleaning of the parking lot, line painting, lighting, removal of snow, trash, rubbish and garbage.

5.2 Janitorial Service. Landlord shall not be required to provide janitorial services for the interior of the Premises.

6. RIGHTS RESERVED.

6.1 Rights Reserved to Landlord. Landlord reserves the following rights on behalf of itself or its agents:

6.1.1 Pass Keys. To have pass keys to the Premises, provided Landlord shall not access the Premises until first providing Tenant with at least forty-eight (48) hours' prior notice. Upon any access to the Premises, Landlord shall make certain it is in compliance with the Health Insurance Portability and Accountability Act and shall minimize any disturbance to Tenant's business operations.

6.1.2 Access for Repairs, etc. Subject to Section 6.1.1 above, to have access for repairs, alterations, additions and improvements to the Premises or to the Building, which shall be accomplished in non-business hours except for emergencies.

7. INSURANCE; INDEMNITY; WAIVER OF SUBROGATION.

7.1 Landlord's Insurance. Landlord shall keep the Premises insured against loss or damage by fire or other casualty to the extent of the full insurable value, thereof, including all improvements, alterations, additions, and changes made to the Building. Landlord agrees to maintain at all times during the Term, commercial general liability insurance naming Tenant as an additional insured in an amount not less than One Million and No/100 Dollars ($1,000,000.00) per person, Two Million and No/100 Dollars ($2,000,000.00) per accident for injuries or damages to persons, and not less than One Hundred Thousand and No/100 Dollars ($100,000.00) for damage to or destruction of property. The insurance Landlord is required to carry under this paragraph shall be referred to in this Lease collectively as the "Landlord's Insurance". Landlord shall deliver to Tenant certificates of the Landlord's Insurance within a reasonable time after Landlord's receipt of a written request therefor.

7.2 Insurance Covering Tenant's Property. Tenant may secure and maintain at its own expense fire and extended coverage insurance insuring Tenant's interest in Tenant's office furniture, equipment, supplies, and other personal property.

7.3 Indemnity. Subject to Section 7.5 below, Tenant shall protect, indemnify and save Landlord harmless from and against all and any liability and expense of any kind, including reasonable attorneys' fees, arising from injuries or damages to persons or property in, on or about the Premises to the extent arising out of or resulting in any way from the negligence or intentional act or omission of Tenant, its agents, contractors or employees during the Term. Landlord shall protect, indemnify and save Tenant harmless from and against all and any liability and expense of any kind, including reasonable attorney' fees, arising from injuries or damages to persons or property in, on or about the Premises arising out of or resulting in any way from any act or omission of Landlord, its agents invitees, servants and employees during the Term.

7.4 Liability Insurance. Tenant agrees to maintain at its expense at all times during the Term commercial general liability insurance naming Landlord as an additional insured in an amount not less than One Million and No/100 Dollars ($1,000,000.00) per person, Three Million and No/100 Dollars ($3,000,000.00) per accident for injuries or damages to persons, and not less than One Hundred Thousand and No/100 Dollars ($100,000.00) for damage to or destruction of Tenant's personal property. Tenant shall deliver to Landlord evidence of such insurance to Landlord within ten (10) days after Tenant's receipt of a written request therefor.

7.5 Waiver of Subrogation. Landlord and Tenant on behalf of themselves and all others claiming under them, including any insurer, waive all claims against each other, including all rights of subrogation, for loss or damage to their respective property (including, but not limited to, the Premises) arising from fire, smoke damage, windstorm, hail, vandalism, theft, malicious mischief and any of the other perils normally insured against in an "all risk" of physical loss policy, regardless of whether insurance against those perils is in effect with respect to such party's property and regardless of the negligence of either party. If either party so requests, the other party shall obtain from its insurer a written waiver of all rights of subrogation that it may have against the other party.

8. FIRE OR OTHER CASUALTY.

8.1 Partial Destruction. In the event of the partial destruction of the Premises by fire or any other casualty that Landlord's contractor reasonably estimates can be repaired within sixty (60) days following the date of such fire or casualty, Landlord shall use its best efforts to restore or repair the Building with reasonable diligence. A just and proportionate part of the rent payable by Tenant, to the extent that such damage or destruction renders the Premises untenantable, shall abate from the date of such damage or destruction until such Premises are repaired or restores.

8.2 Substantial Destruction. If the Premises shall be so damaged by fire or other casualty or happening as to be substantially destroyed, then either Landlord or Tenant shall have the option to terminate this Lease by giving the other party written notice with thirty (30) days after such destruction, and the termination date shall be the date of such fire or other casualty. Following such termination, any unearned rent shall be apportioned and returned to Tenant. If neither party elects to cancel this Lease as aforesaid, then the same shall remain in full force and effect, and the Landlord shall use its best efforts to proceed with all reasonable diligence to repair and replace the Premises to the condition they were in prior to the date of such destruction and, for any period of time the Premises may be rendered untenantable, the rent shall be abated to the same extent.

8.3 Landlord's Duty to Repair. In the event Landlord commences to repair, rebuild or restore the Premises following a fire or other casualty and such repairs, rebuilding or restoration is not completed within one hundred twenty (120) days following the date of such fire or other casualty, Tenant may terminate this Lease within thirty (30) days following such 120-day period by submitting written notice to Landlord, and any unearned rent shall be apportioned and returned to Tenant.

8.4 Right of Termination. Notwithstanding anything else to the contrary contained in this Section 8 or elsewhere in this Lease, Landlord or Tenant, at their option, may terminate this Lease on written notice to the other party given within thirty (30) days after the Premises shall be damaged or destroyed during the last twelve (12) months of the Term so long as Tenant has not already provided Landlord with Tenant's election to exercise a Renewal Term.

9. DEFAULT REMEDIES.

9.1 Events of Default. The occurrence of any of the following acts or events shall constitute events of defaults under this Lease ("Tenant Default"):

9.1.1 Tenant fails to make any payment required hereunder within ten (10) days following Tenant's receipt of written notice from Landlord of nonpayment of Rent;

9.1.2 Tenant fails to fulfill or perform any of Tenant's material covenants, agreements or obligations under this Lease and such failure continues for a period of thirty (30) days following Tenant's receipt of written notice thereof specifying the nature of such failure, provided if such failure cannot reasonably be cured within such 30-day period, then Tenant shall have a reasonable time thereafter so long as Tenant commences such cure within such 30-day period and diligently prosecutes the same through completion; or

9.1.3 If at any time during the Term there shall be filed by or against Tenant, or against any successor tenant then in possession, in any court pursuant to any petition in bankruptcy, alleging an insolvency, for reorganization, for the appointment of a receiver, or for an arrangement under the Bankruptcy Code, or is a similar type of proceeding shall be field and such petition or proceeding is not dismissed within sixty (60) days.

9.2 Landlord's Remedies. Whenever any Tenant Default shall have happened and be subsisting, Landlord may, to the extent permitted by law, take any one or more of the remedial steps, provided Landlord agrees to uses reasonable efforts to mitigate its damages following a Tenant Default:

9.2.1 Landlord may re-enter and take possession of the Premises without terminating this Lease, and lease in their entirety the same for the account of Tenant, holding Tenant liable for the difference in the rent and other reasonable amounts Landlord actually pays to prepare the Premises for such lease.

9.2.2 Landlord may terminate this Lease, exclude Tenant from possession of the Premises, holding Tenant liable for all rent and other amounts payable by Tenant hereunder.

9.2.3 Landlord may take whatever action at law or in equity may appear necessary and desirable to collect the rent and other amounts then due and thereafter to become due or to enforce performance and observance of any obligation, agreement, or covenant of Tenant under this Lease, and in connection with such actions, to recover any or all damages to Landlord for Tenant's violation or breach of this Lease with interest thereon at the then highest lawful rate from the date of payment, plus Landlord's reasonable attorneys' fees and court costs, shall be paid by Tenant to Landlord.

9.3 Landlord Default and Tenant's Remedies. Landlord shall be in default of this Lease in the event Landlord fails to fulfill or perform any of Landlord's material covenants, agreements or obligations under this Lease and such failure continues for a period of thirty (30) days following Landlord's receipt of written notice thereof specifying the nature of such failure, provided if such failure cannot reasonably be cured within such 30-day period, then Landlord shall have a reasonable time thereafter so long as Landlord commences such cure within such 30-

day period and diligently prosecutes the same through completion. In the event of a Landlord default under this Lease, Tenant may terminate this Lease and/or seek any remedies available at law or in equity. Notwithstanding anything to the contrary contained in this Lease, in the event Landlord fails to make repairs required of Landlord that constitute an imminent danger to persons or property or materially interferes with Tenant's business operations within five (5) days after Landlord's receipt of notice specifying such failure, Tenant shall have the right, but not the obligation, to take such action as is reasonably necessary under the circumstances to repair any portion or component of the Premises. To the extent such work performed by Tenant is Landlord's responsibility under this Lease, Landlord shall reimburse Tenant for the cost of the same within twenty (20) days after Landlord's receipt of a reasonably documented invoice therefor. If Landlord fails to reimburse Tenant within such 20-day period, Tenant may offset such amount against rent due hereunder until Tenant is reimbursed in full.

10. **ASSIGNMENT**.

10.1 Assignment and Subletting. Tenant shall not assign, transfer or encumber this Lease without the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, Tenant may, without Landlord's consent, (a) transfer or assign its interest in this Lease by operation of law, merger or otherwise, or sublet or grant any license to use the Premises or any part thereof to any entity that controls, is controlled by or is under common control with Tenant or that directly or indirectly is the legal or beneficial owner of or controls more than 50% of the equity ownership interests of Tenant or in connection with the sale of all or substantially all of Tenant's assets or (b) sublet the Premises, and/or grant any license to use the Premises or any part thereof to any party, but in no event shall Tenant be released from liability hereunder as a result of such assignment or sublease.

11. **NOTICES**.

11.1 All notices to be given by one party to the other under this Lease shall be given in writing, mailed or delivered as follows:

11.2 To Landlord at the following address or to such other address as may be designated in writing:

Halls Centre, LLC
6416 Deane Hill Drive
Knoxville, Tennessee 37919
Attention: John G. Captain

With a copy to:

Joshua B. Bishop, Esq.
Howard & Howard, P.C.
4820 Old Kingston Pike
Knoxville, Tennessee 37919

11.3 To Tenant at the following addresses or to such other address as may be designated in writing:

University Health System, Inc.
2121 Medical Center Way, Suite 330
Knoxville, Tennessee 37920-3282
Attention: Bennett L. Cox, Esq.

With a copy to:

_____
_____
_____

12. **QUIET POSSESSION**.

12.1 Quiet Possession. Landlord warrants that it is lawfully seized and possessed of the Premises, and so long as Tenant shall observe and perform the covenants and agreements binding upon it hereunder, Tenant shall at all times have quiet and peaceful possession of the Premises during the term of this Lease without any hindrance.

13. **CONDEMNATION**.

13.1 Condemnation. If at any time the entire or a substantial part as determined by Landlord or Tenant of the Premises is taken for any public use under any statute or by right of eminent domain or by private purchase in lieu thereof by a body vested with the power of eminent domain, this Lease shall continue until the date of the taking, at which time this Lease shall terminate. In the event the condemnation or purchase takes place but the Premises continues to be tenantable for Tenant's purposes, the rents shall be abated pro-rata, Landlord, at its sole cost and expense, shall restore the Premises to a tenantable condition, and this Lease shall continue otherwise in full force and effect. The termination of this Lease or the abatement of rent by reason of the condemnation or purchase shall be without prejudice to the rights of either Landlord or Tenant to recover compensation and damage caused by the condemnation or taking from the condemnor or taker. Neither Landlord nor Tenant shall have any rights in any award made to the other by reason of such condemnation or taking.

14. **MISCELLANEOUS**.

14.1 Waiver. The failure of Landlord or Tenant to insist upon the strict performance of any of the conditions, covenants, terms or provisions of this Lease, or to exercise any option herein, conferred, shall not be considered or construed as waiving or relinquishing for the future any such conditions, covenants, terms, provisions or options, but the same shall continue and remain in full force and effect.

14.2 Successors. This Lease shall inure to and be binding upon the successors and assigns of Landlord and heirs, administrators, executors, successors and assigns of the Tenant.

14.3 Amendment. All amendments to this Lease shall be in writing and executed by the parties or their respective successors in interest.

14.4 Holding Over. Any holding over after the expiration of the Term with the consent of Landlord shall be construed to be a tenancy from month to month upon the same terms of this Lease, except that the Base Rent shall be increased to an amount equal to 125% of the Base Rent payable hereunder for the immediately preceding Lease Year. Any holding over after the expiration of the Term without the consent of Landlord shall be deemed to be a tenancy at will upon the same terms of this Lease.

14.5 No Partnership. It is understood that Landlord does not, by execution of this Lease, in any way or for any purpose become a partner or joint venture with Tenant in the conduct of Tenant's business.

14.6 Partial Invalidity. If any term or condition of this Lease or the application thereof to any person or event shall to any extent be invalid and unenforceable, the remainder of this Lease and the application of such term, covenant or condition to persons or events other than those to which it is held invalid or unenforceable shall not be affected and each term, covenant and condition of this Lease shall be valid and be enforced to the fullest extent permitted by law.

14.7 Governing Law. This Lease shall be governed by, and construed in accordance with, the laws of the State of Tennessee.

14.8 Attorneys' Fees and Expenses. In the event that either party shall be required to engage legal counsel for the enforcement of any of the terms of this Lease, whether such employment shall require institution of suit or other legal services required to secure compliance on the part of the other party, the non-prevailing party shall be responsible for and shall promptly pay to the prevailing part the reasonable value of said attorneys' fees, and any other expenses incurred as a result of such default.

14.9 Counterparts. This Lease may be executed in two or more counterparts and delivered in electronic, facsimile or original form, and each of which shall constitute an original, but all of which together shall constitute one and the same agreement.

14.10 Brokers. Landlord shall pay Coldwell Banker Wallace and Realty Trust Group (collectively, the "Brokers") a real estate commission pursuant to a separate written agreement executed by Landlord and the Brokers prior to the execution of this Agreement. Tenant represents that there are no other brokers involved in this transaction with the exception of the Brokers defined above.

[*signatures on the following page*]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease as of the day and year of the last party to sign below.

LANDLORD:

HALLS CENTRE, LLC
a Tennessee limited liability company

By: _____
Name: _____
Its: _____
Date: _____

_____
Witness

TENANT:

UNIVERSITY HEALTH SYSTEM, INC.
a Tennessee nonprofit corporation

By: Wm. David Hall
Name: WM. DAVID HALL
Its: EXECUTIVE VICE PRESIDENT
Date: 8/11/20

_____
Witness

EXHIBIT A

Attach Layout of the Land

EXHIBIT B

Landlord and Tenant's Work

Landlord's Work

Landlord shall deliver the Premises to Tenant in its As-Is Where Is condition. Notwithstanding the foregoing, Landlord shall apply for a rezoning from "CA" to either "OB" or "OA" and a Sector Plan amendment from "GC" to "MDR/O" or "O" as defined by the Knoxville-Knox County Planning Commission. Landlord shall use its best efforts to have the Land rezoned "OB" but Tenant acknowledges that "OA" zoning is acceptable as an alternative should the Planning Department indicate it cannot support the "OB" rezoning. Additionally, Landlord shall be permitted to continue to utilize the Premises for the storage of fitness and restaurant equipment for sixty (60) days following the delivery of the Premises by Landlord to Tenant.

Landlord will provide Tenant with a Tenant Improvement Allowance in the amount of Six Million Eight Hundred Ninety-Five Thousand Dollars ($6,895,000.00) (the "Tenant Improvement Allowance") for the construction of permanent improvements to the Premises, which improvements shall be the property of Landlord. The Tenant Finish Allowance shall be paid by Landlord to Tenant and Tenant's General Contractor upon the completion of the Tenant's Work (as defined below). Landlord shall provide Tenant with evidence of the availability of the Tenant Improvement Allowance from Landlord's construction lender upon request.

Additionally, Landlord will provide Tenant with a Common Area Improvement Allowance in the amount of Three Hundred Thousand Dollars ($300,000.00) (the "Common Area Improvement Allowance") for the construction of permanent improvements to the Common Areas located on the Land including the replacement of the mechanical systems to the Premises, the replacement of rooftop HVAC units, re-striping, sealing and repair of the parking lot and landscaping upgrades, which improvements shall be the property of Landlord. The Common Area Improvement Allowance shall be paid by Landlord to Tenant and Tenant's General Contractor upon the completion of the Tenant's Work (as defined below). Landlord shall provide Tenant with evidence of the availability of the Common Area Improvement Allowance from Landlord's construction lender upon request. It is specifically acknowledged that Tenant may utilize any portion of the Common Area Improvement Allowance or the Tenant Improvement Allowance to pay for any overages to the Tenant's Work. Following occupancy of Premises and completion of Tenant's Work, any unused balance of such Tenant Improvement Allowance shall be made available to Tenant for use or disbursement at Tenant's discretion. The Tenant shall be solely responsible for the construction of Tenant's Work and in no event shall Landlord be required to contribute more than the Tenant Improvement Allowance and the Common Area Improvement Allowance toward the cost of Tenant's Work.

Tenant's Work

Tenant shall at Tenant's sole cost and expense design, construct and renovate the Premises and Land in accordance with the Plans (as defined below) which when agreed to by Landlord and Tenant shall be incorporated herein as Exhibit B-1 (collectively, "Tenant's Work").

Prior to the commencement of Tenant's Work, Tenant will provide Landlord with the following: 1) a complete set of plans and specifications detailing Tenant's build out of the Premises prepared by an architect licensed in the state of Tennessee (collectively the "Plans"); 2) a copy of Tenant's contract with the architect/engineer who prepared the foregoing plans and specifications; 3) a copy of Tenant's construction contract with the general contractor who must be licensed in the state of Tennessee; 4) a schedule of values/budget detailing Tenant's projected costs and expenses for the buildout of the Premises; 5) a copy of a builder's risk policy naming the Landlord and the Landlord's lender as additional insureds for the construction of the Premises; 6) a copy of the building permit issued by the governing municipality for the Premises and 7) a performance and payment bond provided by Tenant's contractor, in form and substance satisfactory to Landlord, naming Landlord, Landlord's lender and indemnifying said parties from any liens or claims for payment arising from Tenant's work, including attorney's fees and costs. The bond will be issued by a surety reasonably satisfactory to Landlord and will be in an amount at least equal to the value of Tenant's work as reasonably determined by Landlord. Within thirty (30) days after completion of Tenant's construction within the Premises, Tenant shall provide Landlord with the following: 1) a copy of Tenant's certificate of occupancy for the Premises; 2) a lien waiver from Tenant's general contractor together with any sub-contractor which provides $10,000 or more of services or materials to the Premises and 3) a copy of "As-Built" plans denoting any deviations in the original plans for the Premises.

WARRANTY DEED

The preparer of this deed makes no representation as to the status of the title of the property herein conveyed

SHERRY WI
REGISTER OF DEEDS
KNOX COUNTY

#2008-0118

STATE OF TENNESSEE
COUNTY OF KNOX

THE ACTUAL CONSIDERATION OR VALUE, WHICHEVER IS GREATER, FOR THIS TRANSFER IS $3,325,000.00

Affiant

SUBSCRIBED AND SWORN TO BEFORE ME, THIS THE 5TH DAY OF AUGUST, 2008.

Notary Public

MY COMMISSION EXPIRES: 6-28-2011

(AFFIX SEAL)

CARLA A. DREITLEIN
STATE OF TENNESSEE
NOTARY PUBLIC
Comm. Exp. 6-28-2011
KNOX COUNTY

THIS INSTRUMENT WAS PREPARED BY
Stanley F. Roden, Attorney BPR #7128, 10269 Kingston Pike, Knoxville, TN 37922

ADDRESS NEW OWNER(S) AS FOLLOWS:	SEND TAX BILLS TO:	MAP-PARCEL NUMBER
Halls Centre, LLC	Halls Centre, LLC	038/135.02 (Part of)
(NAME)	(NAME)	
6416 Deane Hill Dr.	6416 Deane Hill Dr.	
(ADDRESS)	(ADDRESS)	
Knoxville, TN 37919	Knoxville, TN 37919	
(CITY) (STATE) (ZIP)	(CITY) (STATE) (ZIP)	

FOR AND CONSIDERATION OF THE SUM OF TEN DOLLARS, CASH IN HAND PAID BY THE HEREINAFTER NAMED GRANTEES, AND OTHER GOOD AND VALUABLE CONSIDERATIONS, THE RECEIPT OF WHICH IS HEREBY ACKNOWLEDGED, WE,

Five Oaks Outlet Centers, Inc.

HEREINAFTER CALLED THE GRANTORS, HAVE BARGAINED AND SOLD, AND BY THESE PRESENTS DO TRANSFER AND CONVEY UNTO

Halls Centre, LLC

HEREINAFTER CALLED THE GRANTEES, THEIR HEIRS AND ASSIGNS, A CERTAIN TRACT OR PARCEL OF LAND IN KNOX COUNTY, STATE OF TENNESSEE, DESCRIBED AS FOLLOWS, TO-WIT:

SITUATED in the Sixth (6th) Civil District of Knox County, Tennessee, and without the corporate limits to the City of Knoxville, Tennessee, and being known and designated as all of Lot 2R, a Resub of Lots 2 and 4 FIVE OAKS OUTLET CENTERS, INC., as shown by Plat of record at Instrument No. 200507190005779, Register's Office, Knox County, Tennessee, and by survey of David L. Hurst, #1886, of Michael Brady, Inc, dated 3/23/2005, revised 5/25/2005, drawing # 04624, to which map reference is here made for a more particular description thereof.

BEING part of the same properties conveyed to Five Oaks Outlet Centers, Inc. by Warranty Deeds from David E. Sharp and wife, Virginia H. Sharp and Frances K. Sharp, widow of Edward L. Sharp, dated 8/26/1997 of record 8/27/1997, Deed Book 2260, Page 1082, and by Warranty Deed from Willow Fork, a Tennessee general partnership composed of John A. Murphy and Mike Channell, dated 8/26/1997, of record 8/27/2007, Deed Book 2260, Page 1090, and by Warranty Deed from David E. Sharp and wife, Virginia H. Sharp and Lisa Sharp Childress and Barry Edward Sharp, only children of Edward L. Sharp, dated 8/26/1997, of record 8/27/1997, Deed Book 2260, Page 1078, all of record in the Register's Office, Knox County, Tennessee.

This conveyance is made subject to all applicable easements, restrictions and building setback lines of record.

unimproved ☐

This is improved ☒ property, known as 7326 Maynardville Pike, Knoxville, TN

(House Number) (Street) (P.O. Address) (City or Town) (Postal Zip)

TO HAVE AND TO HOLD the said tract or parcel of land, with the appurtenances, estate, title and interest thereto belonging to the said GRANTEES, their heirs and assigns forever; and we do covenant with the said GRANTEES that we are lawfully seized and possessed of said land in fee simple, have a good right to convey it and the same is unencumbered, unless otherwise herein set out; and we do further covenant and bind ourselves, our heirs and representatives, to warrant and forever defend the title to the said land to the said GRANTEES, their heirs and assigns, against the lawful claims of all persons whomsoever. Wherever used, the singular number shall include the plural, the plural the singular, and the use of any gender shall be applicable to all genders.

COUNTERSIGNED

AUG 06 2008

JOHN R. WHITEHEAD
KNOX COUNTY
PROPERTY ASSESSOR
BY NH

Knox County Page: 1 of 2
REC'D FOR REC 08/06/2008 10:42:20AM
RECORD FEE: $13.00
M. TAX: $0.00 T. TAX: $12,302.50
200808060008953

Witness our hands this 5th day of August, 2008.

Five Oaks Outlet Centers, Inc.

By: _____
Mike Channell, President

STATE OF TENNESSEE

COUNTY OF KNOX

Before me, the undersigned authority, in and for said County and State aforesaid, personally appeared Mike Channell, with whom I am personally acquainted or proved to me on the basis of satisfactory evidence, and who upon oath, acknowledged himself/herself to be the President of Five Oaks Outlet Centers, Inc. a corporation, the within named bargainor, and that he/she/they as such President, executed the within instrument for the purposes therein contained, by signing the name of the corporation

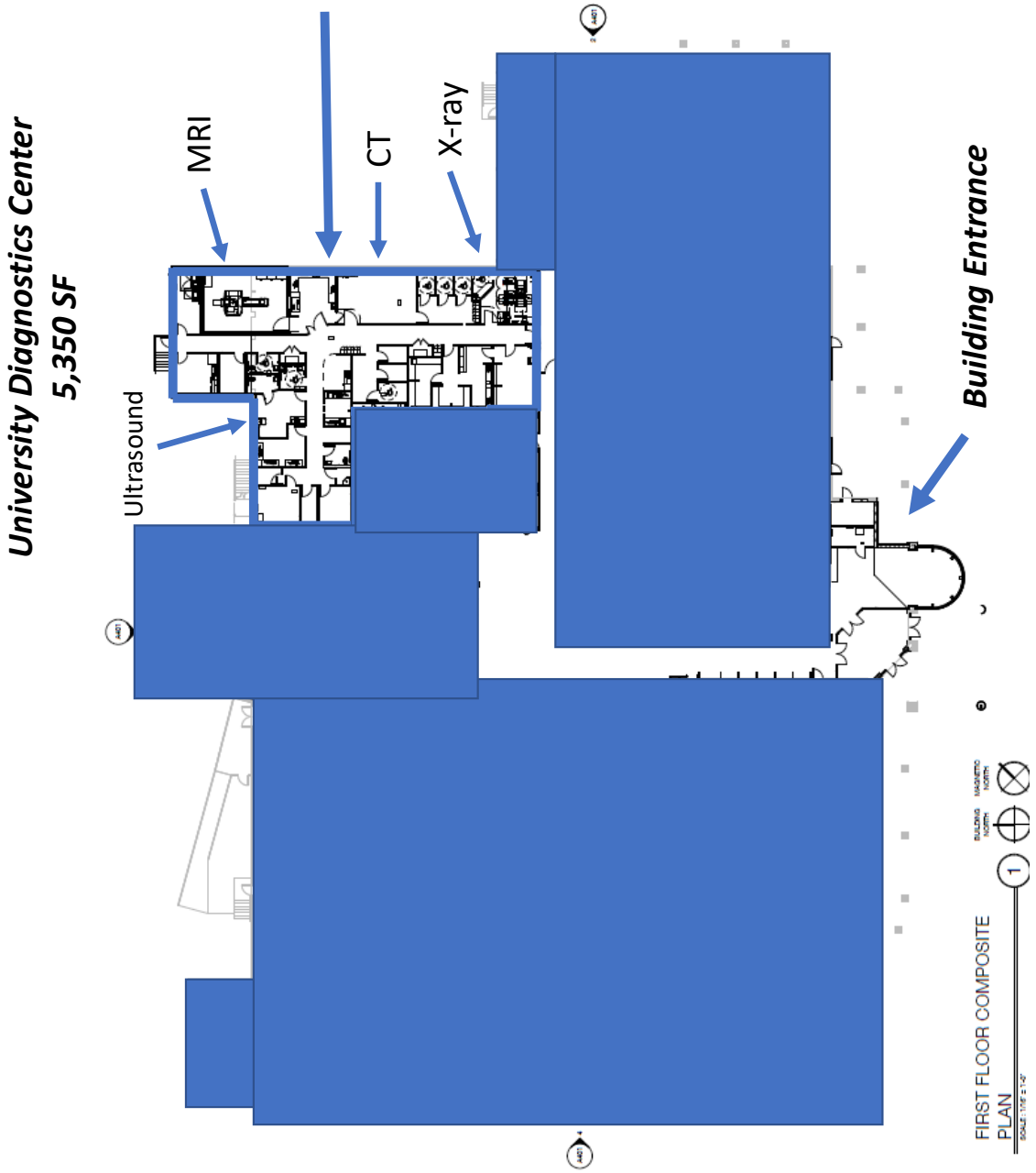
Witness my hand and official seal at Knoxville, Tennessee this 5th day of August, 2008.

Commission expires: 6-28-2011

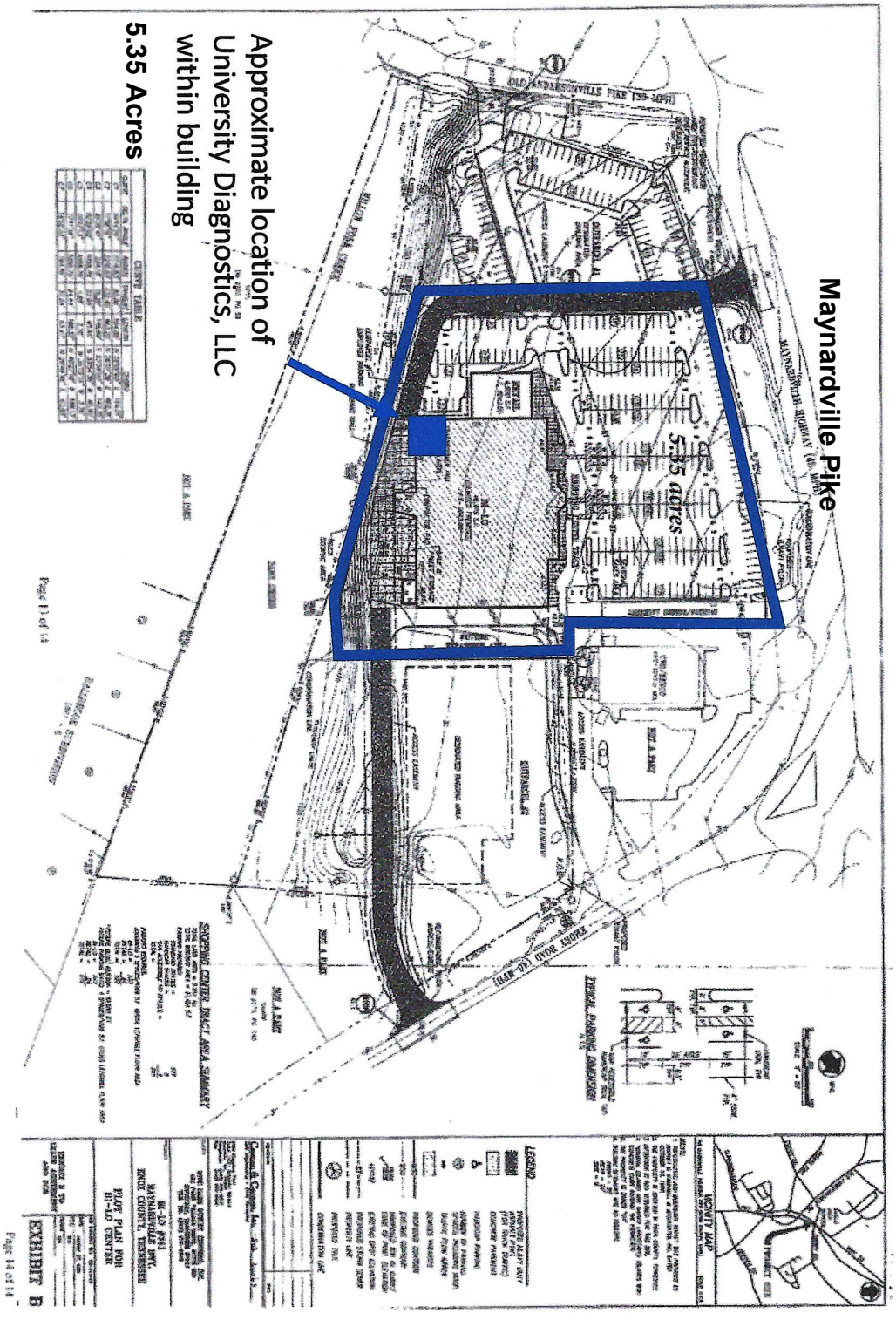
_____
Notary Public

CARLA A. DREITLEIN
STATE OF TENNESSEE NOTARY PUBLIC
Comm. Exp. 6-28-2011
KNOX COUNTY

200808060008953

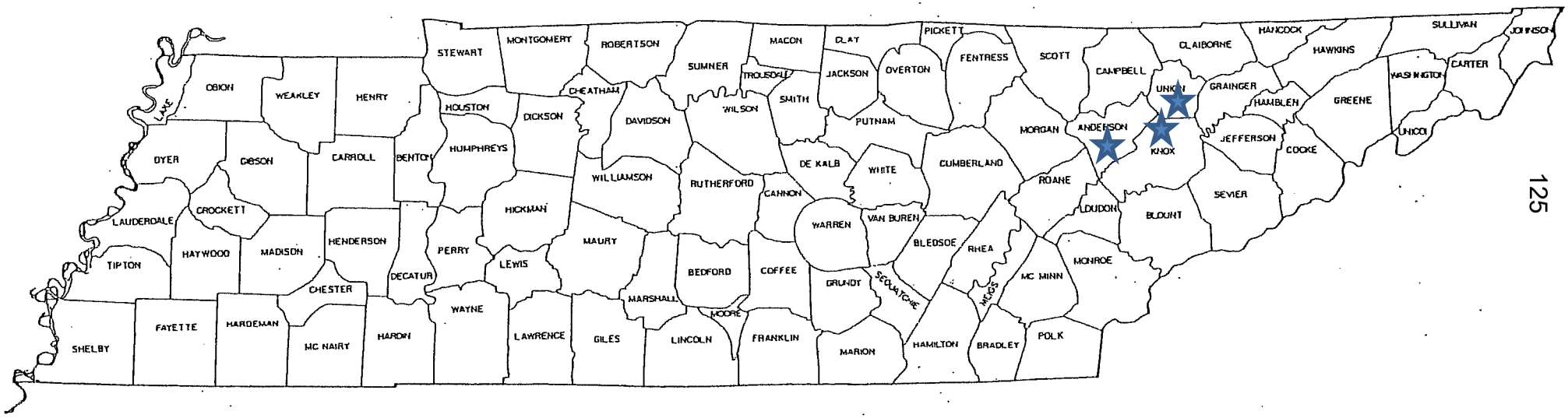


Attachment 10A



Attachment 12A

Service Area for University Diagnostics ODC



Attachment 2N

UTILIZATION OF MRIs IN THE PSA 2019-2021

County	Provider Type	Provider	Year	Number of FTE Units	Total Procedures	Scans per Unit in 2021	Total Gross Charges	Avg. Gross Charge in 2021
Anderson	HOSP	Methodist Medical Center - Oak Ridge	2019	2	5942		$12,560,077.00	
Anderson	HOSP	Methodist Medical Center - Oak Ridge	2020	2	4806		$10,276,991.00	
Anderson	HOSP	Methodist Medical Center - Oak Ridge	2021	2	5372	2686	$11,685,103.00	$2,175.19
Anderson	PO	OrthoTennessee - Anderson County	2019	1	433		$350,799.00	
Anderson	PO	OrthoTennessee - Anderson County	2020	1	349		$257,381.00	
Anderson	PO	OrthoTennessee - Anderson County	2021	1	9	9	$6,809.00	$756.56
Anderson	PO	Tennessee Orthopaedic Clinics - Oak Ridge	2019	1	846		$0.00	
Anderson	PO	Tennessee Orthopaedic Clinics - Oak Ridge	2020	1	701		$0.00	
Anderson	PO	Tennessee Orthopaedic Clinics - Oak Ridge	2021	1	954	954	$1,133,342.00	$1,187.99
Knox	RPO	Abercrombie Radiology	2019	1	2663		$0.00	
Knox	RPO	Abercrombie Radiology	2020	1	2427		$0.00	
Knox	RPO	Abercrombie Radiology	2021	1	2857	2857	$0.00	N/A
Knox	PO	Ancillary Services, Summit Medical Group	2019	1	3009		$3,057,927.00	
Knox	PO	Ancillary Services, Summit Medical Group	2020	1	2781		$2,103,048.00	
Knox	PO	Ancillary Services, Summit Medical Group	2021	1	3207	3207	$2,041,908.00	$636.70
Knox	PO	Ancillary Svcs-Summit Medical Group-Midlake	2019	1	2807		$2,875,707.00	
Knox	PO	Ancillary Svcs-Summit Medical Group-Midlake	2020	1	2777		$2,106,957.00	
Knox	PO	Ancillary Svcs-Summit Medical Group-Midlake	2021	1	3069	3069	$1,971,860.00	$642.51
Knox	HODC	Covenant Health Diagnostic Center West	2019	1	762		$1,643,846.00	
Knox	HODC	Covenant Health Diagnostic Center West	2020	1	576		$1,284,539.00	
Knox	HODC	Covenant Health Diagnostic Center West	2021	1	486	486	$1,081,781.00	$2,225.89
Knox	HOSP	East Tennessee Children's Hospital	2019	1	3649		$11,964,105.00	
Knox	HOSP	East Tennessee Children's Hospital	2020	1	3363		$11,845,921.00	
Knox	HOSP	East Tennessee Children's Hospital	2021	1	3762	3762	$15,983,933.00	$4,248.79
Knox	ODC	East Tennessee Community Open MRI, LLC	2019	2	4126		$3,015,074.00	
Knox	ODC	East Tennessee Community Open MRI, LLC	2020	2	3801		$3,054,202.00	
Knox	ODC	East Tennessee Community Open MRI, LLC	2021	2	4118	2059	$2,944,360.00	$715.00
Knox	HOSP	Fort Sanders Regional Medical Center	2019	2	9378		$19,887,330.00	
Knox	HOSP	Fort Sanders Regional Medical Center	2020	2	8606		$18,191,976.00	
Knox	HOSP	Fort Sanders Regional Medical Center	2021	2	9125	4563	$19,757,567.00	$2,165.21
Knox	PO	Knoxville Comprehensive Breast Center	2019	2	2640		$5,161,309.00	
Knox	PO	Knoxville Comprehensive Breast Center	2020	2	2566		$0.00	
Knox	PO	Knoxville Comprehensive Breast Center	2021	2	2675	1338	$0.00	N/A
Knox	HOSP	North Knoxville Medical Center	2019	1	4605		$20,943,193.00	
Knox	HOSP	North Knoxville Medical Center	2020	1	5808		$0.00	
Knox	HOSP	North Knoxville Medical Center	2021	1	4141	4141	$22,932,391.59	
Knox	PO	OrthoTennessee - Knox County	2018	2	6536		$5,749,905.00	
Knox	PO	OrthoTennessee - Knox County	2019	2	7769		$6,077,537.00	
Knox	PO	OrthoTennessee - Knox County	2020	2	8252		$5,989,470.00	
Knox	PO	OrthoTennessee - Knox County	2021	2	9252	4626	$6,710,687.00	$725.32
Knox	ODC	Outpatient Diagnostic Center of Knoxville	2019	2	7420		$10,118,327.00	
Knox	ODC	Outpatient Diagnostic Center of Knoxville	2020	2	8909		$12,094,456.00	
Knox	ODC	Outpatient Diagnostic Center of Knoxville	2021	2	11254	5627	$15,590,754.00	$1,385.35
Knox	HOSP	Parkwest Medical Center	2019	2	8273		$18,036,081.00	
Knox	HOSP	Parkwest Medical Center	2020	2	7907		$17,438,486.00	
Knox	HOSP	Parkwest Medical Center	2021	2	9863	4932	$21,635,568.00	$2,193.61
Knox	PO	Tennessee Orthopaedic Clinics - Parkwest MRI	2019	1	4561		$0.00	
Knox	PO	Tennessee Orthopaedic Clinics - Parkwest MRI	2020	1	4306		$0.00	
Knox	PO	Tennessee Orthopaedic Clinics - Parkwest MRI	2021	1	4696	4696	$5,748,847.00	$1,224.20
Knox	PO	Tennessee Orthopaedic Clinics - Regional MRI	2019	1	1177		$0.00	
Knox	PO	Tennessee Orthopaedic Clinics - Regional MRI	2020	1	944		$0.00	
Knox	PO	Tennessee Orthopaedic Clinics - Regional MRI	2021	1	1022	1022	$1,189,564.00	$1,163.96
Knox	HOSP	Turkey Creek Medical Center	2019	1	3265		$0.00	
Knox	HOSP	Turkey Creek Medical Center	2020	1	2826		$0.00	
Knox	HOSP	Turkey Creek Medical Center	2021	1	3100	3100	$17,279,007.94	$5,573.87
Knox	HOSP	University of Tennessee Medical Center	2019	5	23662		$83,318,012.00	
Knox	HOSP	University of Tennessee Medical Center	2020	5	21846		$77,561,428.00	
Knox	HOSP	University of Tennessee Medical Center	2021	5	20342	4068	$72,883,099.00	$3,582.89
Total/Avg. for Most Recent Year (2021)				29	99,304	3424	$197,644,189.94	$2,078.08
Average gross charge calculation does not include total procedures of providers who did not report total gross cahrges in 2021								
Source: HFC Medical Equipment Registry - 7/18/2022								

Attachment 5NR

TRANSFER AGREEMENT

In consideration of the needs of the residents of the area served by both institutions named herein, this Agreement is entered into as of this 23rd day of September, 2021. ("Effective Date") by and between, University Diagnostics, LLC ("Transferring Facility") and University Health System, Inc., d/b/a The University of Tennessee Medical Center ("Receiving Facility"), each of which herein may be individually referred to as "Party" or collectively as "Parties."

WHEREAS, the Parties are health care facilities serving the health care needs of the residents of their respective service areas; and

WHEREAS, Transferring Facility may, from time to time, require the services of the Receiving Facility to assist with the provision of health care services to the patients served by Transferring Facility;

NOW, THEREFORE, in consideration of the promises herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1.0 Under this Agreement, the Receiving Facility will provide treatment and hospitalization for patients of the Transferring Facility when said patients require acute inpatient services, on the conditions set forth in this Agreement. Neither Transferring Facility nor Receiving Facility shall make any decision regarding the transfer or reception of a patient in a discriminatory, arbitrary or capricious manner, or in the case of an emergency, on the basis of a patient's insurance status or other ability to make payment. However, this shall in no way require either Party to accept nonemergent patients for transfer when the Receiving Facility is not in patient's managed care organization's ("MCO") provider network ("Network") or for whom the Receiving Facility cannot work out other arrangements with MCO, provided however that there is a facility which is in Network that is willing to accept patient.

2.0 This Agreement shall be governed by, and services performed hereunder shall be provided in a manner consistent with, Tennessee and applicable Federal laws and/or regulations, without regard to principles of conflicts of law. This includes, but is not limited to, the provisions of the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 USCA §1395dd; Tennessee law regarding patient transfer, TCA 68-11-701-705; EMTALA regulations, 42 CFR 489.24; and Tennessee regulation governing patient transfers, Tenn. Reg. §1200-8-1-.05. This provision shall survive the termination of this Agreement.

3.0 The Transferring Facility assumes responsibility for assuring that the patient is transferred using the appropriate method of transportation and is accompanied by the appropriate personnel and equipment during the transfer. The Transferring Facility assumes responsibility for arrangements for and cost of such transportation, personnel and equipment.

4.0 The Transferring Facility shall ensure that the relevant portions of patient's medical record and other relevant information needed to continue the care of the patient are sent with the patient on transport.

5.0 The Receiving Facility agrees to accept the patient for prompt evaluation and, within its capabilities and resources, provide care as indicated after acceptance of patient by a physician at Receiving Facility, contingent upon available space, personnel and resources. The Transferring Facility shall bear no responsibility for the care and treatment provided to any patient after arrival at the Receiving Facility. The Receiving Facility shall bear no responsibility for the care and treatment provided to any patient prior to the arrival at the Receiving Facility.

6.0 It is agreed that services rendered by the Receiving Facility or the Transferring Facility shall be charged to the patient and that neither shall be held responsible for payment of services rendered to the patient by the other. The Parties shall cooperate in the provision of the information for each Party to bill for the services provided by them. Each Party will use its best efforts to abide by all policies, regulations and contractual obligations with regard to billing patients and/or third party payors for services it performs.

7.0 Upon determination by appropriate medical personnel of Receiving Facility that a patient transferred from the Transferring Facility has been stabilized, no longer has an emergency medical condition or no longer requires the specialty services provided at the Receiving Facility, but that the patient does require further hospitalization, Transferring Facility agrees to facilitate identification of an appropriate physician to accept the patient.

8.0 The Parties agree to promptly notify each other in writing of any incident, occurrence, or claim arising out of or in connection with the transfer or medical treatment of a patient transferred under the Agreement and to cooperate with each other in any investigation of said incident, occurrence, or claim.

9.0 Nothing contained in this Agreement shall be construed or deemed to create a relationship of employer and employee, principal and agent, insured and insurer, partnership, joint venture, or any other relationship other than that of independent parties, contracting with each other solely to carry out the purposes recited in the Agreement.

10.0 Both Parties agree to maintain adequate liability coverage to cover themselves, their employees, contractors and agents from any and all liability arising out of or related to the services provided pursuant to this Agreement including, but not limited to, general and professional liability coverage. However, this provision shall not be construed so as to prohibit the Parties from fulfilling this obligation with various programs of insurance, self-insurance and/or self-insured retention. This obligation shall survive the expiration or termination of this Agreement for any reason.

11.0 The term of this Agreement shall begin on the Effective Date and remain in effect until terminated in accordance with this Agreement. Either Party may terminate this Agreement upon thirty (30) days written notice to the other Party. This Agreement may be terminated at anytime upon mutual written consent of the Parties. This Agreement shall automatically terminate should either party fail to maintain licensure or certification as provided by law or regulation.

12.0 Both Parties acknowledge that they will have access to confidential protected health information ("PHI") including, but not limited to, patient identifying information. The parties acknowledge that their performance under this Agreement must comply with the Health Information, as codified at 42 U.S.C. 1320d ("HIPAA"), the Health Information Technology Act of 2009, as codified at 42 U.S.C.A. prec 17901 ("HITECH Act"), and any current and future regulations promulgated under HIPAA or the HITECH Act (HIPAA, HITECH Act and any current and future regulations promulgated under either are collectively referred to as the "Regulations"). Each Party warrants that it is familiar with the requirements of the Regulations and will comply with all the Regulations in connections with their respective performance under this Agreement. The Parties will each cooperate with the respective privacy officials and other compliance officers of the other Party as necessary for both Parties to comply with the Regulations and will sign any documents that are reasonably necessary to maintain compliance with the Regulations.

13.0 This Agreement is intended solely for the benefit of UTMC and Facility. All other parties, named or unnamed in this Agreement, shall have no rights or remedies under this Agreement.

14.0 If any provision of this Agreement is held to be illegal or invalid for any reason, such illegality or invalidity shall not affect the remaining portions of this Agreement unless such illegality or invalidity prevents accomplishment of the goals, objectives, or purposes of the Agreement.

15.0 Any waiver of past breach, default, deficient performance or otherwise, even on multiple occasions, shall not be considered as a waiver of any rights or remedies at law or equity in any future circumstance regardless of similarity to past instances.

16.0 Until the expiration of four (4) years after the furnishing of services pursuant to this Agreement or any greater length of time as may be required by applicable federal statute or regulation, the Parties shall make available

upon written request from the other Party or the Secretary of the United States Department of Health and Human Services, or upon request of the Comptroller General of the United States or any of their duly authorized representatives, this Agreement and books, documents, and records of that are necessary to certify the nature and extent of costs and services provided under this Agreement.

17.0 The Parties enter into this Agreement with the intent of conducting their relationship in full compliance with applicable state, local and federal law, including the Medicare/Medicaid anti-kickback/Fraud and Abuse provisions. Notwithstanding any unanticipated effect of any provisions herein, neither Party will intentionally conduct itself under the terms of this Agreement in a manner to constitute a violation of said statutes.

18.0 Each Party represents and warrants to the other Party that neither it nor its officers, directors and employees (i) are currently excluded, debarred, or otherwise ineligible to participate in the federal health care programs as defined in 42 USC § 1320a-7b(f) (the "Federal Healthcare Programs") or any state healthcare programs; (ii) have been convicted of a criminal offense related to the provision of healthcare items or services or excluded, debarred, or otherwise declared ineligible to participate in the Federal Healthcare Programs or any state healthcare programs; and (iii) are, to the best of its knowledge, under investigation or otherwise aware of any circumstances which may result in it being excluded from participation in the Federal Healthcare Programs or any state healthcare programs. This shall be an ongoing representation and warranty during the term of this Agreement and each Party shall immediately notify the other of any change in the status of the representations and warranty set forth in this section. Any breach of this section shall give a Party the right to terminate this Agreement immediately for cause.

19.0 Any requirements imposed under applicable law or regulation as in effect from time to time, shall, where inconsistent with any provision of this Agreement, be controlling and shall govern rights of the Parties hereto. Any such provisions under applicable law or regulation which will supersede or invalidate any provisions hereof shall not affect the validity of this Agreement and the remaining provisions hereof, unless such a change would prevent the accomplishment of the objectives and purposes of this Agreement as set forth herein.

20.0 No revision in or amendment to this Agreement shall be valid unless such revision or amendment is in writing and executed by all Parties hereto.

IN WITNESS WHEREOF, the Parties have entered into this Agreement to be effective as of Effective Date.

UNIVERSITY DIAGNOSTICS, LLC

BY: W. David Hall

NAME: W. David Hall

DATE: 9/23/21

UNIVERSITY HEALTH SYSTEM, INC.

BY: _____

NAME: J. Ryan Shearer

DATE: 9/23/21

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Knox

Benjamin M. Cunningham, Jr., being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

SIGNATURE/TITLE

Sworn to and subscribed before me the 22nd day of July, 2022 a Notary Public for Knox County, Tennessee.

NOTARY PUBLIC

My commission expires 6/27/23.

TRACEY J. WHITT
STATE OF TENNESSEE NOTARY PUBLIC
Comm. Exp. 6-27-2023
KNOX COUNTY

Supplemental 1
August 8, 2022

RESPONSES TO SUPPLEMENTAL QUESTIONS

CERTIFICATE OF NEED APPLICATION

FOR

UNIVERSITY DIAGNOSTICS, LLC

Establishment of an Outpatient Diagnostic Center
and the Initiation of MRI Services

In the Halls Area of Knoxville,
Knox County, Tennessee

Project No. CN2207-031

August 8, 2022

Contact Person:

Jerry W. Taylor, Esq.
Thompson Burton, PLLC
6100 Tower Circle, Suite 200
Franklin, Tennessee 37067
615-716-2297

Responses to Supplemental Questions
University Diagnostics, LLC
CN2207-031

1. Attachment Medical Equipment

Please complete the attachment located at the following web address for the MRI that will be part of the proposed ODC.

https://www.tn.gov/content/dam/tn/hsda/documents/HSDA_CON_Attachment-MedEquip.pdf

The completed form is attached following this response.

Supplemental 1
August 8, 2022

Attachment - MRI, PET, and/or Linear Accelerator

1a. For Magnetic Resonance Imaging (MRI) in a county with a population less than 175,000, describe the initiation of MRI services or addition of MRI scanners as part of the project, or

1b. For Magnetic Resonance Imaging (MRI) in a county with a population greater than 175,000, describe the initiation of MRI services or addition of MRI scanners as part of the project if more than 5 patients per year under the age of 15 will be treated, and/or

2. Describe the acquisition of any Positron Emission Tomography (PET) scanner that is adding a PET scanner in counties with population less than 175,000 and/or

3. Describe the acquisition of any Linear Accelerator if initiating the service by responding to the following:

A. Complete the chart below for acquired equipment.

☐ Linear Accelerator	Mev _____ Types: ☐ SRS ☐ IMRT ☐ IGRT ☐ Other _____ Total Cost*: _____ ☐ New ☐ Refurbished	☐ By Purchase ☐ By Lease Expected Useful Life (yrs) ___ ☐ If not new, how old? (yrs) _____
X MRI	Tesla: 1.5 Magnet: ☐ Breast ☐ Extremity ☑ Open ☐ Short Bore ☑ Other _____ Total Cost*: $1,268,921 ☑ New ☐ Refurbished	☑ By Purchase ☐ By Lease Expected Useful Life (yrs) 5-10 ☐ If not new, how old? (yrs) _____
☐ PET	☐ PET only ☐ PET/CT ☐ PET/MRI Total Cost*: _____ ☐ New ☐ Refurbished	☐ By Purchase ☐ By Lease Expected Useful Life (yrs) ___ ☐ If not new, how old? (yrs) _____

* As defined by Agency Rule 0720-9-.01(4)(b)

B. In the case of equipment purchase, include a quote and/or proposal from an equipment vendor. In the case of equipment lease, provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments along with the fair market value of the equipment. **A copy of the quote is attached**

C. Compare lease cost of the equipment to its fair market value. Note: Per Agency Rule, the higher cost must be identified in the project cost chart. **N/A**

D. Schedule of Operations:

Location	Days of Operation (*Sunday through Saturday*)	Hours of Operation (*example: 8 am – 3 pm*)
Fixed Site *(Applicant)*	Monday-Friday	8am-5pm
Mobile Locations *(Applicant)*		
(Name of Other Location)		
(Name of Other Location)		

Supplemental 1
August 8, 2022

COMPANY GLN: Purchase Order: 30335823-0-4 REVISION

UNIVERSITY HEALTH SYSTEM, INC Page: 1
Revision Number: 001 Date: 11/08/21

SHIP TERMS: SHIP 3RD PARTY FX 1480-6302-8 FREIGHT: OPTI FREIGHT CO
SHIP VIA: FEDEX 3RD PT

VENDOR: 801-P002
SIEMENS MEDICAL SYSTEMS
CUST# 3994
51 VALLEY STREAM PARKWAY
MALVERN PA 19355

SHIP TO:
UNIVERSITY HEALTH SYSTEM INC
1924 ALCOA HIGHWAY
WAREHOUSE - RECEIVING DOCK
KNOXVILLE TN 37920

CONTACT: CUSTOMER SERVICE
PHONE: 1-888-665-4540
FAX: 1-866-486-3602

CONTACT: Jamie Wheeler
PHONE: (865) 305-9212
FAX: (865) 305-6779
BUYER GLN:
EMAIL ADDRESS: jwheeler@utmck.edu

TERMS	DISCOUNT DAYS	RATE	NET	ACCOUNT NUMBER
NET 30			30	

Deliver on November 29, 2021 unless specified by line
Purchase Order Currency: US DOLLARS

Invoice by mail
Process Level: UTMCK
QUOTE# CPQ-222720

Bill To Address:

University Health System
PO Box 32849
Knoxville TN 37930
United States of America

LINE	ITEM NUMBER / DESCRIPTION	QUANTITY / PRICE	EXTENDED AMOUNT
1	CPQ-222720	1.00 EA	1,268,921.00
	MR MAGNETOM ALTEA - SYSTEM	1,268,921.00	
	Vendor Item Number: SEE QUOTE FOR DETAILS		
	Vendor Item Desc:		

Purchase Order Summary

Goods Total:	1,268,921.00
Order Total:	1,268,921.00

End of Purchase Order: 30335823-0-4

11/8/21

Supplemental 1
August 8, 2022

SIEMENS

Medical Solutions USA, Inc

Name: Robert Ferrero
Zone Finance Vice President, Southeast
4800 North Point Parkway
Alpharetta, GA 30022

Tel.
Fax. +1 (770) 369-8232
Mobile +1 (610) 551-3795
E-mail Robert.ferrero@siemens.com

Date: September 30, 2020

UNIVERSITY HEALTH SYSTEM INC
1924 ALCOA HWY
KNOXVILLE, TN 37920

At your request and for your convenience, Siemens Healthineers has prepared this executive agreement (the **"Executive Agreement"**), dated September 30, 2020 (the **"Effective Date"**) in order to bind the parties to multiple, non-cancellable equipment quotations and/or service proposals (each, as listed below with the accurate revision number, a **"Quotation"**, and collectively the **"Quotations"**).

By executing this Agreement, CUSTOMER hereby represents that (i) it has received and reviewed each individual Quotation and the terms and conditions therein; (ii) accepts and agrees to be bound by each individual Quotation and the terms and conditions contained therein; (iii) each Quotation has been accepted without modification or addition, except where expressly agreed to by the parties; and (iv) agrees to forego executing each individual Quotation and to execute this Agreement as a substitution for signature for each individual Quotation.

Equipment Quotation # (w/ Revision #)	Equipment Quotation Description	Equipment Quotation Amount
CPQ-222018 v0	CT – go.Top	$465,000
CPQ-222057 v0	US – Sequoia	$138,000
CPQ-222744 v0	XPWH – Revelation	$285,000
CPQ-226213 v0	XP – Fusion Max	$185,000
CPQ-222476 v0	MI – Symbia Evo	$286,525
CPQ-222720 vo	MR - Altea	$1,171,134
TOTAL		**$2,530,659**

Pricing is contingent on Customer signing Siemens Service Agreements on each unit prior to the Parties executing the Last Call to Manufacture Letter.

To show their agreement to these terms and intending to be legally bound by this Executive Agreement and the individual Quotations referenced herein, the parties hereby execute this Executive Agreement as of the Effective Date.

Siemens Medical Solutions USA, Inc.

By: _____
Name: Robert Ferrero
Title: _____
Date: Digitally signed by Ferrero Robert Date: 2020.09.30 16:13:56 -04'00'

UNIVERSITY HEALTH SYSTEM INC

By: _____
Name: Ron Collins
Title: VP, Supply Chain
Date: 9/30/2020

Confidential

SIEMENS Healthineers

CONTRACT ADDENDUM
November 03, 2021

Sales Agreement Quotation CPQ-222720 for UNIVERSITY HEALTH SYSTEM INC, Siemens Sales Order Number 30241020, Purchase Order Number NP CPQ-222720, for a MAGNETOM Altea system

This Addendum shall become part of the Sales Agreement CPQ-222720 (equipment) between Siemens Medical Solutions USA, Inc. ("Siemens") and UNIVERSITY HEALTH SYSTEM INC (Customer). If there is any conflict between the terms of this Addendum and the terms of Agreement, the terms of this Addendum shall control. Capitalized terms used herein and not otherwise defined herein, unless the context otherwise requires, shall have the same meanings set forth in the Agreement.

This Addendum is valid for 60 days from date of issuance.

Customer proposes to make the following changes to quote:

Add part(s):
2x 14416972 : Tim Coil Interface 1.5T
1x 14436665 : 2/10/16ch Sentinelle BreastCoil #Ae

The contract total will change from $1,171,134 to $1,268,921.

Please sign below and revise your Purchase Order to account for proposed changes and the new Sales Agreement contract total. This Contract Addendum is specific to the Sales Agreement referenced above. Other Sales Agreements may be referenced and included on your Purchase Order that are not impacted by this Contract Addendum.

Customer must, where applicable, fully and accurately report any change in the net price of this purchase in the applicable cost reporting mechanism or claim for payment filed with the U.S. Department of Health and Human Services (DHHS) or a state agency and must provide, upon request of the Secretary of the DHHS or state agency, the information contained in the Contract Addendum.

If your organization does not plan to issue a revised Purchase Order based on the financial changes outlined in this Contract Addendum, please initial here indicating your agreement to pay the adjusted final invoice based on the terms and conditions of the original agreement pc.

Siemens Medical Solutions USA, Inc.

By (sign): _____
Name: Stuart Clarkson
Title: Area Vice President
Date: November 03, 2021

UNIVERSITY HEALTH SYSTEM INC

By (sign): _____
Name: Ron Collins
Title: VP-Supply Chain
Date: 11/8/21

Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard
Malvern, PA 19355-9998
USA

Phone: +1-888-826-9702
usa.siemens.com/healthcare

2. Item 7A., Ownership

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

A copy of the Active Status verification from the Secretary of State is attached following this response.

Supplemental 1
August 8, 2022

Tre Hargett
Secretary of State

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

Filing Information

Name: **University Diagnostics, LLC**

General Information

SOS Control #	**001241875**	Formation Locale:	DELAWARE
Filing Type:	Limited Liability Company - Foreign	Date Formed:	09/07/2021
	09/27/2021 3:43 PM	Fiscal Year Close	12
Status:	Active	Member Count:	3
Duration Term:	Perpetual		
Managed By:	Member Managed		

Registered Agent Address
BENNETT L. COX
STE 300
2121 MEDICAL CENTER WAY
KNOXVILLE, TN 37920-3282

Principal Address
STE 300
2121 MEDICAL CENTER WAY
KNOXVILLE, TN 37920-3282

The following document(s) was/were filed in this office on the date(s) indicated below:

Date Filed	Filing Description	Image #
03/03/2022	2021 Annual Report	B1171-4329
09/27/2021	Initial Filing	B1098-7744

Record Status Changed From: Pending Review To: Active

Active Assumed Names (if any)	Date	Expires

3. Item 9A., Legal Interest in the Site

The attached Lease Agreement (Attachment 9A Part 2) is not signed by the landlord, Halls Centre LLC. Please provide a fully executed signed copy of the Lease Agreement.

A fully executed copy of the Lease Agreement is attached following this response.

LEASE AGREEMENT

THIS LEASE AGREEMENT (this "Lease"), is made and entered as of the date of the last party to execute this Lease (the "Effective Date"), by and between **HALLS CENTRE LLC,** a Tennessee limited liability company and or its assigns ("Landlord") and **UNIVERSITY HEALTH SYSTEM, INC.**, a Tennessee nonprofit corporation ("Tenant").

WITNESSETH:

WHEREAS, Landlord owns certain real property (the "Land") consisting of approximately 6.94 acres located at or about 7326 Maynardville Pike, Knoxville, Tennessee 37938 and having Knox County Tax ID of 038 13502 as shown in Exhibit A attached hereto, together with the building constructed thereon consisting of approximately 52,976 +/- square feet (the "Building"); and

WHEREAS, Landlord has agreed to lease to Tenant and Tenant has agreed to lease from Landlord a portion of the Building consisting of approximately 46,202 +/- square feet together with the non-exclusive use of the Land in common with other tenants of the Building (if any) upon the terms and conditions hereinafter set forth; and

WHEREAS, it is the desire of both parties, Landlord and Tenant, to reduce the terms of their agreement to writing.

NOW, THEREFORE, for and in consideration of the mutual covenants, agreements representations and warranties set forth herein, and for other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. PREMISES AND TERM.

1.1 Premises. Landlord hereby leases to Tenant, and Tenant hereby leases and accepts, subject to the terms and conditions of this Lease, the medical office space containing approximately 46,202 +/- square feet together with the non-exclusive use of the Land and all easements and rights thereto (collectively, the "Premises"). The parties acknowledge and agree that the Tenant shall be performing the Tenant Improvements (as defined herein) to the Premises which may or may not change the actual or rentable number of square feet within the Premises and that the Rent due from and payable by Tenant hereunder shall not be modified (up or down) based on the actual or rentable number of square feet within the Premises.

1.2 Term. Subject to the terms, covenants and conditions herein, the term of this Lease shall commence on the earlier of (the "Commencement Date"): (i) the date that is one (1) year following the date on which Landlord delivers the Premises to Tenant in substantial conformity with Exhibit B or (ii) the date on which Tenant commences operations within the Premises and said term shall continue for a period of Ten (10) years, unless earlier terminated pursuant to the terms of this Lease (herein referred to as the "Initial Term"). Thereafter, provided that there is no Tenant Default (as defined in Section 9.1 below), Tenant may extend the Initial Term for up

to two (2) additional, consecutive terms of five (5) years each (each a "Renewal Term") upon the same terms herein, except for the Base Rent, which shall be determined as set forth in Section 2.1 below. Tenant shall exercise each Renewal Term by providing Landlord written notice of such election not less than one hundred eighty (180) days prior to the end of the Initial Term or the first Renewal Term, whichever is applicable. As used herein, the term "Lease Year" means a period of twelve (12) consecutive calendar months beginning on the Commencement Date. The Initial Term and the Renewal Term(s) are collectively referred to as the "Term".

2. **RENT.**

2.1 Base Rent. During the term of the Lease, from and after the Commencement Date (as defined above) Tenant shall pay Landlord base rent ("Base Rent") as set forth below together with the Additional Rent as defined below herein (collectively, the Base Rent and the Additional Rent are referred to as "Rent" herein) without set off or demand, except as otherwise expressly provided in this Lease.

Initial Term Lease Year	Annual Base Rent	Monthly Base Rent
1	$1,000,000.00	$83,333.33
2	$1,000,000.00	$83,333.33
3	$1,020,000.00	$85,000.00
4	$1,040,400.00	$86,700.00
5	$1,061,208.00	$88,434.00
6	$1,082,432.16	$90,202.68
7	$1,104,080.80	$92,006.73
8	$1,126,162.42	$93,846.87
9	$1,148,685.67	$95,723.81
10	$1,171,659.38	$97,638.28

The Base Rent payable hereunder during each Lease Year of either the First or Second Renewal Term shall be based upon a fair market value opinion of an independent third party, but in no event shall the annual Base Rent be reduced below $1,000,000.00 per Lease Year. The Tenant shall have the right to request a market rate tenant improvement allowance at the time of exercise which may be agreed upon by Landlord and Tenant and used for permanent improvements to the Premises.

2.2 Security Deposit. *Intentionally Omitted.*

2.3 Late Fee. If Rent is not paid by the tenth (10^{th}) day of the month, a late charge of five percent (5%) per month on the outstanding rental amounts may be assessed by the Landlord and payable by Tenant within ten (10) days after Tenant's receipt of a written notice therefor.

2.4 Additional Rent. Landlord shall reasonably estimate for each calendar year during the Term, Tenant's Proportionate Share (defined herein as 87.21%) of the cost of Landlord's

Insurance (as defined in Section 7.1 below), the Taxes (as hereinafter defined), and the Common Area Maintenance Expenses (as hereinafter defined) (the "Tenant's Estimated Share"). Tenant's Estimated Share shall be divided by 12 and paid in equal monthly installments ("Tenant's Monthly Estimated Share") with each monthly installment of Base Rent. Within one hundred twenty (120) days after the expiration of each calendar year, Landlord shall forward to the Tenant an itemized statement showing the actual amount of the costs of the Landlord's Insurance, the Taxes and the Common Area Maintenance Expenses (the "Tenant's Actual Share"). Should the Tenant's Actual Share, differ from the Tenant's Estimated Share, then either Tenant shall remit to Landlord any amount by which the Tenant's Estimated Share was deficient within thirty (30) days after receiving the itemized statement or Landlord shall refund to Tenant any amount paid in excess of the Tenant's Actual Share simultaneously with its submission of the itemized statement, provided if Landlord fails to pay any excess amount within twenty (20) days after Tenant's receipt of the itemized statement, then Tenant may offset such excess amount against the rent due hereunder until Tenant is reimbursed in full. Landlord shall keep good and accurate books and records of the costs of the Landlord's Insurance, the Taxes and the Common Area Maintenance during the Term in accordance with generally accepted accounting principles, and Tenant or its accountants shall have the right to inspect the same upon thirty (30) days' written notice from Tenant. If any statement of the Tenant's Actual Share previously furnished to Tenant is more than the Tenant's Actual Share shown by an audit, Landlord shall promptly pay the reasonable cost of such audit for the period audited upon its receipt of the audit results. Notwithstanding any such dispute, Landlord shall promptly pay Tenant the amount of any costs of the Tenant's Actual Share shown by such audit to be overpaid by Tenant. The provisions of this paragraph shall survive the expiration or earlier termination of this Lease.

2.4.1 For the purposes of this Lease, "Tenant's Proportionate Share" is hereby deemed to be 87.21%.

2.4.2 For the purposes of this Lease, "Taxes" shall mean all real estate taxes and assessments with respect to the Premises during the Term (excluding federal, state and city income, excess profit, gift, estate, succession, inheritance, franchise and transfer taxes, and any other taxes relating to the operation of Landlord's business, all of which are Landlord's responsibility).

2.4.3 For the purposes of this Lease, "Common Area Maintenance" shall mean all utilities provided to the exterior of the Building/parking lot (if there is a single meter to the Building, then Tenant will pay utilities directly to the provider), the cost of removing trash from the Building/parking lot, the cost of re-sealing and repairing the parking lot, the cost of monitoring, testing and maintaining the sprinkler system for the Building, the costs attributed to the maintenance and repair of the Premises, including painting of the exterior of the Building, landscaping the Land together with a reasonable property management fee not to exceed ten percent (10%) of Tenant's Actual Share.

3. **USE OF PREMISES, USE RESTRICTIONS.**

3.1 Tenant's Use. The Premises shall be used and occupied by Tenant as an outpatient department of the hospital as defined by Centers for Medicare & Medicaid Services ("CMS"), as an independent diagnostic testing facility, medical office or clinic, or other uses related to the operation of any of the foregoing, and for no other use without Landlord's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Tenant shall comply with all rules, regulations and laws of any governmental authority with respect to Tenant's particular use and occupancy of the Premises, as well as any reasonable rules and regulations promulgated by Landlord, provided such reasonable rules and regulations (a) do not materially interfere with the lawful conduct of Tenant in the Premises, (b) have a nondiscriminatory effect, (c) are applied equally to all tenants of the Building and (d) do not increase Tenant's obligations under this Lease.

3.2 Compliance and Restrictions.

3.2.1 Tenant shall not (i) use the Premises or any improvements now or hereafter constructed thereon for the treatment, storage, disposal, burial, or placement of any "hazardous substance", as that term is defined under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as the same may now or hereafter by amended ("CERCLA"), pollutants, contaminants or any other substance, the treatment, storage, disposal, burial or placement of which is regulated under any state, federal or local statute, law, rule, regulation or ordinance, except to the extent that such are reasonably required in the normal practice of any Tenant's medical specialty, and then only to the extent permitted by, and in strict compliance with, applicable law, or (ii) knowingly release, as that term is defined in Section 101(22) of CERCLA, or knowingly permit the release of any hazardous substance, pollutants, contaminants or other substances regulated under applicable federal, state or local statute, rule regulation or ordinance onto the Premises or into the subsurface thereof or into any surface or ground waters unless said use or release is in compliance with all applicable statutes, laws, rules, regulations and ordinances or pursuant to a valid and current permit or permits from all governmental authorities having jurisdiction over the Tenant, the Premises or the use and occupancy of the Premises by Tenant.

3.2.2 Any medical waste generated by Tenant on the Premises shall be segregated and packaged by Tenant as required by applicable laws, rules and regulations, and disposed of by Tenant. Tenant shall comply with all laws relating to the disposal of medical waste. For the purpose of this Lease, medical waste means, without limitation, any substance which, because of its quantity, concentration, or its chemical, radioactive, flammable, explosive, infectious, corrosive, reactive or other characteristics, constitutes or may reasonably be expected to constitute or contribute to a danger or hazard to the public health, safety, or welfare or the environment, all as more fully defined in federal, state and local laws, rules and regulations relating to the disposal of medical waste.

3.3 Signs. Tenant shall not place on any exterior door, wall or window of the Premises any sign or advertising matter without first obtaining Landlord's written approval and consent to such sign, which approval and consent shall not be unreasonably withheld, conditioned or

delayed. Landlord, at Tenant's sole cost and expense, shall provide exterior signage at the Building acceptable to Tenant which identifies Tenant in a prominent fashion. In the event that Landlord constructs a monument sign, at its sole cost and expense, then Tenant shall be able to install signage on the monument sign subject to local codes and ordinances. All signs shall comply with applicable ordinances or other governmental restrictions and the determination of such requirements and the prompt compliance therewith shall be the responsibility of Tenant.

3.4 Utilities. Landlord agrees that the utilities to the Premises will be separately metered. Tenant agrees to pay when due and before delinquent, all charges for Tenant's usage of electric current, gas, sewer, heat, water, telephone, building security/monitoring and all other utilities and all taxes or charges on such utility services which are used on or attributable to the Premises. In no event shall Landlord be liable for any interruption or failure in the supply of any utilities to the Premises unless arising from the negligence or intentional misconduct of Landlord or its agents, contractors or employees. Tenant shall at all times keep the Premises at a temperature sufficiently high to prevent freezing of water pipes and fixtures.

4. LANDLORD'S WORK AND TENANT IMPROVEMENTS; MAINTENANCE AND REPAIRS.

4.1 Landlord and Tenant's Work. Landlord shall deliver the Premises to Tenant in its "As-Is" condition as set forth in Exhibit B (the "Landlord's Work"). Tenant shall at Tenant's sole cost and expense (subject to the reimbursement pursuant to the Tenant Improvement Allowance and the Common Area Improvement Allowance) all of the design, material, labor and equipment required to construct all improvements of the Premises as set forth in Exhibit B (collectively, the "Tenant's Work"). Tenant agrees Tenant's Work will be constructed in a good and workmanlike manner, in accordance with all applicable laws, statutes, ordinances and building codes, governmental rules, regulations and orders relating to the construction of Tenant's Work.

4.2 Tenant's Duty to Repair. Except as may be the responsibility of Landlord pursuant to Section 4.5 below, Tenant shall keep and maintain in good order, condition and repair the interior of the Premises and every part thereof, including, without limitation, the interior portion of all doors, interior windows and plate glass, all plumbing and sewage facilities within the Premises including free flow up to the main sewer line, fixtures, interior walls, floor coverings, ceilings, and fixtures applicable to the interior of the Premises, and all installations made by Tenant under the terms of this Lease and any exhibits thereto, as herein provided. Tenant shall keep and maintain the Premises in a clean, sanitary and safe condition and in accordance with all directions, rules and regulations of the proper official of the government agencies having jurisdiction, at the sole cost and expense of Tenant, and Tenant shall comply with all requirements of law, by statute, ordinance or otherwise, affecting the Premises and all appurtenances thereto. If Tenant does not make any repairs required of Tenant in this Lease within thirty (30) days after its receipt of written notice from Landlord specifying the need of such repair, Landlord may, but shall not be required to, make and complete said repairs and Tenant shall reimburse Landlord for the reasonable cost thereof within a reasonable time after Tenant's receipt of reasonably documented invoice therefor. Tenant shall also allow no nuisance to exist with respect to the Premises.

4.3 Mechanic's Liens. Tenant will not permit any mechanic's lien to be placed on the Premises, or improvements thereon by reason of acts or agreement of Tenant. Nothing in this Lease shall be construed in any way as constituting the consent or request of Landlord to Tenant to contract for, or permit the rendering of, any services or the furnishing of any materials that would give rise to any mechanic's or other liens against the interest of Landlord in the Premises. In the event any such lien is filed, Tenant shall cause it to be discharged of record within thirty (30) days after filing, or shall post a bond or arrange conditional payment, provided any such bond or arrangement is approved by Landlord and their mortgagees.

4.4 Surrender of Premises. At the termination of the Initial Term, or any Renewal Term thereof, Tenant shall deliver the Premises to Landlord in the same condition as received by it on the Commencement Date (subject to the removals hereinafter required), reasonable wear and tear and casualty or condemnation excepted. Tenant shall remove all trade fixtures owned by Tenant (defined as those not installed or purchased by Tenant with the proceeds of the Tenant Improvement Allowance or the Common Area Improvement Allowance), and before surrendering the Premises as aforesaid, shall repair any damage to the Premises caused by removal of such items to the reasonable satisfaction of the Landlord.

4.5 Landlord's Duty to Repair. Landlord, at Landlord's sole cost and expense shall keep and maintain the roof of the Building, the structural portions of the Building (i.e. floor slab (excluding floor coverings), load bearing walls (excluding wall coverings, paint and drywall), the exterior walls of the Building (excluding painting) and the parking lot replacement (excluding ordinary maintenance and repairs which are expressly included as Common Area Maintenance). Tenant shall promptly notify Landlord in writing of the need to perform any maintenance or repairs required hereunder. Notwithstanding the foregoing, it is expressly acknowledged that any repairs or replacement of the roof which are caused by Tenant or Tenant's contractor during the construction of the Tenant's Work shall be repaired or replaced by Tenant.

5. SERVICE.

5.1 Exterior Service. Routine exterior maintenance and repairs and maintenance and repairs to the Common Areas shall be performed by Landlord, at Landlord's expense, and passed through to Tenant as Additional Rent in accordance with Sections 2.4 and 2.4.3 herein. Routine exterior maintenance includes lighting, repairing, and maintaining of the exterior of the Premises, specifically including signage, landscaping and gardening, the maintenance and cleaning of the parking lot, line painting, lighting, removal of snow, trash, rubbish and garbage.

5.2 Janitorial Service. Landlord shall not be required to provide janitorial services for the interior of the Premises.

6. RIGHTS RESERVED.

6.1 Rights Reserved to Landlord. Landlord reserves the following rights on behalf of itself or its agents:

6.1.1 Pass Keys. To have pass keys to the Premises, provided Landlord shall not access the Premises until first providing Tenant with at least forty-eight (48) hours' prior notice. Upon any access to the Premises, Landlord shall make certain it is in compliance with the Health Insurance Portability and Accountability Act and shall minimize any disturbance to Tenant's business operations.

6.1.2 Access for Repairs, etc. Subject to Section 6.1.1 above, to have access for repairs, alterations, additions and improvements to the Premises or to the Building, which shall be accomplished in non-business hours except for emergencies.

7. INSURANCE; INDEMNITY; WAIVER OF SUBROGATION.

7.1 Landlord's Insurance. Landlord shall keep the Premises insured against loss or damage by fire or other casualty to the extent of the full insurable value, thereof, including all improvements, alterations, additions, and changes made to the Building. Landlord agrees to maintain at all times during the Term, commercial general liability insurance naming Tenant as an additional insured in an amount not less than One Million and No/100 Dollars ($1,000,000.00) per person, Two Million and No/100 Dollars ($2,000,000.00) per accident for injuries or damages to persons, and not less than One Hundred Thousand and No/100 Dollars ($100,000.00) for damage to or destruction of property. The insurance Landlord is required to carry under this paragraph shall be referred to in this Lease collectively as the "Landlord's Insurance". Landlord shall deliver to Tenant certificates of the Landlord's Insurance within a reasonable time after Landlord's receipt of a written request therefor.

7.2 Insurance Covering Tenant's Property. Tenant may secure and maintain at its own expense fire and extended coverage insurance insuring Tenant's interest in Tenant's office furniture, equipment, supplies, and other personal property.

7.3 Indemnity. Subject to Section 7.5 below, Tenant shall protect, indemnify and save Landlord harmless from and against all and any liability and expense of any kind, including reasonable attorneys' fees, arising from injuries or damages to persons or property in, on or about the Premises to the extent arising out of or resulting in any way from the negligence or intentional act or omission of Tenant, its agents, contractors or employees during the Term. Landlord shall protect, indemnify and save Tenant harmless from and against all and any liability and expense of any kind, including reasonable attorney' fees, arising from injuries or damages to persons or property in, on or about the Premises arising out of or resulting in any way from any act or omission of Landlord, its agents invitees, servants and employees during the Term.

7.4 Liability Insurance. Tenant agrees to maintain at its expense at all times during the Term commercial general liability insurance naming Landlord as an additional insured in an amount not less than One Million and No/100 Dollars ($1,000,000.00) per person, Three Million and No/100 Dollars ($3,000,000.00) per accident for injuries or damages to persons, and not less than One Hundred Thousand and No/100 Dollars ($100,000.00) for damage to or destruction of Tenant's personal property. Tenant shall deliver to Landlord evidence of such insurance to Landlord within ten (10) days after Tenant's receipt of a written request therefor.

7.5 Waiver of Subrogation. Landlord and Tenant on behalf of themselves and all others claiming under them, including any insurer, waive all claims against each other, including all rights of subrogation, for loss or damage to their respective property (including, but not limited to, the Premises) arising from fire, smoke damage, windstorm, hail, vandalism, theft, malicious mischief and any of the other perils normally insured against in an "all risk" of physical loss policy, regardless of whether insurance against those perils is in effect with respect to such party's property and regardless of the negligence of either party. If either party so requests, the other party shall obtain from its insurer a written waiver of all rights of subrogation that it may have against the other party.

8. FIRE OR OTHER CASUALTY.

8.1 Partial Destruction. In the event of the partial destruction of the Premises by fire or any other casualty that Landlord's contractor reasonably estimates can be repaired within sixty (60) days following the date of such fire or casualty, Landlord shall use its best efforts to restore or repair the Building with reasonable diligence. A just and proportionate part of the rent payable by Tenant, to the extent that such damage or destruction renders the Premises untenantable, shall abate from the date of such damage or destruction until such Premises are repaired or restores.

8.2 Substantial Destruction. If the Premises shall be so damaged by fire or other casualty or happening as to be substantially destroyed, then either Landlord or Tenant shall have the option to terminate this Lease by giving the other party written notice with thirty (30) days after such destruction, and the termination date shall be the date of such fire or other casualty. Following such termination, any unearned rent shall be apportioned and returned to Tenant. If neither party elects to cancel this Lease as aforesaid, then the same shall remain in full force and effect, and the Landlord shall use its best efforts to proceed with all reasonable diligence to repair and replace the Premises to the condition they were in prior to the date of such destruction and, for any period of time the Premises may be rendered untenantable, the rent shall be abated to the same extent.

8.3 Landlord's Duty to Repair. In the event Landlord commences to repair, rebuild or restore the Premises following a fire or other casualty and such repairs, rebuilding or restoration is not completed within one hundred twenty (120) days following the date of such fire or other casualty, Tenant may terminate this Lease within thirty (30) days following such 120-day period by submitting written notice to Landlord, and any unearned rent shall be apportioned and returned to Tenant.

8.4 Right of Termination. Notwithstanding anything else to the contrary contained in this Section 8 or elsewhere in this Lease, Landlord or Tenant, at their option, may terminate this Lease on written notice to the other party given within thirty (30) days after the Premises shall be damaged or destroyed during the last twelve (12) months of the Term so long as Tenant has not already provided Landlord with Tenant's election to exercise a Renewal Term.

9. DEFAULT REMEDIES.

9.1 Events of Default. The occurrence of any of the following acts or events shall constitute events of defaults under this Lease ("Tenant Default"):

9.1.1 Tenant fails to make any payment required hereunder within ten (10) days following Tenant's receipt of written notice from Landlord of nonpayment of Rent;

9.1.2 Tenant fails to fulfill or perform any of Tenant's material covenants, agreements or obligations under this Lease and such failure continues for a period of thirty (30) days following Tenant's receipt of written notice thereof specifying the nature of such failure, provided if such failure cannot reasonably be cured within such 30-day period, then Tenant shall have a reasonable time thereafter so long as Tenant commences such cure within such 30-day period and diligently prosecutes the same through completion; or

9.1.3 If at any time during the Term there shall be filed by or against Tenant, or against any successor tenant then in possession, in any court pursuant to any petition in bankruptcy, alleging an insolvency, for reorganization, for the appointment of a receiver, or for an arrangement under the Bankruptcy Code, or is a similar type of proceeding shall be field and such petition or proceeding is not dismissed within sixty (60) days.

9.2 Landlord's Remedies. Whenever any Tenant Default shall have happened and be subsisting, Landlord may, to the extent permitted by law, take any one or more of the remedial steps, provided Landlord agrees to uses reasonable efforts to mitigate its damages following a Tenant Default:

9.2.1 Landlord may re-enter and take possession of the Premises without terminating this Lease, and lease in their entirety the same for the account of Tenant, holding Tenant liable for the difference in the rent and other reasonable amounts Landlord actually pays to prepare the Premises for such lease.

9.2.2 Landlord may terminate this Lease, exclude Tenant from possession of the Premises, holding Tenant liable for all rent and other amounts payable by Tenant hereunder.

9.2.3 Landlord may take whatever action at law or in equity may appear necessary and desirable to collect the rent and other amounts then due and thereafter to become due or to enforce performance and observance of any obligation, agreement, or covenant of Tenant under this Lease, and in connection with such actions, to recover any or all damages to Landlord for Tenant's violation or breach of this Lease with interest thereon at the then highest lawful rate from the date of payment, plus Landlord's reasonable attorneys' fees and court costs, shall be paid by Tenant to Landlord.

9.3 Landlord Default and Tenant's Remedies. Landlord shall be in default of this Lease in the event Landlord fails to fulfill or perform any of Landlord's material covenants, agreements or obligations under this Lease and such failure continues for a period of thirty (30) days following Landlord's receipt of written notice thereof specifying the nature of such failure, provided if such failure cannot reasonably be cured within such 30-day period, then Landlord shall have a reasonable time thereafter so long as Landlord commences such cure within such 30-

day period and diligently prosecutes the same through completion. In the event of a Landlord default under this Lease, Tenant may terminate this Lease and/or seek any remedies available at law or in equity. Notwithstanding anything to the contrary contained in this Lease, in the event Landlord fails to make repairs required of Landlord that constitute an imminent danger to persons or property or materially interferes with Tenant's business operations within five (5) days after Landlord's receipt of notice specifying such failure, Tenant shall have the right, but not the obligation, to take such action as is reasonably necessary under the circumstances to repair any portion or component of the Premises. To the extent such work performed by Tenant is Landlord's responsibility under this Lease, Landlord shall reimburse Tenant for the cost of the same within twenty (20) days after Landlord's receipt of a reasonably documented invoice therefor. If Landlord fails to reimburse Tenant within such 20-day period, Tenant may offset such amount against rent due hereunder until Tenant is reimbursed in full.

10. **ASSIGNMENT**.

10.1 Assignment and Subletting. Tenant shall not assign, transfer or encumber this Lease without the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, Tenant may, without Landlord's consent, (a) transfer or assign its interest in this Lease by operation of law, merger or otherwise, or sublet or grant any license to use the Premises or any part thereof to any entity that controls, is controlled by or is under common control with Tenant or that directly or indirectly is the legal or beneficial owner of or controls more than 50% of the equity ownership interests of Tenant or in connection with the sale of all or substantially all of Tenant's assets or (b) sublet the Premises, and/or grant any license to use the Premises or any part thereof to any party, but in no event shall Tenant be released from liability hereunder as a result of such assignment or sublease.

11. **NOTICES**.

11.1 All notices to be given by one party to the other under this Lease shall be given in writing, mailed or delivered as follows:

11.2 To Landlord at the following address or to such other address as may be designated in writing:

Halls Centre, LLC
6416 Deane Hill Drive
Knoxville, Tennessee 37919
Attention: John G. Captain

With a copy to:

Joshua B. Bishop, Esq.
Howard & Howard, P.C.
4820 Old Kingston Pike
Knoxville, Tennessee 37919

11.3 To Tenant at the following addresses or to such other address as may be designated in writing:

University Health System, Inc.
2121 Medical Center Way, Suite 330
Knoxville, Tennessee 37920-3282
Attention: Bennett L. Cox, Esq.

With a copy to:

_____
_____
_____

12. **QUIET POSSESSION.**

12.1 Quiet Possession. Landlord warrants that it is lawfully seized and possessed of the Premises, and so long as Tenant shall observe and perform the covenants and agreements binding upon it hereunder, Tenant shall at all times have quiet and peaceful possession of the Premises during the term of this Lease without any hindrance.

13. **CONDEMNATION.**

13.1 Condemnation. If at any time the entire or a substantial part as determined by Landlord or Tenant of the Premises is taken for any public use under any statute or by right of eminent domain or by private purchase in lieu thereof by a body vested with the power of eminent domain, this Lease shall continue until the date of the taking, at which time this Lease shall terminate. In the event the condemnation or purchase takes place but the Premises continues to be tenantable for Tenant's purposes, the rents shall be abated pro-rata, Landlord, at its sole cost and expense, shall restore the Premises to a tenantable condition, and this Lease shall continue otherwise in full force and effect. The termination of this Lease or the abatement of rent by reason of the condemnation or purchase shall be without prejudice to the rights of either Landlord or Tenant to recover compensation and damage caused by the condemnation or taking from the condemnor or taker. Neither Landlord nor Tenant shall have any rights in any award made to the other by reason of such condemnation or taking.

14. **MISCELLANEOUS.**

14.1 Waiver. The failure of Landlord or Tenant to insist upon the strict performance of any of the conditions, covenants, terms or provisions of this Lease, or to exercise any option herein, conferred, shall not be considered or construed as waiving or relinquishing for the future any such conditions, covenants, terms, provisions or options, but the same shall continue and remain in full force and effect.

14.2 Successors. This Lease shall inure to and be binding upon the successors and assigns of Landlord and heirs, administrators, executors, successors and assigns of the Tenant.

14.3 Amendment. All amendments to this Lease shall be in writing and executed by the parties or their respective successors in interest.

14.4 Holding Over. Any holding over after the expiration of the Term with the consent of Landlord shall be construed to be a tenancy from month to month upon the same terms of this Lease, except that the Base Rent shall be increased to an amount equal to 125% of the Base Rent payable hereunder for the immediately preceding Lease Year. Any holding over after the expiration of the Term without the consent of Landlord shall be deemed to be a tenancy at will upon the same terms of this Lease.

14.5 No Partnership. It is understood that Landlord does not, by execution of this Lease, in any way or for any purpose become a partner or joint venture with Tenant in the conduct of Tenant's business.

14.6 Partial Invalidity. If any term or condition of this Lease or the application thereof to any person or event shall to any extent be invalid and unenforceable, the remainder of this Lease and the application of such term, covenant or condition to persons or events other than those to which it is held invalid or unenforceable shall not be affected and each term, covenant and condition of this Lease shall be valid and be enforced to the fullest extent permitted by law.

14.7 Governing Law. This Lease shall be governed by, and construed in accordance with, the laws of the State of Tennessee.

14.8 Attorneys' Fees and Expenses. In the event that either party shall be required to engage legal counsel for the enforcement of any of the terms of this Lease, whether such employment shall require institution of suit or other legal services required to secure compliance on the part of the other party, the non-prevailing party shall be responsible for and shall promptly pay to the prevailing part the reasonable value of said attorneys' fees, and any other expenses incurred as a result of such default.

14.9 Counterparts. This Lease may be executed in two or more counterparts and delivered in electronic, facsimile or original form, and each of which shall constitute an original, but all of which together shall constitute one and the same agreement.

14.10 Brokers. Landlord shall pay Coldwell Banker Wallace and Realty Trust Group (collectively, the "Brokers") a real estate commission pursuant to a separate written agreement executed by Landlord and the Brokers prior to the execution of this Agreement. Tenant represents that there are no other brokers involved in this transaction with the exception of the Brokers defined above.

[*signatures on the following page*]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease as of the day and year of the last party to sign below.

LANDLORD:

HALLS CENTRE, LLC
a Tennessee limited liability company

By: _____
Name: JOHN CAPTAIN
Its: CHIEF MANAGER
Date: 8/20/2020

_____
Witness

TENANT:

UNIVERSITY HEALTH SYSTEM, INC.
a Tennessee nonprofit corporation

By: Wm. David Hall
Name: WM. DAVID HALL
Its: EXECUTIVE VICE PRESIDENT
Date: 8/11/20

_____
Witness

Supplemental 1
August 8, 2022

EXHIBIT A

Attach Layout of the Land

EXHIBIT B

Landlord and Tenant's Work

Landlord's Work

Landlord shall deliver the Premises to Tenant in its As-Is Where Is condition. Notwithstanding the foregoing, Landlord shall apply for a rezoning from "CA" to either "OB" or "OA" and a Sector Plan amendment from "GC" to "MDR/O" or "O" as defined by the Knoxville-Knox County Planning Commission. Landlord shall use its best efforts to have the Land rezoned "OB" but Tenant acknowledges that "OA" zoning is acceptable as an alternative should the Planning Department indicate it cannot support the "OB" rezoning. Additionally, Landlord shall be permitted to continue to utilize the Premises for the storage of fitness and restaurant equipment for sixty (60) days following the delivery of the Premises by Landlord to Tenant.

Landlord will provide Tenant with a Tenant Improvement Allowance in the amount of Six Million Eight Hundred Ninety-Five Thousand Dollars ($6,895,000.00) (the "Tenant Improvement Allowance") for the construction of permanent improvements to the Premises, which improvements shall be the property of Landlord. The Tenant Finish Allowance shall be paid by Landlord to Tenant and Tenant's General Contractor upon the completion of the Tenant's Work (as defined below). Landlord shall provide Tenant with evidence of the availability of the Tenant Improvement Allowance from Landlord's construction lender upon request.

Additionally, Landlord will provide Tenant with a Common Area Improvement Allowance in the amount of Three Hundred Thousand Dollars ($300,000.00) (the "Common Area Improvement Allowance") for the construction of permanent improvements to the Common Areas located on the Land including the replacement of the mechanical systems to the Premises, the replacement of rooftop HVAC units, re-striping, sealing and repair of the parking lot and landscaping upgrades, which improvements shall be the property of Landlord. The Common Area Improvement Allowance shall be paid by Landlord to Tenant and Tenant's General Contractor upon the completion of the Tenant's Work (as defined below). Landlord shall provide Tenant with evidence of the availability of the Common Area Improvement Allowance from Landlord's construction lender upon request. It is specifically acknowledged that Tenant may utilize any portion of the Common Area Improvement Allowance or the Tenant Improvement Allowance to pay for any overages to the Tenant's Work. Following occupancy of Premises and completion of Tenant's Work, any unused balance of such Tenant Improvement Allowance shall be made available to Tenant for use or disbursement at Tenant's discretion. The Tenant shall be solely responsible for the construction of Tenant's Work and in no event shall Landlord be required to contribute more than the Tenant Improvement Allowance and the Common Area Improvement Allowance toward the cost of Tenant's Work.

Tenant's Work

Tenant shall at Tenant's sole cost and expense design, construct and renovate the Premises and Land in accordance with the Plans (as defined below) which when agreed to by Landlord and Tenant shall be incorporated herein as Exhibit B-1 (collectively, "Tenant's Work").

Prior to the commencement of Tenant's Work, Tenant will provide Landlord with the following: 1) a complete set of plans and specifications detailing Tenant's build out of the Premises prepared by an architect licensed in the state of Tennessee (collectively the "Plans"); 2) a copy of Tenant's contract with the architect/engineer who prepared the foregoing plans and specifications; 3) a copy of Tenant's construction contract with the general contractor who must be licensed in the state of Tennessee; 4) a schedule of values/budget detailing Tenant's projected costs and expenses for the buildout of the Premises; 5) a copy of a builder's risk policy naming the Landlord and the Landlord's lender as additional insureds for the construction of the Premises; 6) a copy of the building permit issued by the governing municipality for the Premises and 7) a performance and payment bond provided by Tenant's contractor, in form and substance satisfactory to Landlord, naming Landlord, Landlord's lender and indemnifying said parties from any liens or claims for payment arising from Tenant's work, including attorney's fees and costs. The bond will be issued by a surety reasonably satisfactory to Landlord and will be in an amount at least equal to the value of Tenant's work as reasonably determined by Landlord. Within thirty (30) days after completion of Tenant's construction within the Premises, Tenant shall provide Landlord with the following: 1) a copy of Tenant's certificate of occupancy for the Premises; 2) a lien waiver from Tenant's general contractor together with any sub-contractor which provides $10,000 or more of services or materials to the Premises and 3) a copy of "As-Built" plans denoting any deviations in the original plans for the Premises.

4. Item 1E., Existing Service Providers

Please identify the types of diagnostic services that are available at the Covenant Health Diagnostic Center.

As stated in the application, Covenant Diagnostic Center has no JAR on file, so that information is not publicly available. To the best of the applicant's knowledge after inquiries, the services offered by that ODC are: CT, MRI, Mammography, Dexa (bone density), Fluoroscopy, and X-Ray.

Please relabel the facility identified as Diagnostic Centers of Tennessee as Outpatient Diagnostic Center of Knoxville in table on Page 7 and resubmit (labeled as Page 7R).

Replacement page 7R with the revised table is attached following this response.

5. Item 3N. Demographics

The demographics chart on page 12 is noted. However, it appears that some of the following data may contain errors:

- **Median Household Income – State of TN Total**
- **Number of TennCare Enrollees – Anderson County, PSA Total and State of Tennessee Total. (Assuming the June 2022 TennCare Enrollment Report was the source used by the applicant).**

Please revise and submit a replacement Page 12 (labeled as Page 12R).

A revised population and demographics table incorporating these revisions included on Replacement Page 12R, attached following this response.

6. **Item 5N.**

Please identify the data sources utilized in the development of the table on Page 13 for each column.

The sources for the substantive data columns are:

Patients:	Joint Annual Reports
Total Procedures:	Joint Annual Reports
CT & MRI volume for 2018-2020:	Joint Annual Reports
CT & MRI volume fir 2021:	HFC Equipment Registry

A revised table, which corrects a few minor entry errors in the table and includes utilization data for 2021, is included on Replacement Page 13R, attached following this response.

Please identify the number of MRI and CT units at each facility and any differences in the types of MRI and CT services i.e. (specialty, mobile, open, shared, pediatric, etc.) available at the other service area ODC facilities.

There is not room on the referenced table to include the additional information, so a separate table was created for this purpose. It is found on Replacement Page 13R1, which is attached following this response.

Please include historical utilization X-Ray and Ultrasound utilization of service area ODC facilities in addition to MRI and CT unit utilization.

Please provide a State ID number for each facility.

Both sets of requested data are included in the table found on Replacement page 13R1, attached following this response.

Please provide a map with each existing ODC facility in the service area identified.

A map with the requested information is attached following this response.

7. Item 6N.

Provide the details regarding the methodology used to project utilization for the facility of 6,562 patients in Year One and 7,164 patients in Year Two of the proposed project. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

The historical numbers below are for a 12-month period ending June 30, 2022. They represent the volume of patients residing in Anderson and Union Counties, and in the 7 zip codes closest to the site, who came to the UTMC main campus HOPD imaging center and ODC-Knoxville (owned by OIA, a partner in University Diagnostics) for imaging services.

County	Zip Code	UTMC Patient Volume	ODC Patient Volume	Total Patient Volume
Knox	37721	1,355	360	1,715
Knox	37849	1,875	456	2,331
Knox	37912	2,236	602	2,838
Knox	37917	3,966	845	4,811
Knox	37918	4,497	1,154	5,651
Knox	37924	1,442	461	1,903
Knox	37938	1,567	378	1,945
Anderson	All	2,660	717	3,377
Union	All	1,318	360	1,678
Total		20,916	5,333	26,249

It was assumed 25% of the volume at the existing facilities from this service area would relocate to the new location in Year 1. As a conservative estimate, this methodology does not assume any patient growth from 2021-2022. The conservative assumption that only 25% of existing patients would relocate to the proposed new facility in Year 1 took into consideration factors including: (1) some patients will continue to come to UTMC because they also have other services or procedures being performed; (2) many times patients will choose a location closer to where they work, rather than closer to where they live. Many patients work in the downtown Knoxville area. An approximately 9% growth factor was applied for the Year 2 patient volume, which is reasonable especially in light of the conservative assumptions relied upon to derive the Year 1 projections. A factor of approximately 1.6% was used to convert the number of patients to the number of procedures. This factor was the best estimates of business executives from the two imaging centers.

Of the projected Year One and Year Two patients, what percentage will represent patients that will transfer from existing applicant affiliated facilities and what percentage will be new patients?

It is assumed that all the projected patients will come from existing patients of UTMC and OIA.

Item 2C.

Please clarify if the applicant plans to contract with TennCare Select.

Yes, the intent is to also contract with TennCare Select.

8. Project Completion Forecast Chart

It is noted that building construction is projected to be completed within 2 months. Please address the reasonableness of this timeline given the need to obtain approval of the architectural plans through the Plans Review Section. What is the scope of work required to complete construction of the new ODC facility?

The space was originally intended to be an imaging HOPD of UTMC. The plans were submitted to the DOH for review based on that intent. Later, discussions with OIA and URAD led to the decision to jointly own and operate an ODC. The plans for what was at the time of plan submission an imaging HOPD have already been approved by the DOH. It is not believed the plans will have to be re-reviewed, since the building standards and codes are more stringent for an HOPD than for an ODC. However, if a re-review is necessary, it should be a very expedited review since the plans have already been fully reviewed.

9. Service Specific Criteria, (Outpatient Diagnostic Centers, Item 3.C)
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?

The CT unit is a 128-slice Siemens go.Top. It is an upgraded model of Siemens' successful CT Scanner line with a unique Mobile Workflow and smart tools that allow the technologists to stay with its patients longer and provide closer care. The Siemens go.Top includes many AI-powered scan automations and innovations from Siemens high-end scanners. The go.Top comes with the image quality and dose reduction technologies as well as built-in solutions for lower lifecycle costs. Studies indicate that the go.Top CT line allows for technologists to spend 90% more time in the same room as their patients resulting in a 62% increase in positive patient experiences.

Neither the JARs nor the HFC Equipment Registry data provided include the "slice" capabilities or other capabilities of the CTs at the existing ODCs.

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

Yes, it will be used for all of those purposes.

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

The Siemens MAGNETOM Altea is a 1.5T **Open Bore** system. "Open Bore" means a 70 cm bore as opposed to traditional MRI scanners with only a 60 cm bore. This avoids the patient being placed in a long, relatively tight tube, which is difficult for some claustrophobic patients. It also accommodates the wider and larger body size of obese patients. It is often less "scary" for pediatric patients, although a relatively few number of pediatrics are expected to be scanned at the ODC.

10. Service Specific Criteria, (Outpatient Diagnostic Centers, Item 2)
Please include page numbers on Attachment 1N(1).

Please revise the first page of Attachment 1N(1) to reflect URAD LLC as the 5% owner of the applicant.

A revised Attachment 1N(1) is attached following this response.

Please provide additional data and methodology to support the need for the project as it related to the proximity of the new facility to the projected residences of the existing patient base and for the applicant's affiliates as well as the projected shift in patients to the new facility once it is operational.

The historical numbers below are for a12 month period ending June 30, 2022. They represent the volume of patients residing in Anderson and Union Counties, and in the 7 zip codes closest to the site, who came to the UTMC main campus HOPD imaging center and ODC-Knoxville (owned by OIA, a partner in University Diagnostics) for imaging services.

County	Zip Code	UTMC Patient Volume	ODC Patient Volume	Total Patient Volume
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Knox	37938	1,567	378	1,945
Anderson	All	2,660	717	3,377
Union	All	1,318	360	1,678
Total		20,916	5,333	26,249

It was assumed 25% of the volume at the existing facilities from this service area would relocate to the new location in Year 1. As a conservative estimate, this methodology does not assume any patient growth from 2021-2022. The conservative assumption that only 25% of existing patients would relocate to the proposed new facility in Year 1 took into consideration factors including: (1) some patients will continue to come to UTMC because they also have other services or procedures being performed; (2) many times patients will choose a location closer to where they work, rather than closer to where they live. Many patients work in the downtown Knoxville area. A factor of approximately 1.6% was used to convert the number of patients to the number of procedures. This factor was the best estimates of business executives from the two imaging centers.

An approximately 9% growth factor was applied for the Year 2 patient volume, which is reasonable, especially in light of the conservative assumptions relied upon to derive the Year 1 projections. It is assumed that all the projected patients will come from existing patients of UTMC and OIA.

11. **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.

It is expected that approximately 1% or less of patients will be age 14 and under. That would be 65 pediatric patients in Year 1.

12. **Service Specific Criteria, (MRI, Item 4, Need Standard for Non-Specialty MRI Units) Attachment 5N (Utilization of MRIs in the PSA 2019-2021) does not include 2021 utilization for North Knoxville Medical Center. Please revise and resubmit Attachment 5N with revised calculations for 2021 MRI utilization in the service area (labeled as Attachment 5NR).**

    A revised Attachment 5N, labeled Attachment 5NR is attached following this response.

13. **Service Specific Criteria, (MRI, Item 7.a. Patient Safety and Quality of Care) Please provide documentation of FDA approval for the specific MRI Unit proposed for this project.**

    A copy of the FDA approval letter is attached following this response.

FDA U.S. FOOD & DRUG ADMINISTRATION

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

March 31, 2021

Re: K203443
Trade/Device Name: MAGNETOM Vida, MAGNETOM Sola, MAGNETOM Lumina, MAGNETOM Altea with syngo MR XA31A
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: February 26, 2021
Received: March 1, 2021

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,

Michael D. O'Hara 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203443

MAGNETOM Vida, MAGNETOM Sola, MAGNETOM Lumina,
MAGNETOM Altea with syngo MR XA31A

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 displays 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.

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Section 5 510(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: March 29, 2021

Manufacturer:

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Registration Number: 3002808157

Siemens Shenzhen Magnetic Resonance LTD.
Siemens MRI Center
Hi-Tech Industrial park (middle)
Gaoxin C. Ave., 2nd
Shenzhen 518057, P.R. CHINA
Registration Number: 3004754211

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/ Trade name:	MAGNETOM Vida, MAGNETOM Sola, MAGNETOM Lumina, MAGNETOM Altea with *syngo* MR XA31A
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:	K192924
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 are 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

MAGNETOM Vida, MAGNETOM Sola, MAGNETOM Lumina, MAGNETOM Altea with software *syngo* MR XA31A includes new and modified hardware and software compared to the predicate device, MAGNETOM Vida with software

syngo MR XA20A. A high-level summary of the new and modified hardware and software is provided below:

Hardware

New Hardware

- The **Nexaris Dockable Table** is a new variant of the MR patient table which is used for intraoperative or interventional imaging. It enables the patient transfer between OR tables and the MR system without repositioning on the MR patient table and vice versa during interventional procedures and surgeries. Additionally, it can be used for diagnostic imaging.
- The **Nexaris Head Frame** holds up to two Ultra Flex Large 18 coils. It can be used for head imaging in combination with the Nexaris Dockable Table when the patient is positioned on the transfer board but not pinned in a head clamp.
- New **Computer**

New Coils

- The **Nexaris Spine 36** is used in combination with and without transfer board for body imaging on the Nexaris Dockable Table.
- The **Flex Loop Large** local coil is a 1Ch receive only multipurpose coil.

Modified Hardware

- The **Beat Sensor** is a contact less method for generating **cardiac triggers** as an alternative to the already existing ECG or pulse triggers. It is based on a measurement of the modulation of a weak magnetic Pilot Tone, caused by conformation changes in conductive tissues.

Software

New Features and Applications

- **SVS_EDIT** is a special variant of the SVS_SE pulse sequence type, which acquires two different spectra (one with editing pulses on resonance, one with editing pulses off resonance) within a single sequence.
- **BEAT_FQ_nav** allows the user to make use of navigator echo based respiratory gating for flow imaging to acquire 4D flow data. Both navigator echo based respiratory gating as well as flow imaging are part of the predicate device already. New is merely the combination of both.
- The **HASTE_interactive** pulse sequence type extends the existing HASTE pulse sequence type by offering the possibility to interactively change imaging parameters.
- **GRE_WAVE** is a special variant of the GRE pulse sequence type which allows larger acceleration factors, measuring one or two contrasts. GRE Wave results in higher signal-to-noise ratio for larger acceleration factors which can be leveraged to allow fast high-resolution 3D susceptibility-weighted imaging.
- The **Prostate Dot Engine** provides an assisted and guided workflow for prostate imaging. This automated workflow leads to higher reproducibility of

slice angulation and coverage; this may support exams not having to be repeated.

- **Injector coupling** is a software application that allows the connection of certain contrast agent injectors to the MR system for simplified, synchronized contrast injection and examination start.

Modified Features and Applications

- An optimized **high bandwidth inversion recovery** pulse is combined with gradient echo readout to improve diagnostic image quality when imaging myocardial tissue.
- The **AbsoluteShim** mode is a shimming procedure based on a 3-echo gradient echo protocol.
- **Deep Resolve Sharp** is an interpolation algorithm based on trained convolutional neuronal networks which increases the perceived sharpness of the interpolated images.
- **Deep Resolve Gain** is a reconstruction option which improves the SNR of the scanned images
- The **3D ASL sequence (tgse_asl)** now provides relCBF maps, by implementing an additional M0 scan and performing the corresponding reconstruction method. It also provides BAT maps in multiple inversion time(multi-TI) imaging.

Other Modifications and / or Minor Changes

- **Elastography-AddIn** synchronizes settings between the Elastography sequence and the active driver.
- **HASTE MoCo** is an image-based motion correction in the average-dimension for the HASTE pulse sequence type.
- The **Needle Intervention AddIn** provides a user interface for workflow improvement of MR-guided needle interventions under real-time imaging conditions. It supports planning a needle trajectory, laser-based localization of the entry point as well as automatic slice positioning.
- The **PhaseRev Dot Addin/Component** supports the measurement workflow of the user by automatically flipping the direction of the phase encoding gradient.
- **Coil independent pulse sequences** remove the coil information from the pulse sequences and generate this information during run-time from automatic coil detection and localization.
- The adjustment mode **"offcenter"** triggers a transmitter adjustment method that is specialized for offcenter imaging. The transmitter adjustment determines the RF voltage that is required to excite a certain B1 field.

7. Substantial Equivalence

MAGNETOM Vida, MAGNETOM Sola, MAGNETOM Lumina, MAGNETOM Altea with software *syngo* MR XA31A are substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with *syngo* MR XA20A	K192924, cleared March 11, 2020	LNH LNI, MOS	Siemens Healthcare GmbH

MAGNETOM Vida, MAGNETOM Sola, MAGNETOM Lumina, MAGNETOM Altea with software *syngo* MR XA31A include hardware and software already cleared on the following reference devices:

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Sola with *syngo* MR XA20A	K192496, cleared February 28, 2020	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Lumina with *syngo* MR XA20A	K192924, cleared March 11, 2020	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Altea with *syngo* MR XA20A	K192496, cleared February 28, 2020	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Area, MAGNETOM Skyra, MAGNETOM Prisma/Prisma^{fit} with *syngo* MR XA30A	K202014, cleared September 08, 2020	LNH LNI, MOS	Siemens Healthcare GmbH

8. Technological Characteristics

The subject devices, MAGNETOM Vida, MAGNETOM Sola, MAGNETOM Lumina, MAGNETOM Altea with software *syngo* MR XA31A, 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.

As seen above there are some differences in technological characteristics between the subject devices and predicate device, including different hardware and modified 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 and algorithms. - 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 safety and electromagnetic compatibility (EMC)	Only separate testing for Nexaris Dockable Table	IEC 60601-1-2

The results from each set of tests demonstrate that the devices perform as intended and are thus 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
SVS_EDIT	[1] Mescher et al, NMR Biomed 11, 266–272 (1998)
	[2] Mikkelsen et al, NeuroImage 159, 32–45 (2017)
	[3] Saleh et al, NeuroImage 189, 425–431 (2019)
GRE_WAVE	[4] B. Bilgic et al., "Wave-CAIPI for Highly Accelerated 3D Imaging." MRM 73(6):2152-2162 (2015)
	[5] F. Breuer et al., Controlled aliasing in volumetric parallel imaging (2D CAIPIRINHA)." MRM 55(3):549-56 (2006)
Prostate Dot Engine	[6] Essner M, Zinsser D, Kündel M, et. al. Performance of an Automated Workflow for Magnetic Resonance Imaging of the Prostate: Comparison With a Manual Workflow. Invest Radiol. 2020 May;55(5):277-284. Doi: 10.1097.
	[7] Horger W, Thoermer G, Weiland E, et. al. Prostate Dot Engine – a system guided and assisted workflow to improve consistency in prostate MR exams.

	[8] Yadong C, Siyuan H, Chunmei Li, et. al. Performance and Reproducibility of a Day Optimizing Throughput (Dot) Workflow Engine in Automated Prostate MRI Positioning. Abstract accepted for the 28th annual meeting of the International Society of Magnetic Resonance in Medicine (ISMRM).
Deep Resolve Gain	[9] Kellman P. et al. Image Reconstruction in SNR Units: A General Method for SNR Measurement. MRM 2005; 54:1439. Erratum in MRM 2007; 58:311.
	[10] Blu T. et al. The SURE-LET approach to image denoising. IEEE Transactions on Image Processing 16(11):2778-86
Improvement of TGSE_ASL	[11] D C. Alsop, J A. Detre, et al. Recommended Implementation of Arterial Spin Labeled Perfusion MRI for Clinical Applications: A consensus of the ISMRM Perfusion Study Group and the European Consortium for ASL in Dementia. Magn Reson Med. 2015 Jan; 73(1): 102–116.
	[12] R B. Buxton, L R. Frank, et al. A general kinetic model for quantitative perfusion imaging with arterial spin labeling. Magn Reson Med. 1998 Sep; 40(3):383-96.
	[13] S. Yang, B. Zhao, et al. Improving the Grading Accuracy of Astrocytic Neoplasms Noninvasively by Combining Timing Information with Cerebral Blood Flow: A Multi-TI Arterial Spin-Labeling MR Imaging Study. Am. J. Neuroradiol. 2016 Dec; 37 (12) 2209-2216
	[14] P G Qiao, C Han, et al. Clinical assessment of cerebral hemodynamics in Moyamoya disease via multiple inversion time arterial spin labeling and dynamic susceptibility contrast-magnetic resonance imaging: A comparative study. J Neuroradiol. 2017 Jul;44(4):273-280.
	[15] Y Shen, B Zhao, et al. Cerebral Hemodynamic and White Matter Changes of Type 2 Diabetes Revealed by Multi-TI Arterial Spin Labeling and Double Inversion Recovery Sequence. Front Neurol. 2017; 8: 717.

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 Sola, MAGNETOM Lumina, MAGNETOM Altea with software *syngo* MR XA31A 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 II (ES/ EMC)	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	ES60601-1:2005/(R)2012 and A1:2012	ANSI AAMI
19-8	General II (ES/ EMC)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	60601-1-2 Edition 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 b:2015	IEC
5-40	General I (QS/ RM)	Medical devices - Application of risk management to medical devices	14971 Second edition 2007-03-01	ISO
5-114	General I (QS/ RM)	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1:2015	ANSI AAMI IEC
13-79	Software/ Informatics	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	62304:2006/A1:2016	ANSI AAMI IEC
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4-2010	NEMA
12-288	Radiology	Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images	MS 9-2008 (R2014)	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	10993-1:2009/(R)2013	ANSI AAMI ISO

Supplemental 1
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12.Conclusion as to Substantial Equivalence

MAGNETOM Vida, MAGNETOM Sola, MAGNETOM Lumina, MAGNETOM Altea with software *syngo* MR XA31A have the same intended use and same basic technological characteristics than the predicate device system, MAGNETOM Vida with *syngo* MR XA20A, with respect to the magnetic resonance features and functionalities. While there are some differences in technical 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 Sola, MAGNETOM Lumina, MAGNETOM Altea with software *syngo* MR XA31A are substantially equivalent to the currently marketed device MAGNETOM Vida with software *syngo* MR XA20A (K192924, cleared on March 11, 2020).

Supplemental 1
August 8, 2022

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF KNOX

Name of Facility or Project: University Diagnostics, LLC

I, Benjamin M. Cunningham IV, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that Ihave reviewed all the supplemental information submitted herewith, and that it is true, accurate, and complete.

CFO
Signature & Title

Sworn to and subscribed before me, a Notary Public, this the 8th day of August, 2022, witness my hand at office in the County and State written above.

NOTARY PUBLIC

TRACEY J. WHITT
STATE OF TENNESSEE NOTARY PUBLIC
Comm. Exp. 6-27-2023
KNOX COUNTY

My commission expires: 6/27/23

HF-0043

Revised 7/02

Supplemental 2
August 10, 2022

RESPONSES TO 2nd SUPPLEMENTAL QUESTIONS

CERTIFICATE OF NEED APPLICATION

FOR

UNIVERSITY DIAGNOSTICS, LLC

Establishment of an Outpatient Diagnostic Center and the Initiation of MRI Services

In the Halls Area of Knoxville, Knox County, Tennessee

Project No. CN2207-031

August 10, 2022

Contact Person:

Jerry W. Taylor, Esq.
Thompson Burton, PLLC
6100 Tower Circle, Suite 200
Franklin, Tennessee 37067
615-716-2297

Supplemental 2
August 10, 2022

1. **Attachment Medical Equipment**

Please clarify whether the MRI will include a breast coil. If so, please select Breast on the Medical Equipment form.

The MRI unit will include a breast coil. The revised form is attached following this response.

Supplemental 2
August 10, 2022

Attachment - MRI, PET, and/or Linear Accelerator

1a. For Magnetic Resonance Imaging (MRI) in a county with a population less than 175,000, describe the initiation of MRI services or addition of MRI scanners as part of the project, or

1b. For Magnetic Resonance Imaging (MRI) in a county with a population greater than 175,000, describe the initiation of MRI services or addition of MRI scanners as part of the project if more than 5 patients per year under the age of 15 will be treated, and/or

2. Describe the acquisition of any Positron Emission Tomography (PET) scanner that is adding a PET scanner in counties with population less than 175,000 and/or

3. Describe the acquisition of any Linear Accelerator if initiating the service by responding to the following:

A. Complete the chart below for acquired equipment.

☐ Linear Accelerator	Mev _____ Types: ☐ SRS ☐ IMRT ☐ IGRT ☐ Other _____		
	Total Cost*: _____ ☐ New	☐ Refurbished	☐ By Purchase ☐ By Lease Expected Useful Life (yrs) ___ ☐ If not new, how old? (yrs) _____
X MRI	Tesla: 1.5 Magnet: ☑ Breast ☐ Extremity ☑ Open ☐ Short Bore ☑ Other _____		
	Total Cost*: $1,268,921 ☑ New	☐ Refurbished	☑ By Purchase ☐ By Lease Expected Useful Life (yrs) 5-10 ☐ If not new, how old? (yrs) _____
☐ PET	☐ PET only	☐ PET/CT ☐ PET/MRI	
	Total Cost*: _____ ☐ New	☐ Refurbished	☐ By Purchase ☐ By Lease Expected Useful Life (yrs) ___ ☐ If not new, how old? (yrs) _____

* As defined by Agency Rule 0720-9-.01(4)(b)

B. In the case of equipment purchase, include a quote and/or proposal from an equipment vendor. In the case of equipment lease, provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments along with the fair market value of the equipment. **A copy of the quote is attached**

C. Compare lease cost of the equipment to its fair market value. Note: Per Agency Rule, the higher cost must be identified in the project cost chart. **N/A**

D. Schedule of Operations:

Location	Days of Operation (*Sunday through Saturday*)	Hours of Operation (*example: 8 am – 3 pm*)
Fixed Site *(Applicant)*	Monday-Friday	8am-5pm
Mobile Locations *(Applicant)*		
(Name of Other Location)		
(Name of Other Location)		

2. Item 5N.

Replacement Page 13R is noted. However it appears that the number of MRI units listed at Covenant Health Diagnostic Center aka Fort Sanders West Diagnostic Center (HOPD) are incorrect. Please revise and resubmit Page 13R (labeled as Page 13R2).

Replacement Page 13R2 with the corrected number of units at referenced facility is attached following this response.

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

Please include page numbers on Attachment 1N(1).

Attachment 1N(1) with page numbers inserted is attached following this response. For completeness, also attached following this response is Attachment 1N(1)R with page numbers.

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF KNOX

Name of Facility or Project: University Diagnostics, LLC

I, Benjamin M. Cunningham, Jr. after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all the supplemental information submitted herewith, and that it is true, accurate, and complete.

CFO
Signature & Title

Sworn to and subscribed before me, a Notary Public, this the 9th day of August, 2022, witness my hand at office in the County and State written above.

NOTARY PUBLIC

TRACEY J. WHITT
STATE OF TENNESSEE NOTARY PUBLIC
Comm. Exp. 6-27-2023
KNOX COUNTY

My commission expires: 6/27/23

HF-0043

Revised 7/02