

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 23, 2019

Findings Date: August 23, 2019

Project Analyst: Celia C. Inman

Assistant Chief: Lisa Pittman

Project ID #: G-11725-19

Facility: Wake Forest Baptist Imaging - Kernersville

FID #: 190280

County: Forsyth

Applicant: Wake Forest Baptist Imaging, LLC

Project: Develop a diagnostic center by relocating CT and mammography equipment, and adding bone density equipment

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Wake Forest Baptist Imaging, LLC (WFBI), the applicant, proposes to develop a new diagnostic center by acquiring new bone density equipment and relocating existing computed tomography (CT) and mammography equipment to the WFBI clinic which currently offers x-ray and ultrasound services at 861 Old Winston Road, Kernersville, Forsyth County. The total cost of the imaging equipment will exceed the statutory threshold of \$500,000; therefore, the equipment qualifies the clinic as a diagnostic center, which is a new institutional health service, which requires a Certificate of Need (CON).

N.C. Gen. Stat. 131E-176(7a) states:

“Diagnostic center” means a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.”

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP),
- acquire any medical equipment for which there is a need determination in the 2019 SMFP, or
- offer a new institutional health service for which there are any policies in the 2019 SMFP.

Therefore Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a diagnostic center, Wake Forest Baptist Imaging–Kernersville (WFBI-K), by acquiring bone density equipment and relocating CT and mammography equipment to WFBI’s existing Kernersville medical clinic which currently offers x-ray and ultrasound services.

In Section C.1, pages 17-21, the applicant describes the proposed project and discusses the medical diagnostic equipment. The applicant lists the imaging equipment and provides a brief description of the equipment on pages 18-21, as follows:

- Digital x-ray (existing diagnostic equipment)

- Ultrasound (existing diagnostic equipment)
- CT Scanner (proposed relocated WFBI diagnostic equipment)
- 3D Mammography (proposed relocated WFBI diagnostic equipment)
- Bone Densitometer/DEXA (proposed new diagnostic equipment)

In early 2019, WFBI requested and received a “No Review” to acquire and/or relocate x-ray and ultrasound equipment to develop a new imaging clinic in Kernersville, Forsyth County. The total combined cost or fair market value (FMV) of the equipment and the upfit to make the equipment operational was \$228,566, which is under the \$500,000 threshold that constitutes a diagnostic center. The applicant now proposes to acquire a bone densitometer (DEXA) and relocate a WFBI CT scanner and mammography system to add to the existing x-ray and ultrasound equipment at the imaging clinic. The cost and/or FMV of the proposed imaging equipment is \$278,737 and the cost to upfit the space necessary to support the imaging equipment is \$64,000. The combined costs of the existing and proposed medical diagnostic equipment ($\$228,566 + \$278,737 + \$64,000 = \$571,303$) exceeds \$500,000 and thus requires a certificate of need for a diagnostic center.

Designation as a Diagnostic Center

In Exhibit 10, the applicant provides documentation of the cost and/or FMV of the existing x-ray and ultrasound equipment. In Exhibit 4, the applicant provides the vendor quotes and/or FMV of the proposed additional medical diagnostic equipment which will establish the proposed diagnostic center, as shown below.

Diagnostic Equipment	Method of Valuation	Total Cost
Existing Equipment		
X-Ray	Cost	\$141,995
Ultrasound	FMV	\$36,986
Space Upfit	Cost	\$40,000
Total Existing Equipment		\$228,566
Proposed Equipment		
CT Scanner	FMV	\$36,600
CT Room Move	Cost	\$58,000
Mammography Equipment	FMV	\$123,433
Mammography Installation	Cost	\$10,900
Bone Density (DEXA)	Cost	\$49,804
Space Upfit		\$64,000
Total Proposed Equipment*		\$342,737
Total Diagnostic Center*		\$571,303

*Exclusive of Sales Tax

The combined value of the proposed medical diagnostic equipment, costing \$10,000 or more exceeds the statutory threshold of \$500,000; therefore, the equipment qualifies the clinic as a diagnostic center, which is a new institutional health service, which requires a CON.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2019 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C.4, page 33, the applicant states that the service area for the proposed diagnostic center is Forsyth County. Facilities may also serve residents not included in their service area.

The proposed diagnostic center is a new facility and therefore has no historical patient origin. However, on page 22 the applicant provides the calendar year (CY) 2019 year-to-date (YTD) patient origin for the existing imaging clinic which has been providing x-ray and ultrasound diagnostic imaging services since March 2019, as summarized below.

**WFBI Clinic-Kernersville
Historical Patient Origin
CY2019YTD**

County	Percent of Total
Forsyth	70.4%
Guilford	15.5%
Stokes	3.4%
Davidson	2.1%
Davie	1.6%
Randolph	1.0%
Surry	0.8%
Rockingham	0.6%
Other*	4.5%
Total	100.0%

Totals may not sum due to rounding

*Other includes <1% patient origin from the remaining counties in North Carolina and other states.

In Section C.3, page 23, the applicant provides the projected patient origin for the proposed diagnostic center for the first three full fiscal years (FY), CY2021-CY2023, as summarized in the table below.

**WFBI-Kernersville
Projected Patient Origin
CY2021-CY2023**

County	Percent of Total
Forsyth	70.4%
Guilford	15.5%
Stokes	3.4%
Davidson	2.1%
Davie	1.6%
Randolph	1.0%
Surry	0.8%
Rockingham	0.6%
Other*	4.5%
Total	100.0%

Totals may not sum due to rounding

*Other includes <1% patient origin from the remaining counties in North Carolina and other states.

In Section C.3(c), page 24, the applicant discusses the assumptions and methodology used to project the number of patients by county. The applicant states that it determined that the recent CY2019YTD patient origin for x-ray and ultrasound at the WFBI clinic is a reasonable proxy for projecting patient origin at the proposed diagnostic center which will offer x-ray, ultrasound, CT, mammography and bone densitometry.

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 24-34, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On page 24, the applicant states that the need for the proposed project is based on numerous factors, as listed below and discussed thereafter:

- WFBI's mission to maintain quality care delivery, promote cost effective care, and improve geographic access (pages 25-30),
- WFBI's high utilization of existing medical diagnostic equipment (pages 30-32),
- Enhanced geographic access to freestanding, non-hospital-based imaging services (pages 31-32), and
- The projected growth of the service area population presumes continued increases in demand (pages 32-34).

Maintain quality care delivery, promote cost effective care, and improve geographic access

In Section C.4, page 25, the applicant discusses its focus on providing the best value by offering high-quality imaging at an outpatient price in a friendly, patient centered environment. On page 26, the applicant states that the proposal is consistent with the SMFP basic principle of promoting cost effective healthcare approaches. On page 27, the applicant states that the proposed project will expand the capacity of WFBI's well-utilized diagnostic imaging services and enhance geographic access in Forsyth County.

Utilization of existing diagnostic equipment

On page 30, the applicant provides a table showing the three-year compound annual growth rate (CAGR) for WFBI's Winston-Salem Diagnostic Center (WFBI-WS), showing a 3-year CAGR of more than 10% for CT and bone density and 2.6%, 4.0% and 7.6% for ultrasound, x-ray and mammography, respectively. The applicant states:

"WFBI has experienced robust growth in utilization of its diagnostic imaging services which supports WFBI's proposal to expand its capacity for CT, mammography, and bone density in a new geographic location that will enhance access for local residents."

Access to non-hospital imaging services

In Section C.4, page 30, the applicant discusses the demand for outpatient diagnostic imaging services and states that such services are supported by the growth of the medical staff at Wake Forest Baptist Hospital (WFBH) who need expanded diagnostic imaging services for their patients. On page 31, the applicant states:

"In summary, WFBH has a large and growing medical staff that is comprised of diverse physician specialties who refer patients to WFBI's outpatient imaging services. The proposed project will expand WFBI's capacity to better meet the needs of its referring physicians while also improving access for local residents."

Growth of service area

In Section C.4, page 33, the applicant states that the Forsyth County population will increase by 1.0% annually, or by 15,531 residents from 2019 to 2023, with the population of women age 40 and older increasing at a slightly greater rate. The applicant states that this data supports the ongoing need for medical diagnostic services.

The information provided by the applicant is reasonable and adequately supported for the following reasons:

- Reliable data sources are used to support assertions about population growth and medical need for the proposed services.
- The applicant uses the data to make reasonable and adequately supported assumptions about service area residents' future need for the proposed services.

Projected Utilization

In Section Q, Form C, the applicant provides the historical utilization for the clinic’s existing x-ray and ultrasound services and the projected utilization for all proposed services for the first three full fiscal years of operation following completion of the project, as summarized in the following table.

**Wake Forest Baptist Imaging - Kernersville
 Diagnostic Center
 Form C: Utilizations**

Each Service Component	Prior Full FY CY2019*	Interim FY CY2020**	1st Full FY CY2021	2nd Full FY CY2022	3rd Full FY CY2023
CT Services					
# of Units	NA	1	1	1	1
# of Scans	NA	654	1,803	2,332	3,239
# of HECT Units [^]	NA	1,078	2,972	3,844	5,341
X-ray Services					
# of Units	1	1	1	1	1
# of Procedures	1,458	1,767	2,339	2,945	3,586
Mammography					
# of Units	NA	1	1	1	1
# of Procedures	NA	1,065	3,057	4,059	5,141
Ultrasound					
# of Units	1	1	1	1	1
# of Procedures	833	1,412	1,885	2,383	2,904
Bone Density (DEXA)					
# of Units	NA	1	1	1	1
# of Procedures	NA	520	1,286	1,680	2,099

*Annualized data based on March-April 2019 utilization for existing x-ray and ultrasound

**Utilization of existing x-ray and ultrasound is representative of 12 months; utilization for CT, mammography, and bone density represents partial year utilization July 1, 2020 through December 31, 2020

[^]HECT units based on WFBI’s historical experience at its Winston-Salem diagnostic center

In Section Q, pages 106-119, the applicant provides the assumptions and methodology used to project utilization, as follows:

Methodology

Step 1: Project utilization at WFBI-WS prior to any shift of equipment or procedures

Assumptions

- On page 106, the applicant provides WFBI-WS's historical utilization CY2015-CY2018, as summarized below.

**WFBI-WS Diagnostic Center
 Historical Utilization**

Each Service Component	CY2015	CY2016	CY2017	CY2018	3-Yr CAGR
Bone Density	2,539	2,836	3,512	3,580	12.1%
CT Scanner	3,863	4,425	4,958	5,366	11.6%
Mammography	9,719	10,528	11,655	12,122	7.6%
X-ray	6,114	6,311	6,559	6,877	4.0%
Ultrasound	7,548	8,053	8,076	8,151	2.6%

- The applicant assumes the following annual growth rates are reasonable for projecting individual diagnostic services at WFBI-WS.

Each Service Component	3-Yr CAGR
Bone Density	5.0%
CT Scanner	5.0%
Mammography	5.0%
X-ray	4.0%
Ultrasound	2.6%

On page 107, applying the 3-yr CAGR provided above, the applicant provides the projected utilization at WFBI-WS, as summarized below.

**WFBI-WS Diagnostic Center
 Projected Utilization**

Each Service Component	CY2019	CY2020	CY2021	CY2022	CY2023
Bone Density	3,759	3,947	4,144	4,352	4,569
CT Scanner	5,634	5,916	6,212	6,522	6,849
Mammography	12,728	13,365	14,033	14,734	15,471
X-ray	7,152	7,438	7,735	8,044	8,366
Ultrasound	8,363	8,580	8,802	9,031	9,265

Step 2: Project utilization for existing x-ray and ultrasound services at WFBI-Kernersville

Assumptions

- WFBI-Kernersville clinic opened in March 2019 providing x-ray and ultrasound services.
- WFBI-Kernersville’s fiscal year is the calendar year, January 1 through December 31. Thus, the first three full fiscal years of the project will be CY2021-CY2023.
- The applicant assumes a portion of the existing WFBI-WS x-ray and ultrasound diagnostic procedures will shift to WFBI-K. On pages 109-110, the applicant provides the shift by percent and by procedure, as summarized in the following tables.

Projected Percentage of Services to Shift from WFBI-WS to WFBI-K

Modality	CY2020	CY2021	CY2022	CY2023
X-ray	20.4%	25.4%	30.4%	35.4%
Ultrasound	15.0%	20.0%	25.0%	30.0%

Annual percent shifts are based on WFBI’s operational experience providing diagnostic services in Forsyth County, historical patient origin for x-ray and ultrasound, and current inventory and capacity constraints for existing modalities at WFBI-WS

**WFBI X-ray and Ultrasound Services
 Projected Procedure Shift from WFBI-WS to WFBI-K**

Modality	CY2020	CY2021	CY2022	CY2023
X-ray	1,517	1,964	2,445	2,961
Ultrasound	1,287	1,760	2,258	2,779

- On page 110, the applicant also assumes an incremental growth rate in diagnostic procedures at WFBI-K based on operational experience, referral relationships, need for access to outpatient services, capacity constraints at WFBI-WS, population growth and aging, WFBH physician recruitment and letters of support (Exhibit 11), as summarized below.

Projected Incremental Increase in Procedures per Day at WFBI-K

Modality	CY2020	CY2021	CY2022	CY2023
X-ray	1.0	1.5	2.0	2.5
Ultrasound	0.5	0.5	0.5	0.5

On page 111, the applicant provides the projected x-ray and ultrasound utilization at WFBI-K after the shift of patients from WFBI-WS and the incremental increase, as summarized in the following tables.

WFBI-K Projected X-ray Procedures

		CY2019*	CY2020	CY2021	CY2022	CY2023
A	X-ray Procedures Based on Patient Shift from WFBI-WS	1,458	1,517	1,964	2,445	2,961
B	Average Procedures per Day Based on Shift		6.1	7.9	9.8	11.8
C	Incremental Procedures per Day		1.0	1.5	2.0	2.5
D	Incremental Annual Procedures		250	375	500	625
E	Total X-ray Procedures	1,458	1,767	2,339	2,945	3,586
F	Average X-ray Procedures per Day	7.0	7.1	9.4	11.8	14.3

Numbers may not foot due to rounding

*Annualized based on average 7 procedures per day

A = WFBI-K CY2019 Annualized procedures; CY2020-CY2023 Projected shift in x-ray procedures from WFBI-WS

B = A /250

C = Incremental procedures per day as stated on page 110 of application and in assumption above

D = C x 250

E = A+ D

F = E /250

WFBI-K Projected Ultrasound Procedures

		CY2019*	CY2020	CY2021	CY2022	CY2023
A	Ultrasound Procedures Based on Patient Shift from WFBI-WS	833	1,287	1,760	2,258	2,779
B	Average Procedures per Day Based on Shift		5.1	7	9	11.1
C	Incremental Procedures per Day		0.5	0.5	0.5	0.5
D	Incremental Annual Procedures		125	125	125	125
E	Total Ultrasound Procedures	833	1,412	1,885	2,383	2,904
F	Average Ultrasound Procedures per Day	3.3	5.6	7.5	9.5	11.6

Numbers may not foot due to rounding

*Annualized based on average 4 procedures per day

A = WFBI-K CY2019 Annualized procedures; CY2020-CY2023 Projected shift in ultrasound procedures from WFBI-WS

B = A /250

C = Incremental procedures per day as stated on page 110 of application and in assumption above

D = C x 250

E = A+ D

F = E /250

Step 3: Project utilization for new services at WFBI-Kernersville: CT, mammography, and bone density

Assumptions

- The applicant will relocate one CT scanner and one mammography machine from WFBI-WS to WFBI-K.
- The applicant will acquire one new bone density machine.

- On pages 112-113, the applicant assumes a portion of the existing WFBI-WS CT, mammography and bone density diagnostic patients will shift to WFBI-K, as summarized by percent and procedures in the tables below.

Projected Percentage of Services to Shift from WFBI-WS to WFBI-K

Modality	CY2020	CY2021	CY2022	CY2023
Bone Density	20.0%	25.0%	30.0%	35.0%
CT	20.0%	25.0%	30.0%	40.0%
Mammography	15.0%	20.0%	25.0%	30.0%

Annual percent shifts are based on WFBI's operational experience providing diagnostic services in Forsyth County, historical patient origin, and current inventory and capacity constraints for existing modalities at WFBI-WS

Projected Procedures to Shift from WFBI-WS to WFBI-K

Modality	CY2020	CY2021	CY2022	CY2023
Bone Density	395	1,036	1,305	1,599
CT	592	1,553	1,957	2,739
Mammography	1,002	2,807	3,684	4,641

- On page 113, he applicant also assumes an incremental growth rate in diagnostic procedures at WFBI-K based on operational experience, referral relationships, need for access to outpatient services, capacity constraints at WFBI-WS, population growth and aging, WFBH physician recruitment and letters of support (Exhibit 11), as summarized below.

Projected Incremental Increase in Procedures per Day at WFBI-K

Modality	CY2020	CY2021	CY2022	CY2023
Bone Density	0.5	1.0	1.5	2.0
CT	0.5	1.0	1.5	2.0
Mammography	0.5	1.0	1.5	2.0

On pages 114-115, the applicant provides the projected bone density, CT and mammography utilization at WFBI-K after the shift of equipment and procedures from WFBI-WS and the incremental increase, as summarized in the following tables.

WFBI-K Projected Bone Density Procedures

		CY2020*	CY2021	CY2022	CY2023
A	Bone Density Procedures Based on Patient Shift from WFBI-WS	395	1,036	1,305	1,599
B	Average Procedures per Day Based on Shift	3.2	4.1	5.2	6.4
C	Incremental Procedures per Day	0.5	1	1.5	2
D	Incremental Annual Procedures	125	250	375	500
E	Total Bone Density Procedures	520	1,286	1,680	2,099
F	Average Bone Density Procedures per Day	4.2	5.1	6.7	8.4

Numbers may not foot due to rounding

*Reflects interim year CY2020 (July-December)

A = CY2020-CY2023 Projected shift in procedures from WFBI-WS

B = A /250

C = Incremental procedures per day as stated on page 110 of application and in assumption above

D = C x 250

E = A+ D

F = E /250

WFBI-K Projected CT Procedures

		CY2020*	CY2021	CY2022	CY2023
A	CT Procedures Based on Patient Shift from WFBI-WS	592	1,553	1,957	2,739
B	Average Procedures per Day Based on Shift	4.7	6.2	7.8	11.0
C	Incremental Procedures per Day	0.5	1.0	1.5	2.0
D	Incremental Annual Procedures	62.5	250	375	500
E	Total CT Procedures	654	1,803	2,332	3,239
F	Average CT Procedures per Day	5.2	7.2	9.3	13.0

Numbers may not foot due to rounding

*Reflects interim year CY2020 (July-December)

A = CY2020-CY2023 Projected shift in procedures from WFBI-WS

B = A /250

C = Incremental procedures per day as stated on page 110 of application and in assumption above

D = C x 250

E = A+ D

F = E /250

WFBI-K Projected Mammography Procedures

		CY2020*	CY2021	CY2022	CY2023
A	Mammography Procedures Based on Patient Shift from WFBI-WS	1,002	2,807	3,684	4,641
B	Average Procedures per Day Based on Shift	8.0	11.2	14.7	18.6
C	Incremental Procedures per Day	0.5	1	1.5	2
D	Incremental Annual Procedures	63	250	375	500
E	Total Mammography Procedures	1,065	3,057	4,059	5,141
F	Average Mammography Procedures per Day	8.5	12.2	16.2	20.6

Numbers may not foot due to rounding

*Reflects interim year CY2020 (July-December)

A = CY2020-CY2023 Projected shift in procedures from WFBI-WS

B = A /250

C = Incremental procedures per day as stated on page 110 of application and in assumption above

D = C x 250

E = A+ D

F = E /250

On page 111, the applicant provides a table showing the projected utilization for x-ray and ultrasound at WFBI-K based on the methodology and steps above. On page 116, the applicant provides the projected utilization for bone density, CT, and mammography, based on the steps above. The following table combines the information on pages 111 and 116, showing the projected utilization for all services proposed at WFBI-K.

WFBI-K Projected Utilization

	CY2019*	CY2020	CY2021	CY2022	CY2023
Bone Density		520	1,286	1,680	2,099
CT		654	1,803	2,332	3,239
Mammography		1,065	3,057	4,059	5,141
X-ray	1,458	1,767	2,339	2,945	3,586
Ultrasound	833	1,412	1,885	2,383	2,904

Step 4: Projected utilization at WFBI-WS after shift of equipment and procedures to WFBI-Kernersville

On page 116, the applicant provides a table showing the projected utilization for WFBI-WS based on the projected growth rates in Step 1 and the shift of patients to WFBI-K described in Steps 2 and 3, as summarized below.

WFBI-Winston-Salem Projected Diagnostic Center Procedures

	CY2019*	CY2020	CY2021	CY2022	CY2023
Bone Density	3,759	3,552	3,108	3,046	2,970
CT	5,634	5,324	4,659	4,566	4,109
Mammography	12,728	12,362	11,226	11,051	10,830
X-ray	5,694	5,921	5,771	5,600	5,405
Ultrasound	7,529	7,293	7,042	6,773	6,485

*For conservatism, the applicant assumes all CY2019 x-ray and ultrasound procedures are based on patient shifts from WFBI-WS

On page 117, the applicant compares the projected utilization at WFBI-K and WFBI-WS. On page 118, the applicant states:

The projected utilization of the proposed diagnostic equipment at WFBI-Kernersville is comparable to the utilization of existing diagnostic equipment at WFBI-Winston-Salem. The projected average procedures per day for the proposed additional modalities at WFBI-Kernersville are conservative compared to the utilization of the same modalities at WFBI-Winston-Salem. The projected average procedures per day for x-ray and ultrasound at WFBI-Kernersville are slightly higher compared to WFBI-Winston-Salem; however, this stands to reason because WFBI-Winston-Salem operates a greater complement of x-ray and ultrasound equipment than WFBI-Kernersville. Additionally, x-ray and ultrasound are existing modalities at WFBI-Kernersville that have already demonstrated substantive ramp up of procedures per day.”

Step 5: Convert CT procedures to HECTS

Assumptions

- On page 118, the applicant provides a table showing the WFBI-WS CY2018 CT procedures converted to HECT units using the conversion factors as provided in the application.
- WFBI-WS’s CY2018 HECT to CT scan ratio is 1.6 to 1.0 (8,847 HECTs / 5,366 scans).

- The applicant states that because the CT scanner and some procedures are being relocated from WFBI-WS, it is reasonable to assume the same ratio of HECTs to CT scans for the proposed project; therefore, the same HECT to CT scan ratio will apply to WFBI-K, resulting in the following projected HECT units at WFBI-WS and WFBI-K after project completion.

Year	WFBI-Winston-Salem		WFBI-Kernersville	
	CT Scans	HECT Units	CT Scans	HECT Units
CY2018	5,366	8,847		
CY2019	5,634	9,289		
CY2020	5,916 [5,324]	9,753 [8,778]	654	1,078
CY2021	6,212 [4,659]	10,241 [7,681]	1,803	2,972
CY2022	6,522 [4,566]	10,753 [7,528]	2,332	3,844
CY2023	6,849 [4,109]	11,291 [6,775]	3,239	5,341

Totals may not foot due to rounding

The table provided by the applicant on page 119 erroneously uses the number of CT scans projected for WFBI-WS prior to the shift to WFBI-K; therefore, the number of CT scans and HECT units shown for WFBI-WS is overstated each year following project completion (CY2020-CY2023). The table above shows both the number of CT scans and HECT units, as provided by the applicant in the table on page 119 and the [correct number of scans], as provided by the applicant on page 116, with the correct calculation of [HECT units], as provided by the Project Analyst. However, this difference has no impact for the decision on the relocation of the CT scanner or the development of the proposed diagnostic center.

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected population increase and aging in the service area is expected to support ongoing diagnostic services.
- Utilization is projected for each specific diagnostic service type, applying reasonable assumptions based on the applicant’s experience with diagnostic services in Forsyth County.

Access

In Section C.11, page 42, the applicant discusses access to the proposed services. The applicant states:

“WFBI is fully committed to the health and well-being of all patients. WFBI has historically provided care and services to medically underserved populations.

. . .

. . . WFBI will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.

Diagnostic services at WFBI’s proposed Kernersville diagnostic center will be available to and accessible by any patient having a clinical need for those services.”

In Section L.1(a), page 86, the applicant provides information on Forsyth County patients served at WFBI-WS, showing that 78% and 37% of CY2018 services were provided to women and persons 65 and older, respectively. The applicant states that statistics related to racial and ethnic minority data were not available.

The proposed facility is not an existing facility. The clinic began offering only x-ray and ultrasound services in March 2019; therefore, there is no current patient information on all five diagnostic services to be provided. However, on page 87, the applicant provides WFBI-WS’s CY2018 payor mix, which shows that between 0.6% and 3.9% of services were provided to self-pay/charity care persons, between 9.7% and 15.5% of services were provided to persons covered by Medicare, and between 1.3% and 6.8% of services were provided to persons covered by Medicaid in the five medical diagnostic services to be provided at the proposed diagnostic center.

In Section L.3(a), page 88, the applicant provides the proposed payor mix in the third full fiscal year of operation for each of the five proposed diagnostic services, as summarized below.

**Wake Forest Baptist Imaging - Kernersville
 Diagnostic Center
 CY2023**

Payor Source	X-ray	Ultrasound	Mammography	Bone Density	CT
Self-Pay /Charity Care	3.9%	1.6%	1.1%	0.6%	1.2%
Medicare*	13.6%	9.7%	11.5%	13.5%	15.5%
Medicaid *	6.8%	3.9%	1.3%	2.3%	2.4%
Insurance*	75.2%	84.7%	86.1%	83.5%	80.6%
Other (Gov’t)	0.5%	0.1%	0.1%	0.1%	0.3%
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%

* Includes any managed care plans
 Totals may not sum due to rounding

On page 89, the applicant provides the assumptions and methodology used to project payor source, stating that the projected payor mix at WFBI-K is based on the CY2018 WFBI-WS payor mix for the same services.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on the review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate the existing CT scanner and one of two mammography machines from WFBI-WS to the proposed diagnostic center at WFBI-K. Therefore, Criterion (3a) is applicable to this review.

In Section D, page 47, the applicant states:

“Upon relocation of the CT scanner and mammography machine to Kernersville, WFBI will backfill the respective equipment with new equipment at WFBI-Winston-Salem. As a result, WFBI-Winston-Salem will have the same number of CT scanners (1) and mammography machines (2) as it currently operates. Thus, the needs of patients currently utilizing imaging services at WFBI-Winston-Salem will continue to be met following completion of the project.”

In Section Q, page 116, the applicant provides the projected utilization at WFBI-WS after the relocation of the equipment and the shift of procedures to WFBI-K, as summarized below.

WFBI-Winston-Salem Projected Diagnostic Center Procedures

	CY2019	CY2020	CY2021	CY2022	CY2023
Bone Density	3,759	3,552	3,108	3,046	2,970
CT	5,634	5,324	4,659	4,566	4,109
Mammography	12,728	12,362	11,226	11,051	10,830
X-ray	5,694	5,921	5,771	5,600	5,405
Ultrasound	7,529	7,293	7,042	6,773	6,485

In Section Q, the applicant provides the assumptions and methodology used to project utilization. The discussion on projected utilization, assumptions and methodology in Criterion (3) is incorporated herein by reference. Projected utilization is reasonable and adequately supported for the following reasons:

- Projected population increase and aging in the service area is expected to support ongoing diagnostic services.
- Utilization is projected for each specific diagnostic service type, applying reasonable assumptions based on the applicant's experience with existing diagnostic services in Forsyth County.
- A reasonable portion of services will shift from WFBI-WS to the proposed diagnostic center based on the applicant's experience with existing physician referral patterns.
- The applicant states that WFBI-WS will maintain the current number of CT and mammography units at WFBI-WS by replacing the relocated units with newly acquired units.

In Section D, page 51, the applicant states:

“This project will have no negative impact on the groups identified in subparts (a)-(g) of Section D.5. As WFBI intends to replace the relocated CT scanner and mammography machine with new equipment, there will be no change in access to these services at WFBI-Winston-Salem.

...

... WFBI will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on the review, the Agency concludes that the applicant demonstrates that:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
 - The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to develop a new diagnostic center by acquiring bone density equipment and relocating CT and mammography equipment to the existing WFBI Kernersville medical clinic which currently offers x-ray and ultrasound services.

In Section E.2, pages 53-54, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The other alternatives considered were:

1. Maintain the Status Quo – the applicant states that maintaining the status quo would not be the most effective alternative to promote the delivery of high quality, cost effective outpatient diagnostic services. Therefore, the applicant rejects the status quo.
2. Develop the Proposed Diagnostic Center in Another Location – the applicant states that developing the proposed diagnostic center in another location would not optimize synergies and promote resource-sharing opportunities for more cost-effective care as compared to developing additional diagnostic modalities at the existing clinic location. Thus, the applicant states that developing the proposed diagnostic center in another location would be both a less effective and more costly alternative.
3. Acquire Different Quantities of Medical Diagnostic Equipment – the applicant states that clinical and administrative leadership has decided that the proposed mix of medical diagnostic equipment will adequately meet the qualitative and quantitative needs of WFBI and its referring physicians. Therefore, developing a different mix or quantity of diagnostic equipment was rejected as a less effective alternative at this time.

On page 54, the applicant states that the project, as proposed, is the most effective alternative for patients to benefit from the high-quality, low-cost diagnostic imaging services in a location that enhances geographic access in Forsyth County.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the identified need for the following reasons:

- The application is conforming to all statutory criteria.
- The applicant provides credible information to explain why the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Wake Forest Baptist Imaging, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Wake Forest Baptist Imaging, LLC shall materially comply with the last made representation.**
 - 2. Wake Forest Baptist Imaging, LLC shall develop a new diagnostic imaging center with computed tomography, X-ray, ultrasound, mammography, and bone density diagnostic equipment.**
 - 3. Wake Forest Baptist Imaging, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 4. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, Wake Forest Baptist Imaging, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
 - 5. Wake Forest Baptist Imaging, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new diagnostic center by acquiring bone density equipment and relocating CT and mammography equipment to the existing WFBI Kernersville medical clinic which currently offers x-ray and ultrasound services.

Capital and Working Capital Costs

In Section Q, on Form F.1a, the applicant projects the total capital cost of the project as shown below in the table.

**Wake Forest Baptist Imaging-Kernersville
 Diagnostic Center
 Capital Cost**

	Total
Construction / Renovation Contract(s)	\$64,000
Medical Equipment, including Sales Tax	\$286,750
Consultant Fees	\$45,000
Contingency	\$5,000
Total	\$400,750

In Section F.1, page 57, and Section Q, the applicant provides the assumptions used to project the capital cost. See Exhibits 4 and 5 for documentation on vendor quotes and construction related costs. See Exhibit 2 for a letter from the owner of the medical office building committing to lease additional space to develop the proposed diagnostic center.

In Section F, pages 59-60, the applicant projects there will be no start-up costs and initial operating expenses will be \$140,000 for a total working capital of \$140,000. In Section Q, Assumption 10, the applicant provides the assumptions used to project the working capital needs of the project.

Availability of Funds

In Section F, page 57, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	WFBI (Applicant 1)	(Applicant 2)	Total
Loans	\$0	\$0	\$0
Accumulated reserves or OE *	\$45,000	\$0	\$45,000
Bonds	\$0	\$0	\$0
Other (vendor loan)	\$195,717	\$0	\$195,717
Other (equipment already owned)	\$160,033	\$0	\$250,720
Total Financing **	\$400,750	\$0	\$400,750

* OE = Owner's Equity.

**Total financing should equal line 14 in Form F.1a Capital Cost.

In supplemental information requested by the Agency during the expedited review of the project, the applicant clarifies the capital cost financing summarized above, stating:

“The \$250,720 shown in the final column of the table on page 57 is a typographical error. That figure should have been \$160,033 to match the total in the second column regarding equipment already owned (the fair market value (FMV) of the CT (\$36,600) plus the FMV of the mammography equipment (\$123,433)).”

The applicant also provides an explanation of the amount listed above for Other (vendor loan), as follows:

“The total of \$195,717 represents the following items:

- *\$49,804 (DEXA scanner vendor quote), plus applicable sales tax of 6.75%*
- *\$58,000 (CT relocation fee), plus applicable sales tax of 6.75%*
- *\$10,900 (mammography relocation fee), plus applicable sales tax of 6.75%*
- *\$64,000 facility renovation cost estimate*
- *\$5,000 project contingency”*

In Section F, page 60, the applicant states that the working capital needs of the project will be funded through cash or cash equivalents, accumulated reserves, or owner’s equity.

See Exhibit 6 for a letter from Chief Manager for WFBI committing to fund the project and documentation of available funding on behalf of Wake Forest Baptist Imaging, LLC for the project’s capital and working capital costs. Exhibit 6 contains the Wake Forest Baptist Imaging, LLC balance sheet for the period ending April 30, 2019, showing adequate available funds. The exhibit also contains a proposed lease in the amount of \$450,000 for the GE Prodigy iDXA and the building upfit from GE Healthcare Equipment Finance. In the supplemental information requested by the Agency, the applicant states that the funding document from GE for \$450,000, simply shows more than adequate availability of funding from GE Healthcare Equipment Finance. The applicant anticipates the need for only \$195,717, as listed above.

Financial Feasibility

The applicant provides a pro forma financial statement, Form F.2, for the first three full fiscal years of operation following completion of the project for the proposed WFBI-K diagnostic center. The applicant projects that revenues exceed expenses for the diagnostic center in the each of the first three years, as summarized in the table below.

**Wake Forest Baptist Imaging-Kernersville
 Diagnostic Center**

	1st Full FY CY2021	2nd Full FY CY2022	3rd Full FY CY2023
Total Procedures*	10,370	13,398	16,969
Total Gross Revenues (Charges)	\$4,059,449	\$5,254,780	\$6,908,754
Total Contractual Adjustments	\$2,446,896	\$3,154,336	\$4,192,187
Total Net Revenue	\$1,612,552	\$2,100,443	\$2,716,568
Average Net Revenue per Procedure	\$156	\$157	\$160
Total Operating Expenses (Costs)	\$1,208,687	\$1,512,868	\$1,811,397
Average Operating Expense per Procedure	\$117	\$113	\$107
Net Income	\$403,865	\$587,576	\$905,170

*Total Procedures include x-ray, ultrasound, CT, mammography, and bone density from Section Q Assumptions (1) and from page 111 for x-ray and ultrasound procedures and page 116 for bone density, CT and mammography procedures

Source: Section Q Form F.2

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- supplemental information requested by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new diagnostic center by acquiring bone density equipment and relocating CT and mammography equipment to the existing WFBI Kernersville medical clinic which currently offers x-ray and ultrasound services.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2019 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C.4, page 33, the applicant states that the service area for the proposed diagnostic center is Forsyth County. Facilities may also serve residents not included in their service area.

In Section G.1, page 65, the applicant states that WFBI currently operates an existing diagnostic center in Winston-Salem, Forsyth County and North Carolina Baptist Hospital (NCBH), which is a member of WFBI, currently operates Clemmons Diagnostic Center in Forsyth County. The applicant refers to NCBH as Wake Forest Baptist Hospital (WFBH) in Section C.4, pages 30-31, and uses the names interchangeably throughout the application. The applicant states that it is also aware that NCBH and Novant Health also operate similar medical diagnostic equipment in their respective hospital facilities in the proposed service area.

On pages 66-67, the applicant states that utilization data for equipment in diagnostic centers is not available and provides the following information summarizing FY2018 utilization of similar diagnostic equipment located in the hospitals in Forsyth County.

Provider	Units/ Procedures	Ultrasound	Mammography	Bone Density	X-ray	CT
North Carolina Baptist Hospital	Units	17	6	1	25	10
	Procedures	25,291	19,076	914	129,064	62,650
Novant Health Forsyth Medical Center	Units	8	NA	NA	13	4
	Procedures	25,452	NA	NA	112,584	59,116
Novant Health Kernersville Medical Center	Units	2	3	1	5	1
	Procedures	4,424	8,646	1,532	17	14,803
Novant Health Clemmons Medical Center	Units	1	NA	NA	3	1
	Procedures	2,096	NA	NA	15,806	9,031

Source: pages 66 and 67 of application, based on 2019 Hospital License Renewal Applications.

In Section G.3, page 67, the applicant explains why it believes the proposal would not result in an unnecessary duplication of existing or approved diagnostic centers in the proposed service area. The applicant states:

“The relocation and purchase of the identified WFBI medical diagnostic equipment will result in the establishment of a new diagnostic center in Kernersville. WFBI’s proposal

will not result in unnecessary duplication of existing or approved health service capabilities. WFBI adequately demonstrates the need to maintain, relocate, and purchase the identified medical diagnostic equipment. See Section C, Criterion (3) for discussion of need for the proposed project from qualitative and quantitative perspectives.

WFBI is the largest freestanding outpatient diagnostic provider to WFBH. The proposed diagnostic center is needed by the specialty providers who refer their patients to WFBI, to aid them in diagnosing their patients' illnesses or conditions."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant uses reasonable assumptions to project the need for services in the proposed service area.
- The applicant uses reasonable assumptions to project the proposed utilization in the service area and for the proposed facility.
- The applicant adequately demonstrates that the proposed diagnostic center is needed in addition to the existing and/or approved diagnostic centers in the service area.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the above stated reasons.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section Q, Form H, the applicant provides projected full-time equivalent (FTE) positions for the proposed new diagnostic center for the first three full fiscal years of operation following completion of the project, as summarized in the following table.

**Wake Forest Baptist Imaging-Kernersville
 Diagnostic Center Staffing**

Position	CY2021	CY2022	CY2023
	FTE Positions	FTE Positions	FTE Positions
Administrator	0.30	0.40	0.50
Business Office Supervisor	0.30	0.40	0.50
X-ray Radiology Technologists	0.85	1.00	1.00
Ultrasound Technologists	0.85	1.00	1.00
CT Technologists	0.75	1.00	1.00
Sales Liason	0.30	0.40	0.50
Business Office Spec1	0.75	1.00	1.25
Mammography/DEXA Technologists	1.00	1.25	1.50
Clinical Manager	0.30	0.40	0.50
TOTAL	5.40	6.85	7.75

In Section H.1, page 69, and in Section Q, the applicant discusses the assumptions and methodology used to determine staffing needs. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form H and Form F.3, which are found in Section Q. In Section H.2 and H.3, pages 70-71, the applicant describes WFBI's experience and process for recruiting and retaining staff and its proposed training and continuing education programs. Exhibit 3 contains a letter from John M. Holbert, MD, stating his willingness to serve as Medical Director at the proposed diagnostic center. The applicant provides letters of support and referral documentation in Exhibit 11.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I.1, page 72, the applicant states that the following ancillary and support services are necessary for the proposed services and explains how these services will be made available:

- administration,
- patient scheduling,
- accounting and billing,
- medical records,
- human resources/payroll,
- staff education,
- infection control,
- quality and performance improvement,
- information technology,
- equipment maintenance, and
- housekeeping/linens.

In Section I, pages 72-73, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 11.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to develop a new diagnostic center by acquiring bone density equipment and relocating CT and mammography equipment to the existing WFBI Kernersville medical clinic which currently offers x-ray and ultrasound services.

In Section K.2, page 77, the applicant states that it will upfit approximately 4,844 square feet of space for the diagnostic center within the existing medical office building in Kernersville. Exhibit 5 contains the line drawings.

In Section K.3(a), pages 77-78, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Section Q and Exhibit 5.

On page 78, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provide supporting documentation in Section Q.

On page 78, the applicant discusses any applicable energy saving features that will be incorporated into the renovation plans.

On pages 79-83, the applicant identifies the proposed site and provides information on the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.1(a), page 85, the applicant discusses payor mix and states that WFBI began offering limited imaging services at the Kernersville clinic in March 2019; therefore the proposed center has limited historical payor mix data.

On page 87, the applicant provides the historical payor mix for the WFBI-WS diagnostic center, as summarized in the table below.

**Wake Forest Baptist Imaging -Winston-Salem
 Diagnostic Center
 CY2018**

Payor Source	X-ray	Ultrasound	Mammography	Bone Density	CT
Self-Pay /Charity Care	3.9%	1.6%	1.1%	0.6%	1.2%
Medicare*	13.6%	9.7%	11.5%	13.5%	15.5%
Medicaid *	6.8%	3.9%	1.3%	2.3%	2.4%
Insurance*	75.2%	84.7%	86.1%	83.5%	80.6%
Other (Gov't)	0.5%	0.1%	0.1%	0.1%	0.3%
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%

* Includes any managed care plans
 Totals may not sum due to rounding

On page 86, the applicant provides the following comparison of the demographical information on the Forsyth County residents with the Forsyth County patients at WFBI-WS during CY2018.

	Percentage of Total Forsyth County Patients Served during the Last Full FY	Percentage of the Population of Forsyth County
Female	78.0%	52.5%
Male	22.0%	47.5%
Unknown	Not Available	Not Available
64 and Younger	63.0%	84.4%
65 and Older	37.0%	15.6%
American Indian	Not Available	0.8%
Asian	Not Available	2.5%
Black or African-American	Not Available	27.4%
Native Hawaiian or Pacific Islander	Not Available	0.1%
White or Caucasian	Not Available	56.2%
Other Race	Not Available	13.0%
Declined / Unavailable	Not Available	0.0%

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in Forsyth County and in the applicant's proposed service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 87, the applicant states it has no obligation. The applicant further states:

“However, WFBI does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay.”

In Section L.2(c-d), page 88, the applicant states that there have been no patient civil rights equal access complaints filed against WFBI or any other related entity in the past five years.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.3(a), page 88, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

**Wake Forest Baptist Imaging-Kernersville
 Diagnostic Center
 CY2023**

Payor Source	X-ray	Ultrasound	Mammography	Bone Density	CT
Self-Pay /Charity Care	3.9%	1.6%	1.1%	0.6%	1.2%
Medicare*	13.6%	9.7%	11.5%	13.5%	15.5%
Medicaid *	6.8%	3.9%	1.3%	2.3%	2.4%
Insurance*	75.2%	84.7%	86.1%	83.5%	80.6%
Other (Gov't)	0.5%	0.1%	0.1%	0.1%	0.3%
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%

* Includes any managed care plans
 Totals may not sum due to rounding

As shown in the table above, during the third full fiscal year of operation, the applicant projects that between 0.6% and 3.9% of services will be provided to self-pay/charity care persons, between 9.7% and 15.5% of services will be provided to persons covered by Medicare, and between 1.3% and 6.8% of services will be provided to persons covered by Medicaid in each of the five medical diagnostic services to be provided at the proposed diagnostic center.

On page 89, the applicant provides the assumptions and methodology used to project payor source, stating that the projected payor mix at WFBI-K is based on the CY2018 WFBI-WS payor mix for the same services.

The projected payor mix is reasonable and adequately supported for the following reasons:

- the projected payor mix is based on the last full fiscal year of payor mix data for the same diagnostic services at WFBI-WS, and
- the applicant adequately demonstrates that medically underserved populations will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.5, page 90, the applicant describes the range of means by which a person will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 91, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit 7.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new diagnostic center by acquiring bone density equipment and relocating CT and mammography equipment to the existing WFBI medical clinic which currently offers x-ray and ultrasound services.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2019 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C.4, page 33, the applicant states that the service area for the proposed diagnostic center is Forsyth County. Facilities may also serve residents not included in their service area.

In Section G.1, page 65, the applicant states that WFBI currently operates an existing diagnostic center in Winston-Salem, Forsyth County and NCBH, which is a member of

WFBI, currently operates Clemmons Diagnostic Center in Forsyth County. The applicant states that it is also aware that NCBH and Novant Health also operate similar medical diagnostic equipment in their hospital facilities in the proposed service area.

On pages 66-67, the applicant states that utilization data for equipment in diagnostic centers is not available and provides the following information summarizing FY2018 utilization of similar diagnostic equipment located in the hospitals in Forsyth County.

Provider	Units/ Procedures	Ultrasound	Mammography	Bone Density	X-ray	CT
North Carolina Baptist Hospital	Units	17	6	1	25	10
	Procedures	25,291	19,076	914	129,064	62,650
Novant Health Forsyth Medical Center	Units	8	NA	NA	13	4
	Procedures	25,452	NA	NA	112,584	59,116
Novant Health Kernersville Medical Center	Units	2	3	1	5	1
	Procedures	4,424	8,646	1,532	17	14,803
Novant Health Clemmons Medical Center	Units	1	NA	NA	3	1
	Procedures	2,096	NA	NA	15,806	9,031

Source: pages 66 and 67 of application, based on 2019 Hospital License Renewal Applications.

In Section N, pages 93-98, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 93, the applicant states that the proposed new diagnostic center will have a positive effect on competition in the service area. The applicant further states:

“The proposed project will promote cost effective, high quality medical diagnostic imaging services that will be broadly accessible by local residents, as described in Section N.2 below. The project will enable WFBI to better meet the needs of WFBI’s existing patient population, and to ensure more timely provision of and convenient access to outpatient medical diagnostic imaging services for all area residents. WFBI assumes no adverse effect on current providers of medical diagnostic services in Forsyth County, as WFBI physicians have been longtime existing providers of these medical diagnostic services in Forsyth County.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits),
- Quality services will be provided (see Section O of the application and any exhibits), and
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- information which was publicly available during the review and used by the Agency, and
- supplemental information requested by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section A.6, page 12, the applicant identifies Outpatient Imaging Affiliates, LLC (OIA) as its management company. In Section O.3, page 102, the applicant identifies Wake Forest Baptist Medical Center (WFBMC) as a member of WFBI and lists the hospital facilities that WFBMC operates in North Carolina: North Carolina Baptist Hospital, Lexington Medical Center, Davie Medical Center, and Wilkes Regional Medical Center.

In Section O.3, pages 102-103, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care at any facilities owned, operated, or managed in North Carolina by WFBI, OIA, WFBMC, or related entities, other than the February 2018 pathology issue at NCBH, which has since been brought back into compliance with Medicare Conditions of Participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no other incidents related to quality of care at any WFBI, OIA, or WFBMC related entity. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to

demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The applicant proposes to develop a new diagnostic center by acquiring bone density equipment and relocating CT and mammography equipment to the existing WFBI medical clinic which currently offers x-ray and ultrasound services in Kernersville, Forsyth County.

The Criteria and Standards for Diagnostic Centers promulgated in 10A NCAC 14C .1800 were repealed. The Criteria and Standards for Major Medical Equipment promulgated in 10A NCAC 14C .3100 were repealed. The Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300 are not applicable to this review because the applicant is not acquiring new CT equipment, but rather relocating existing CT equipment within the service area.