

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 14, 2017

Findings Date: July 14, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: M-11330-17

Facility: Cape Fear Valley Outpatient Imaging – Spout Springs, LLC

FID #: 170189

County: Harnett

Applicant: Cape Fear Valley Outpatient Imaging – Spout Springs, LLC

Project: Develop a new diagnostic center with a CT scanner, X-ray unit, ultrasound unit and mammography unit

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.

C

Cape Fear Valley Outpatient Imaging – Spout Springs, LLC (CFV, or the applicant) proposes to develop a new freestanding diagnostic center to be located in Spout Springs, an unincorporated area in the southwestern corner of Harnett County. CFV is wholly owned by Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Medical Center. CFV proposes to provide CT scanner, X-ray, mammography and ultrasound services in the diagnostic center. The applicant also proposes to install a mobile MRI pad to be able to provide future mobile MRI services.

Need Determination

There is no need determination in the 2017 State Medical Facilities Plan (SMFP) applicable to the development of a diagnostic center or acquisition of any of the diagnostic services proposed in this application.

Policies

There is one policy in the 2017 SMFP applicable to this review, *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*. *Policy GEN-4*, on page 33 of the 2017 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million, but less than \$5 million. In Section B.11, pages 13 - 14, and Section K.4, pages 69 - 71, the applicant states it will work with experienced architects, engineers, and others to ensure energy efficient systems are utilized. The applicant provides a May 1, 2017 letter signed by an architect in Exhibit B-11 that confirms the applicant’s plans to maintain efficient energy operations and maintain costs in the proposed diagnostic center.

The applicant adequately demonstrates conformance with the requirements of *Policy GEN-4*.

Conclusion

In summary, the application is conforming to *Policy GEN-4*, therefore the application is conforming to this criterion.

- (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 new freestanding diagnostic center to be located in Spout Springs, an unincorporated area in the southwestern corner of Harnett County. The applicant proposes to provide CT scanner, X-ray, mammography and ultrasound services in the diagnostic center, and to install a mobile MRI pad to be able to provide future mobile MRI services. The proposed diagnostic center will be developed in shelled out space in a physician office building for which the applicant received an exemption from Certificate of Need review, and will be operated by CFVHS. In Section C.1, page 15, the applicant describes the project as follows:

“CFV Outpatient Imaging – Spout Springs is the next step toward fulfillment of CFVHS’s commitment to the residents of Harnett County. CFV Outpatient Imaging – Spout Springs will provide Harnett County residents with accessible, high quality, and cost-effective, outpatient diagnostic imaging in a comfortable and convenient location closer to home. CFV Outpatient Imaging – Spout Springs will be linked electronically with the CFVHS Radiology Department to assure continuity in medical records for patients receiving care at CFV Outpatient Imaging – Spout Springs. While a freestanding facility, CFV Outpatient Imaging – Spout Springs virtually will operate as part of the larger Radiology service at CFVHS.”

Patient Origin

The 2017 State Medical Facilities Plan (SMFP) does not define a service area for diagnostic centers, CT scanners, or ultrasound, X-ray or mammography services. However, 10A NCAC 14C §.2300(4), Criteria and Standards for Computed Tomography Equipment defines a Computed Tomography (CT) scanner service area as: *“a geographical area defined by the applicant from which the applicant projects to serve patients.”* Providers may serve residents of counties not included in their service area.

In Section C.3, pages 19 – 20, the applicant provides projected patient origin for all proposed services to be provided in the diagnostic center, summarized in the following tables:

CFV Outpatient Imaging – Spout Springs Percent Patient Origin PY 1 – PY 3

COUNTY	CT SCANNER			X-RAY			ULTRASOUND			MAMMOGRAPHY		
	PY 1	PY 2	PY 3	PY 1	PY 2	PY 3	PY 1	PY 2	PY 3	PY 1	PY 2	PY 3
Harnett	91.4%	91.0%	90.7%	91.4%	91.0%	90.7%	91.4%	91.0%	90.7%	89.4%	88.9%	88.6%
All Other	8.6%	9.0%	9.3%	8.6%	9.0%	9.3%	8.6%	9.0%	9.3%	10.6%	11.1%	11.4%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

*the applicant states “all other” includes Lee and Moore counties.

In Section C.1(c), pages 20 – 22, the applicant provides the assumptions it used to project patient origin, summarized as follows:

- The applicant analyzed an area in southwestern Harnett County consisting of six ZIP codes.
- Two of the ZIP codes overlap Moore and Lee county boundaries.
- One ZIP code includes the northwestern corner of Cumberland County, north of Fort Bragg.
- The applicant divided two ZIP codes in northern Harnett County, close to Lillington and Central Harnett Hospital, by census tracts. The applicant then removed the census tracts that are closer to Central Harnett Hospital to more effectively represent the population that would seek services at the proposed diagnostic center, south of the census tract line and south of Central Harnett Hospital.
- The applicant assumes patient origin for CT, ultrasound and mammography services will be greater from Harnett County than from surrounding counties.

The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section C.1, pages 23 – 28, the applicant describes the factors which it states support the need for a free-standing diagnostic imaging center in Harnett County, summarized below:

- Population growth in Harnett County was 13th in the state from 2012 to 2017, and is expected to outpace population growth in the state as a whole, even though it will slow somewhat between 2017 to 2022 (p. 24).
- Harnett, Wake and Durham counties are predicted to be among the fastest growing counties in the state from 2017 to 2022. Thus, locating the proposed diagnostic imaging services in Harnett County will create more availability for those imaging services in Wake and Durham Counties, since patients living in Harnett County will now remain in the county rather than travel to surrounding counties for those services (p. 24).
- In the 6 ZIP codes that comprise the proposed service area, two of the six ZIP codes overlap into Moore and Lee counties. Therefore, the applicant removed three census tracts within those ZIP codes that are located closest to CHH and Lillington from the analysis. The three census tracts that were removed accounted for approximately 14% of the total population in those two ZIP code areas (p. 25).
- The total service area population is projected to grow by a compound annual growth rate (CAGR) of 1.6% from 2017 to 2022, as illustrated in the following table:

Projected Service Area Population – CFV Outpatient Imaging

COUNTY	ZIP	2017	2018	2019	2020	2021	2022	CAGR
Lee/Harnett	27332	33,796	34,292	34,795	35,306	38,824	36,350	1.5%
Harnett	27505	7,392	7,510	7,629	7,751	7,874	7,999	1.6%
Harnett	27546	21,191	21,432	21,676	21,923	22,173	22,426	1.1%
Harnett	28326	22,584	23,047	23,520	24,002	24,494	24,996	2.1%
Harnett	28390	22,866	23,281	23,681	24,089	24,504	24,926	1.7%
Moore/Harnett	28394	5,243	5,295	5,348	5,402	5,456	5,511	1.0%
Adjusted to remove three census tracts from ZIP codes 27546 and 27505		-14%	-14%	-14%	-14%	-14%	-14%	
Total Service Area Population		97,259	98,776	100,319	101,886	103,480	105,099	1.6%
Harnett County Total		129,996	131,395	132,791	134,189	135,589	136,985	1.0%

Source: Truven, US Census

- There is considerable residential and commercial development in the area, including military housing developments, since it is close to Fort Bragg in Cumberland County (pages 25 – 27).
- Some population group changes combined with new government regulations regarding reimbursement rates for imaging services are increasing the utilization of freestanding diagnostic imaging centers that are associated with large health care systems (page 28, Exhibit E-2).
- Current physician services in the service area are limited; therefore, CFVHS and CHH are collaborating to recruit new physicians to the area. Over 100 area physicians indicate their support for the project and their intent to refer patients to the proposed diagnostic imaging center (page 28, Exhibit H-4(a)).

Projected Utilization

In Section C.4, pages 29 – 43, the applicant projects utilization for each modality proposed to be offered in the diagnostic center using similar steps for each modality, which are discussed below. The steps for determining volume for each modality begins with the population to be served, which was determined in Section C.1, page 25. Therefore, the analysis begins with Step 2 of the applicant’s methodology for each modality.

CT Scanner Volume

The applicant projects volume for the CT scanner based on four steps, the first of which is the population to be served.

- Step 2 - Having identified the population to be served by the CT scanner, the applicant calculated a statewide and a regional use rate, based on publicly available usage data submitted by providers, which includes Hospital License Renewal Applications (LRAs). The applicant states the use rate is conservative in both instances, since the publicly available data represents only a percentage of the total CT scan volume in both the state and the region (pages 30 – 31). Below is a table that summarizes the applicant's calculations:

State and Regional CT Use Rates

STATE	CT TOTAL
Total Volume all Hospitals	1,787,886
Valley Regional Imaging* Data	4,628
Combined Hospitals and VRI	1,792,514
2016 NC Population	10,158,475
Use Rate per 1,000	176.46
REGIONAL	TOTAL
Total Bladen, Cumberland, Harnett, Hoke, Lee, Moore, Robeson provider CT Volume	94,797
2016 Population Above Counties	832,074
Regional Use Rate per 1,000	113.93

*Valley Regional Imaging is a freestanding imaging center in Fayetteville in Cumberland County that is a joint venture between CFVHS and Valley Radiology.

Due to the inability to gather complete data, the applicant chose to use the state use rate, which is higher than the regional use rate, in its growth calculations.

- Step 3 - The applicant calculated future total CT scanner volume for the service area. The applicant assumes 25% of the calculated volume will be patients who receive CT services in an emergency department (ED) and thus subtracts 25% from its total projections. In addition, the applicant states the projected date of opening is April 2019. Therefore, the Project Years are April 2019 to March 2020 (PY 1), April 2020 – March 2021 (PY 2), and March 2021 – April 2022 (PY 3). See the following table, from page 31:

Projected Service Area CT Volume

	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
Total SA Pop.	97,259	98,776	100,319	101,886	103,480	105,099
CT Use Rate	176.46	176.46	176.46	176.46	176.46	176.46
Projected Need	17,162	17,430	17,702	17,978	18,259	18,545
CONVERT TO PROJECT YEARS				PY 1	PY 2	PY 3
Projected Service Area Volume Need*				17,771	18,049	18,332
Less CT Performed in ED (25%)				13,328	13,536	13,748

*Calculated by adding 75% of prior CY projected need to 25% of present CY projected need to convert project years to calendar years.

- Step 4 - The applicant calculated a market share based on the use rate to project future CT scanner volume at CFV. The applicant assumes CT volume will be equally distributed across the six ZIP codes according to each ZIP code's population distribution. The applicant divided the six ZIP codes into three separate areas to determine a market share of each, based on the following assumptions (pages 31 – 32):
 1. The four ZIP codes in Harnett and Cumberland counties represent the largest market. The applicant assumes a 35%, 40% and 45% market share from this area in Project Years 1, 2 and 3, respectively.

2. The ZIP code that overlaps into Lee County represents a small portion within Harnett County; therefore, the applicant assumes a 5%, 6% and 7% market share from this area in in Project Years 1, 2 and 3, respectively.
 3. The ZIP code that overlaps into Moore County represents a small portion within Harnett County; therefore, the applicant assumes a 5%, 6% and 7% market share from this area in in Project Years 1, 2 and 3, respectively.
- The combined market share assumptions equal 23.1%, 26.5% and 29.9% of the entire six ZIP code area (page 32, Exhibit C.4, Table 16). See the following table, from page 32 of the application:

CFV Projected CT Volume

	PY 1 4/19 – 3/20	PY 2 4/20 – 3/21	PY 3 4/21 – 3/22
Projected Service Area CT Volume (Non ED)	13,328	13,536	13,748
CFV Outpatient Imaging Projected Market Share	23.1%	26.5%	29.9%
CFV Outpatient Imaging Projected CT Volume	3,072	3,581	4,106

- The applicant compared its market share projections to historical HECT distribution in rural community hospitals in Exhibit C.4 and determined its projections to be consistent with the historical trend. The applicant projects a total of over 4,000 CT scans in the third project year, which is 6,126 HECTs (page 32).

The Criteria and Standards for Computed Tomography Equipment, promulgated at 10A NCAC 14C §.2303(1) states that “*each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment*” The applicant projects in excess of 5,100 HECTs in the third year of operation.

X-Ray Volume

The applicant projects X-ray volume based on four steps, the first of which is the population to be served.

- Step 2 - Having identified the population to be served by the X-ray equipment, the applicant calculated a statewide and a regional use rate, based on publicly available usage data submitted by providers, which includes Hospital LRAs. The applicant states the use rate is conservative in both instances, since the publicly available data represents only a percentage of the total X-ray volume in both the state and the region (pages 33 – 34). Below is a table that summarizes the applicant's calculations:

State and Regional X-Ray Use Rates

STATE	X-RAY TOTAL
Total Volume all Hospitals	2,684,883
Valley Regional Imaging Data	10,370
Combined Hospitals and VRI	2,695,613
2016 NC Population	10,158,475
Use Rate per 1,000	265.36
REGIONAL	X-RAY TOTAL
Total Bladen, Cumberland, Harnett, Hoke, Lee, Moore, Robeson provider X-Ray Volume*	225,654
2016 Population Above Counties	832,074
Regional Use Rate per 1,000	271.19

*The applicant states this total includes VRI volume

On page 34, the applicant states it uses the higher use rate in its volume projections, since both numbers are conservative (due to unavailability of complete data).

- *Step 3* – Using population projections and the use rate from Step 2, the applicant calculated future X-ray volume for the entire service area, as illustrated in the following table, from page 34:

Projected Service Area X-Ray Volume

	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
Total SA Pop.	97,259	98,776	100,319	101,886	103,480	105,099
X-Ray Use Rate	271.19	271.19	271.19	271.19	271.19	271.19
Projected Need	26,376	26,788	27,206	27,631	28,063	28,502
CONVERT TO PROJECT YEARS				PY 1	PY 2	PY 3
Projected Service Area Volume Need*				27,312	27,739	28,173

*Calculated by adding 75% of prior CY projected need to 25% of present CY projected need.

- *Step 4* - The applicant calculated a market share based on the use rate to project future X-Ray volume at CFV. The applicant assumes X-Ray volume will be equally distributed across the six ZIP codes according to each ZIP code’s population distribution. The applicant divided the six ZIP codes into three separate areas to determine a market share of each, based on the following assumptions (page 35):
 4. The four ZIP codes in Harnett and Cumberland counties represent the largest market. The applicant assumes a 35%, 40% and 45% market share from this area in Project Years 1, 2 and 3, respectively.
 5. The ZIP code that overlaps into Lee County represents a small portion within Harnett County; therefore, the applicant assumes a 5%, 6% and 7% market share from this area in Project Years 1, 2 and 3, respectively.
 6. The ZIP code that overlaps into Moore County represents a small portion within Harnett County; therefore, the applicant assumes a 5%, 6% and 7% market share from this area in Project Years 1, 2 and 3, respectively.

- The combined market share assumptions equal 23.1%, 26.5% and 29.9% of the entire six ZIP code area (page 35, Exhibit C.4, Table 16). See the following table, from page 35 of the application:

CFV Projected X-Ray Volume

	PY 1 4/19 – 3/20	PY 2 4/20 – 3/21	PY 3 4/21 – 3/22
Projected Service Area X-Ray Volume	27,312	27,739	28,173
CFV Outpatient Imaging Projected Market Share	23.1%	26.5%	29.9%
CFV Outpatient Imaging Projected X-Ray Volume	6,296	7,339	8,414

On page 35, the applicant states one X-ray unit, as proposed in this application, is sufficient to meet the projected demand of 8,414 X-rays in Project Year 3.

Ultrasound Volume

The applicant projects ultrasound volume based on four steps, the first of which is the population to be served.

- Step 2 - Having identified the population to be served by the ultrasound equipment, the applicant calculated a statewide and a regional use rate, based on publicly available usage data submitted by providers, which includes Hospital LRAs. The applicant states the use rate is conservative in both instances, since the publicly available data represents only a percentage of the total ultrasound volume in both the state and the region (pages 36 - 37). Below is a table that summarizes the applicant's calculations:

State and Regional Ultrasound Use Rates

STATE	ULTRASOUND TOTAL
Total Volume all Hospitals	717,620
Valley Regional Imaging Data	10,945
Combined Hospitals and VRI	728,565
2016 NC Population	10,158,475
Use Rate per 1,000	71.72
REGIONAL	ULTRASOUND TOTAL
Total Bladen, Cumberland, Harnett, Hoke, Lee, Moore, Robeson provider X-Ray Volume*	62,973
2016 Population Above Counties	832,074
Regional Use Rate per 1,000	75.68

*The applicant states this total includes VRI volume

On page 37, the applicant states it uses the higher use rate in its projections of future volume, since both numbers are conservative (due to unavailability of complete data).

- Step 3 – Using population projections and the use rate from Step 2, the applicant calculated future ultrasound volume for the entire service area, as illustrated in the following table, from page 38:

Projected Service Area Ultrasound Volume

	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
Total SA Pop.	97,259	98,776	100,319	101,886	103,480	105,099
Ultrasound Use Rate	75.68	75.68	75.68	75.68	75.68	75.68
Projected Need	7,361	7,476	7,592	7,711	7,832	7,954
CONVERT TO PROJECT YEARS				PY 1	PY 2	PY 3
Projected Service Area Volume Need*				7,622	7,741	7,862

*Calculated by adding 75% of prior CY projected need to 25% of present CY projected need.

- Step 4 - The applicant calculated a market share based on the use rate to project future ultrasound volume at CFV. The applicant assumes ultrasound volume will be equally distributed across the six ZIP codes according to each ZIP code’s population distribution. The applicant divided the six ZIP codes into three separate areas to determine a market share of each, based on the following assumptions (page 35):
 7. The four ZIP codes in Harnett and Cumberland counties represent the largest market. The applicant assumes a 35%, 40% and 45% market share from this area in Project Years 1, 2 and 3, respectively.
 8. The ZIP code that overlaps into Lee County represents a small portion within Harnett County; therefore, the applicant assumes a 5%, 6% and 7% market share from this area in Project Years 1, 2 and 3, respectively.
 9. The ZIP code that overlaps into Moore County represents a small portion within Harnett County; therefore, the applicant assumes a 5%, 6% and 7% market share from this area in Project Years 1, 2 and 3, respectively.
- The combined market share assumptions equal 23.1%, 26.5% and 29.9% of the entire six ZIP code area (page 38, Exhibit C.4, Table 16). See the following table, from page 39 of the application:

CFV Projected Ultrasound Volume

	PY 1	PY 2	PY 3
	4/19 – 3/20	4/20 – 3/21	4/21 – 3/22
Projected Service Area Ultrasound Volume	7,622	7,741	7,862
CFV Outpatient Imaging Projected Market Share	23.1%	26.5%	29.9%
CFV Outpatient Imaging Projected Ultrasound Volume	1,757	2,048	2,348

On page 39, the applicant states one ultrasound unit, as proposed in this application, is sufficient to meet the projected demand of 2,348 ultrasounds in Project Year 3.

Mammography Volume

- Step 1: Population to be Served - The applicant based its mammography population to be served on the same six ZIP codes as for the other services, but only included females over the age of 45 within those six ZIP codes. The applicant subtracted the same census tract areas that are closest to Lillington and CHH services, and calculated the following population to be served:

Projected Service Area Population Female Age 45+

COUNTY	ZIP	2017	2018	2019	2020	2021	2022	CAGR	ADJUSTED POPULATION	
Lee	27332	6,636	6,917	7,062	7,210	7,361	7,515	2.1%	7,515	38.3%
Harnett	27505	1,384	1,457	1,494	1,533	1,573	1,614	2.6%		
Harnett	27546	3,706	3,866	3,949	4,033	4,119	4,207	2.1%		
Harnett	28326	3,120	3,386	3,527	3,674	3,827	3,987	4.2%		
Harnett	28390	3,501	3,700	3,804	3,911	4,021	4,134	2.8%	10,743	54.7%
Moore	28394	1,256	1,298	1,319	1,341	1,363	1,385	1.6%	1,385	7.1%
Total SA Population		19,603	20,623	21,155	21,702	22,264	22,842	2.6%		
Adjusted to remove three census tracts from ZIP codes 27546 and 27505		-14%	-14%	-14%	-14%	-14%	-14%			
Subtotal Census Tract Population		2,744	2,887	2,962	3,038	3,117	3,198			
Adjusted Service Area Population		16,859	17,736	18,193	18,664	19,147	19,644	2.6%	19,644	100.0%

The applicant projects that, by the third Project Year, the population of women over age 45 in the projected service area will be near 20,000.

- *Step 2* - Having identified the population to be served by the mammography equipment, the applicant calculated a statewide and a regional use rate, based on publicly available usage data submitted by providers, which includes Hospital LRAs. The applicant states the use rate is conservative in both instances, since the publicly available data represents only a percentage of the total ultrasound volume in both the state and the region (pages 40 - 41). Below is a table that summarizes the applicant's calculations:

State and Regional Mammography Use Rates

STATE		ULTRASOUND TOTAL
Total Volume all Hospitals		660,935
Valley Regional Imaging Data		33,409
Combined Hospitals and VRI		694,344
2016 NC Population of females > 45 years		2,263,396
Use Rate per 1,000		306.77
REGIONAL		ULTRASOUND TOTAL
Total Bladen, Cumberland, Harnett, Hoke, Lee, Moore, Robeson provider X-Ray Volume*		69,325
2016 Population Above Counties of females > 45 years		171,147
Regional Use Rate per 1,000		405.06

*The applicant states this total includes VRI volume

On page 41, the applicant states it uses the higher use rate in its projections of future volume, since both numbers are conservative (due to unavailability of complete data).

- *Step 3* – Using population projections and the use rate from Step 2, the applicant calculated future mammography volume for the entire service area, as illustrated in the following table, from page 41:

Projected Service Area Mammography Volume

	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
Total SA Pop.	17,291	17,736	18,193	18,664	19,147	19,644
Ultrasound Use Rate	405.06					
Projected Need	7,084	7,184	7,369	7,560	7,756	7,957
CONVERT TO PROJECT YEARS				PY 1	PY 2	PY 3
Projected Service Area Volume Need*				7,417	7,609	7,806

*Calculated by adding 75% of prior CY projected need to 25% of present CY projected need.

- *Step 4* - The applicant calculated a market share based on the use rate to project future mammography volume at CFV. The applicant assumes mammography volume will be equally distributed across the six ZIP codes according to each ZIP code’s population distribution. The applicant divided the six ZIP codes into three separate areas to determine a market share of each, based on the following assumptions (page 42):
 10. The four ZIP codes in Harnett and Cumberland counties represent the largest market. The applicant assumes a 35%, 40% and 45% market share from this area in Project Years 1, 2 and 3, respectively.
 11. The ZIP code that overlaps into Lee County represents a small portion within Harnett County; therefore, the applicant assumes a 5%, 6% and 7% market share from this area in Project Years 1, 2 and 3, respectively.
 12. The ZIP code that overlaps into Moore County represents a small portion within Harnett County; therefore, the applicant assumes a 5%, 6% and 7% market share from this area in Project Years 1, 2 and 3, respectively.
- The combined market share assumptions equal 21.4%, 24.6% and 27.8% of the entire six ZIP code area (page 38, Exhibit C.4). See the following table, from page 42 of the application:

CFV Projected Mammography Volume

	PY 1	PY 2	PY 3
	4/19 – 3/20	4/20 – 3/21	4/21 – 3/22
Projected Service Area Mammography Volume	7,417	7,609	7,806
CFV Outpatient Imaging Projected Market Share	21.4%	24.6%	27.8%
CFV Outpatient Imaging Projected Mammography Volume	1,588	1,871	2,169

On page 42, the applicant states one mammography unit, as proposed in this application, is sufficient to meet the projected demand of 2,169 ultrasounds in Project Year 3.

In each of the analyses with respect to each of the service modalities proposed in this application, the applicant used publicly available historical data and an analysis of the population to be served within the service area by modality. The North Carolina Division of Health Service Regulation Division of Radiation Protection indicates that there are far more units of each proposed imaging modality than are required to report utilization (pages 30 – 40). Therefore, the historical utilization on which the applicant bases its data is conservative and understated. Use of conservative data to

project utilization of CT, X-ray, ultrasound and mammography equipment in a freestanding diagnostic center to be located in an area where none currently exists is reasonable.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for proposed diagnostic center, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (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.

NA

- (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

In Section E.2, page 52, the applicant describes the alternatives considered prior to submitting this application for the proposed project: develop the proposed freestanding outpatient imaging center as a wholly owned LLC or to joint venture with area radiologists. The applicant states that developing a diagnostic center is, in itself, a cost-effective proposal since it offers lower copays for patients. The applicant considered a joint venture with local radiologists, but states that alternative was not a timely one, because it would take longer to achieve. The applicant states physician partners can easily purchase membership in the LLC when details of the joint venture are determined.

After considering the alternatives, the applicant states the alternative represented in the application is the more effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Cape Fear Valley Outpatient Imaging – Spout Springs, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Cape Fear Valley Outpatient Imaging – Spout Springs, 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.**
 3. **Cape Fear Valley Outpatient Imaging – Spout Springs, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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

In Sections F and Q, the applicant projects the total capital cost for the project will be \$2,000,657.82. The proposed capital cost consists of the following:

CAPITAL COST CATEGORY	TOTAL
Construction/Renovation Contracts	\$806,927
Landscaping	\$14,154
Design/Management/Testing Fees	\$101,376
Imaging Equipment	\$891,632
Non-imaging Equipment	\$137,753
Interiors and Signage	\$11,323
Contingency	\$37,493
Total Capital Cost	\$2,000,658

*On page 107, the applicant provides cost in dollars and cents. The analyst rounded up or down accordingly to provide whole dollar amounts in the table.

In Section F.3, pages 55 - 56, the applicant projects start-up costs for one month in the amount of \$37,184, and initial operating expenses for a three-month period in the amount of \$292,992, for a total working capital expense of \$330,176.

Availability of Funds

In Section F.2, page 54, the applicant states that the project will be financed with the accumulated reserves or owner’s equity of Cumberland County Hospital System, d/b/a Cape Fear Valley Health System. In Exhibit F.3 the applicant provides an April 17, 2017 letter signed by the Chief Financial Officer for CFVHS, which confirms the availability of sufficient accumulated reserves to cover the total capital and working capital costs associated with the development of the project.

Exhibit F.2 contains the most recent audited financial statements for The CCHS d/b/a CFVHS for the years ending December 31, 2016 and December 31, 2015. The balance sheet indicates that as of December 31, 2016, CFVHS had \$885,645,000 in total assets, \$49,175,000 in cash and cash

equivalents, and \$359,805,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

In Section Q, the applicant totaled all of the imaging modality procedures to be provided in each of the three project years, and used the total number of imaging procedures in its Pro Formas. See the following table, from Section Q, page 112:

Total Imaging Utilization Project Years 1 - 3

MODALITY	PY 1 (4/19 – 3/20)	PY 2 (4/20 – 3/21)	PY 3 (4/21 – 3/22)
CT Scans	3,072	3,581	4,106
X-Rays	6,296	7,339	8,414
Ultrasound Procedures	1,757	2,048	2,348
Mammography Procedures	1,588	1,871	2,169
Total	12,713	14,839	17,036

Using those totals, the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below.

	PY 1 (4/19 – 3/20)	PY 2 (4/20 – 3/21)	PY 3 (4/21 – 3/22)
Projected # of Total Procedures	12,713	14,839	17,036
Projected Average Charge*	\$238.93	\$243.70	\$248.59
Gross Patient Revenue	\$3,037,455	\$3,616,318	\$4,235,018
Deductions from Gross Patient Revenue	\$2,158,478	\$2,569,830	\$3,009,491
Net Patient Revenue	\$878,977	\$1,046,487	\$1,225,526
Total Expenses	\$772,692	\$923,610	\$1,034,796
Net Income	\$106,285	\$122,878	\$190,731

*Calculated by (Gross Patient Revenue / Projected # of Cases)

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. 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.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (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 freestanding diagnostic center to be located in Spout Springs, an unincorporated area in the southwestern corner of Harnett County, and to provide CT scanner, X-ray, mammography and ultrasound services in the diagnostic center. The applicant also proposes to install a mobile MRI pad to be able to provide future mobile MRI services.

The 2017 SMFP does not define the service area for any of the diagnostic imaging equipment proposed in this application. The Criteria and Standards for CT Equipment (10A NCAC 14C .2300), which are applicable to this review, state that an applicant's service area for CT scanner services is self-defined. In Section C.2, page 59, the applicant provides a map that illustrates the radius of the six ZIP codes that define the applicant's service area, and on page 60, the applicant provides a table to illustrate the providers of similar imaging modalities in the service area. Thus, the applicant's service area for the proposed diagnostic center includes 6 ZIP codes in Harnett, Lee and Moore Counties. However, facilities may serve residents of counties not included in their service area.

The proposal will result in the addition of one CT scanner to be located in Harnett County. There is currently one CT scanner in Harnett County, located at Central Harnett Hospital (CHH). However, the applicant's service area as defined eliminates the census tracts that include the ZIP code for Lillington, where CHH is located. In Section C, pages 30 – 40, the applicant states that the North Carolina Division of Health Service Regulation Division of Radiation Protection indicates that there are far more units of X-ray, ultrasound and mammography than are required to report utilization; therefore, it is not possible to ascertain the exact utilization of these modalities. However, there are no other freestanding diagnostic centers in the proposed service area. Moreover, the applicant has excluded from its service area those ZIP codes that are geographically closer to and thus more likely to travel to CHH for services.

The applicant adequately demonstrates the need to develop a diagnostic center with one CT scanner and ultrasound, mammography and X-ray equipment. The discussion regarding need found in Criterion (3) is incorporated herein by reference. Consequently, the applicant adequately demonstrates that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming to this criterion.

- (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 projects staffing for the proposed diagnostic center. The applicant projects a total of 6.9 full-time equivalent (FTE) positions to staff the diagnostic services at CFV, as shown in the following table:

CFV Outpatient Imaging Projected Staffing

Employee Title	# FTEs
Radiology	
Technician	2.8
Clerical	2.1
Administrative	1.0
Business Office	
Biller	1.0
Total	6.9

In Section Q, Form H, the applicant also provides the salary per FTE for each position. In Section H.4, page 64, the applicant states that Dr. David Allison has expressed an interest in serving as the Medical Director for the diagnostic center. In addition, the applicant states there are several radiologists associated with Valley Radiology in Harnett County who have expressed their support for the project and who have agreed to provide rotations in the diagnostic center. An April 17, 2017 letter signed by Dr. Allison expressing an interest in serving as medical director is included in Exhibit H.4b, and physician letters of support are provided in Exhibit H.4a. In Section H.2, pages 62 – 63, the applicant states that it expects no difficulty recruiting needed staff for the proposed diagnostic center. The applicant states it has been recruiting for 60 years and thus has contacts and methods in place, but also utilizes social media such as Facebook and LinkedIn to recruit younger staff and professionals.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed diagnostic imaging services. Therefore, the application is conforming to this criterion.

- (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, pages 65 - 67, the applicant demonstrates that it will make available the necessary ancillary and support services to support the proposed project. In Exhibit I.1, the applicant provides an April 17, 2017 letter from the Chief Operating Officer of CFVHS, documenting that these services will be provided at the proposed diagnostic center. Furthermore, in Section I, the applicant states that CFVHS has established relationships with area healthcare and social services providers which it will continue to have and will extend to the proposed diagnostic center following the proposed project's completion. In Exhibit I.2, the applicant provides several letters of support from area physicians and community organizations who express support for the proposed diagnostic center.

The applicant adequately demonstrates that the necessary ancillary and support services will be available that that the proposed services will be coordinated with the existing health care system. Therefore, 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

- (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

- (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 in 3,470 square feet of space in a medical office building to be developed by CFVHS. The project will be new construction in shelled space located at the intersection of highways 24 and 87 in southwestern Harnett County. Exhibit F.1 contains a certified cost estimate from an architect that estimates construction costs that are consistent with the capital cost projections provided by the applicant in Section Q, page 107 of the application. Line drawings and a site plan are also provided in Exhibit K.1. In Section K, pages 69 - 73, and Exhibit F.1, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, 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;

NA

The applicant is proposing to develop a new facility and therefore has no current data to report.

(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;

NA

The applicant is proposing to develop a new facility and states it is not under any obligation to provide uncompensated care.

(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, page 76, the applicant projects the following payor mix for BBCC's diagnostic services during the second operating year (CY2019):

PAYOR CATEGORY	PERCENT OF TOTAL
Commercial Insurance/Managed Care	30.1%
Medicaid	19.0%
Medicare	28.0%
Military	9.8%
Other Government	1.8%
Self Pay	11.2%
Total	100.0%

On page 76 the applicant states that projected payor mix is based upon the historical outpatient services payor mix for the ZIP codes comprising the service area. The applicant states the information was obtained from the Truven Outpatient Database. The applicant also provides copies of their policies with regard to charity care in Exhibit C.10. The applicant adequately demonstrates that the medically underserved population will have access to the proposed diagnostic imaging services. Therefore, 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 76, the applicant states referral to the diagnostic center must be by a physician. In Exhibit H.4a, the applicant provides over 100 letters signed by area physicians, each of which indicates that physician will refer patients as appropriate to the proposed diagnostic center. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, 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.1, page 77, the applicant states that CFVHS has established clinical training agreements for nursing and residency programs with area colleges and universities. The applicant provides a list of these colleges and universities on page 78, and states these agreements will continue and will include the proposed diagnostic center following completion of the proposed project. Exhibit M.2 contains copies of examples of existing health professional training agreements and a list of training programs with which the applicants have relationships. The information provided is reasonable and adequately supports a determination that 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 freestanding diagnostic center to be located in Spout Springs, an unincorporated area in the southwestern corner of Harnett County, and to provide CT scanner, X-ray, mammography and ultrasound services. The applicant also proposes to install a mobile MRI pad to be able to provide future mobile MRI services.

The 2017 SMFP does not define the service area for any of the diagnostic imaging equipment proposed in this application. The Criteria and Standards for CT Equipment (10A NCAC 14C .2300), which are applicable to this review, state that an applicant's service area for CT scanner services is self-defined. In Section C.2, page 59, the applicant provides a map that illustrates the radius of the six ZIP codes that define the applicant's service area, and on page 60, the applicant provides a table to illustrate the providers of similar imaging modalities in the service area. Thus, the applicant's service area for the proposed diagnostic center includes 6 ZIP codes in Harnett, Lee and Moore Counties. However, facilities may serve residents of counties not included in their service area. The only other CT scanner in Harnett County is at Central Harnett Hospital, located approximately 22 miles from the proposed location of the diagnostic center. The applicant's defined service area removes the census tracts that include CHH; therefore, the CT scanner located at CHH is not within the applicant's defined service area. The other equipment proposed in this application - X-ray, ultrasound and mammography – are currently hospital based. There is no other free-standing diagnostic imaging center in the proposed service area.

In Section N.2, pages 82 - 83, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed diagnostic imaging services. See also Sections II, III, V, VI and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant adequately demonstrates that it will provide access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(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

The applicant does not own or manage any other imaging facilities in North Carolina. The Cape Fear Valley Health System owns and operates one other diagnostic imaging center, Hoke Imaging, located in Raeford, in Hoke County, and a minority share in Valley Regional Imaging, which is a free-standing imaging center in Fayetteville, in Cumberland County. CFVHS manages several other hospitals in the area, as shown in the following table:

HOSPITAL	LOCATION
Cape Fear Valley Medical Center	Fayetteville, Cumberland County
Highsmith-Rainey Specialty Hospital	Fayetteville, Cumberland County
Bladen County Hospital	Elizabethtown, Bladen County
Behavioral Health Care	Fayetteville, Cumberland County
Hoke Hospital	Raeford, Hoke County

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, neither of the facilities is currently out of compliance with CMS Conditions of Participation, nor have any other incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by Cape Fear Valley Health System.

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 Cape Fear Valley Health System, the applicant provides 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 application is conforming or conditionally conforming to all applicable Criteria and Standards for Computed Tomography Equipment, promulgated in 10A NCAC 14C .2300. The specific criteria are discussed below:

SECTION .2300 - CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) *An applicant proposing to acquire a CT scanner shall demonstrate each of the following:*

(1) *each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;*

-C- In Section C, page 32, the applicant demonstrates that the proposed CT scanner will perform 6,126 HECT units in the third year of operation. See also Exhibit C.4, Table 2, page 133.

(2) *each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application; and*

-NA- Neither CFVHS nor CFV own a controlling interest in any other CT scanner in the proposed service area.

(3) *each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.*

-NA- Neither CFVHS nor CFV own a controlling interest in any other CT scanner in the proposed service area.