

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 24, 2021

Findings Date: February 24, 2021

Project Analyst: Kim Meymandi

Team Leader: Gloria C. Hale

Project ID #: G-11992-20

Facility: Novant Health Forsyth Medical Center

FID #: 923174

County: Forsyth

Applicant(s): Forsyth Memorial Hospital, Inc.

Novant Health, Inc.

Project: Retain existing CT Simulator previously approved to be replaced

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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

Forsyth Memorial Hospital, Inc., doing business as Novant Health Forsyth Medical Center and Novant Health, Inc. (Novant), referred to collectively hereinafter as “the applicant” or “NHFMC” proposes to retain an existing CT simulator previously approved to be replaced.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP)
- acquire any medical equipment for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP)
- offer a new institutional health service for which there are any policies in the 2020 State Medical Facilities Plan (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- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to retain an existing CT simulator previously approved to be replaced. In Section C, page 29 the applicant identifies the existing CT simulator as a Philips CT Simulator, Model #453567088051, Serial #97370 (hereinafter referred to as “the existing simulator”). On August 19, 2019, the Agency approved a request from the applicant to exempt from CON review the acquisition of a Siemens Somatom Confidence CT Simulator to replace the existing CT Simulator. The determination made by the Agency was based on representations that the existing unit would be removed from North Carolina and not be used again without obtaining a CON. On April 28, 2020 the Agency approved a request to extend by 90 days the time to dispose of the existing simulator. In June 2020, the applicant states that the Siemens Somatom Confidence CT Simulator was installed and an existing Fluro-Simulator at Novant Health Forsyth Medical Center (NHFMC) was removed from the state rather than the existing simulator identified in the August 2019 letter of exemption. On September 11, 2020 the Agency approved a second request to extend by 90 days the time to remove from service the existing simulator. This proposal seeks to permanently retain and operate the existing simulator.

Patient Origin

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2020 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C, pages 32-33, the applicant defines the service area for the proposed project. The applicant states that the primary service area is Forsyth County and the secondary service area includes the surrounding counties of Surry, Stokes, Davidson, Yadkin, Davie and Wilkes. Facilities may also serve residents of counties not included in the service area.

In Sections C.2 and C.3, pages 32-33, the applicant provides the historical (FY2019) patient origin for CT simulator services at NHFMC, and the projected patient origin for the first three full fiscal years of operation (FY2022-FY2024) of the proposed project, as shown in the following tables:

**Historical Patient Origin
 NHFMC CT Simulator Services FY2019**

COUNTY	LAST FULL FY (1/1/19 – 12/31/19)	
	# PATIENTS	% OF TOTAL
Forsyth	700	48.1%
Primary Service Area Subtotal	700	48.1%
Surry	150	10.3%
Stokes	115	7.9%
Davidson	109	7.5%
Yadkin	83	5.7%
Davie	74	5.1%
Wilkes	59	4.1%
Secondary Service Area Subtotal	590	40.6%
In-Migration*	164	11.3%
Total	1,454	100.0%

*In-Migration includes 18 North Carolina counties and several states.

Projected Patient Origin

COUNTY	1 st Full FY FY2022		2 nd Full FY FY2023		3 rd Full FY FY2024	
	# Pts	% of Total	# Pts	% of Total	# Pts	% of Total
Forsyth	690	48.1%	714	48.1%	740	48.1%
Primary Service Area Subtotal	690	48.1%	714	48.1%	740	48.1%
Surry	148	10.3%	153	10.3%	158	10.3%
Stokes	113	7.9%	117	7.9%	122	7.9%
Davidson	108	7.5%	111	7.5%	115	7.5%
Yadkin	82	5.7%	85	5.7%	88	5.7%
Davie	73	5.1%	76	5.1%	78	5.1%
Wilkes	59	4.1%	61	4.1%	63	4.1%
Secondary Service Area Subtotal	583	40.6%	603	40.6%	624	40.6%
In-Migration*	162	11.3%	168	11.3%	174	11.3%
Total	1,435	100.0%	1,485	100.0%	1,538	100.0%

*In-Migration includes 18 North Carolina counties and several states.

In Section C, page 33, the applicant states that the projected patient origin is based on the historical patient origin for CT simulator services at NHFMC. The applicant's assumptions are reasonable and adequately supported, based on the following:

- The projected patient origin is consistent with the historical patient origin.
- The applicant does not propose to develop any services or make any changes to its facility that could foreseeably impact the projected patient origin in more than minor ways.

Analysis of Need

In Section C, pages 34-40 the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 34, the applicant states:

“NHFMC has utilized two simulators, a dedicated CT simulator and a Fluoro-Simulator (2-D), for over a decade to plan radiation for thousands of patients annually. It is necessary for NHFMC to continue operating two simulators because NHFMC has annually ranked in the Top 5 radiation therapy programs, out of 72 programs, in North Carolina by total ESTVs performed, which directly relates to the number of CT simulations performed and NHFMC has to take precautions in case a simulator is taken out of service due to maintenance or repair and the medical center must continue to have the ability to provide simulation for those patients receiving radiation therapy.

The Philips CT simulator will:

- *Meet the current demand for simulation services and continue to achieve sufficient volumes to maintain its operation in Forsyth County.*
- *Maintain patient access and throughput to Simulation services in the service area.”*

On pages 34-40, the applicant states that the need the patients have for the proposed project is based on the following factors:

Population Trends of the Service Area (pages 35-36)

The applicant uses data from the North Carolina Office of State Budget and Management (NCOSBM) to demonstrate the need based on the population growth in the service area. The applicant states that between 2020 and 2025, Forsyth County is projected to grow steadily from 383,123 to 400,595, a 4.6 percent growth rate. During the same time period the extended service area, which includes Davidson, Davie, Stokes, Surry, Yadkin, and Wilkes counties and comprises 40.6 percent of the total projected simulation patients at NHFMC, is projected to grow from 443,170 to 454,405, a 2.5 percent growth rate. The growth rate of the 65+ population in years 2020-2025 is projected to be 15.5 percent and 12.0 percent in Forsyth County and the Extended Service Area, respectively. The applicant also provides data showing that the incidence of cancer increases with age. The population and cancer rate data provided by the applicant is shown in the tables below.

Projected Population Growth Forsyth County

	2015	2020	2025 (Projected)	2015-2020	2020-2025
				Percent Growth	Percent Growth
<18 Population	86,332	87,060	87,967	0.8%	1.0%
18-44 Population	129,873	136,761	145,058	5.3%	6.1%
45-64 Population	95,530	96,663	95,231	1.2%	-1.5%
65+ Population	53,643	62,639	72,339	16.8%	15.5%
Total Population	365,378	383,123	400,595	4.9%	4.6%
Percent <18	23.6%	22.7%	22.0%		
Percent 18-44	35.5%	35.7%	36.2%		
Percent 45-64	26.1%	25.2%	23.8%		
Percent 65+	14.7%	16.3%	18.1%		

Source: Section C, page 35, 2019 NCOSBM

Projected Population Growth Extended Service Area

	2015	2020	2025 (Projected)	2015-2020	2020-2025
				Percent Growth	Percent Growth
<18 Population	92,654	88,912	88,622	-4.0%	-0.3%
18-44 Population	136,598	140,756	147,130	3.0%	4.5%
45-64 Population	124,862	125,051	119,557	0.2%	-4.4%
65+ Population	78,197	88,451	99,096	13.1%	12.0%
Total Population	432,311	443,170	454,405	2.5%	2.5%
Percent <18	21.4%	20.1%	19.5%		
Percent 18-44	31.6%	31.8%	32.4%		
Percent 45-64	28.9%	28.2%	26.3%		
Percent 65+	18.1%	20.0%	21.8%		

Source: Section C, page 36, 2019 NCOSBM

NC Cancer Rates by Age Group

All Cancers	0-19	20-24	45-64	65 and above
Incidence Rate per 100,000	17.2	111.9	809.1	2,014.1
Mortality Rate per 100,000	1.9	15.7	193.6	837.6

Source: Section C, page 36, April 2020 NC Central Cancer Registry

Forsyth County Life Expectancy (page 37)

The applicant states the life expectancy of Forsyth County residents has increased in every age group, gender, and race from 1990-1992 to 2016-2018. The applicant states that the increase in life expectancy increases the chance of cancer incidence thereby increasing the need for linear accelerator treatment services and thus simulator usage. The applicant provides the following tables to demonstrate the increase in life expectancy for residents in Forsyth County.

1990 – 1992 Forsyth County Life Expectancy

	Total	Male	Female	White	African American
65-69	17.3	14.7	19.2	17.7	15.6
70-74	14	11.7	15.5	14.3	12.8
75-79	11.2	9.1	12.4	11.4	10.4
80-84	8.7	7.1	9.5	8.8	8.4
85+	6.9	5.7	7.3	6.8	7.3

Source: NC State Center for Health Statistics, schs.dph.ncdhs.gov/data/lifexpectancy

2016 – 2018 Forsyth County Life Expectancy

	Total	Male	Female	White	African American
65-69	19.3	17.8	20.4	19.6	18.4
70-74	15.6	14.4	16.6	15.8	15.2
75-79	12.3	11.2	13.1	12.3	12.4
80-84	9.3	8.5	9.8	9.2	9.7
85+	6.7	6.1	7.1	6.6	7.6

Source: NC State Center for Health Statistics, schs.dph.ncdhs.gov/data/lifexpectancy

Change in Forsyth County Life Expectancy

	Total	Male	Female	White	African American
65-69	2.0	3.1	1.2	1.9	2.8
70-74	1.6	2.7	1.1	1.5	2.4
75-79	1.1	2.1	0.7	0.9	2.0
80-84	0.6	1.4	0.3	0.4	1.3
85+	-0.2	0.4	-0.2	-0.2	0.3

Source: (2016-2018 Life Expectancy-1990-1992 Life Expectancy)

% Change in Forsyth County Life Expectancy

	Total	Male	Female	White	African American
65-69	11.6%	21.1%	6.3%	10.7%	17.9%
70-74	11.4%	23.1%	7.1%	10.5%	18.8%
75-79	9.8%	23.1%	5.6%	7.9%	19.2%
80-84	6.9%	19.7%	3.2%	4.5%	15.5%
85+	-2.9%	7.0%	-2.7%	-2.9%	4.1%

Source: (Change In Life Expectancy / 1990-1992 Life Expectancy)

Cancer Case and Death Trends for Forsyth County and the Extended Service Area (Pages 38-39)

The applicant states that the number of new cancer cases and deaths is projected to increase. The applicant provides a table with the number of cases in 2015 and the projected number of cases for 2020 with the percent of increase or decline calculated for each of four types of cancer for Forsyth County and each county in the extended service area. In addition, the applicant provides another table showing the number of cancer deaths by each of four types of cancer for 2015 and projected for 2020 for Forsyth County and each county in the extended service area. During the 5-year period of 2015 to 2020, the applicant states that the numbers in the tables show an increase in the rate of new cancer cases except prostate and an increase in the

number of cancer deaths except lung/bronchus cancers. The applicant states these increases are directly related to the need for CT simulator services given the critical role it plays in the planning and treatment of cancer. The information provided by the applicant from the 2015 and 2020 NC Central Cancer Registry is shown in the tables below.

2015 Cancer Cases

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Forsyth	2,067	309	359	278	167
Davidson	1,036	158	171	149	83
Davie	287	45	47	41	23
Stokes	315	48	52	45	25
Surry	485	75	80	68	40
Wilkes	486	76	78	70	40
Yadkin	251	39	41	36	20

2020 Projected New Cancer Cases

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Forsyth	2,254	327	407	263	169
Davidson	1,120	165	193	143	84
Davie	315	47	54	39	24
Stokes	338	51	58	42	25
Surry	500	75	86	61	38
Wilkes	514	78	86	64	39
Yadkin	266	40	45	33	20

Percent Change in Cancer Cases 2015-2020

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Forsyth	9.0%	5.8%	13.4%	-5.4%	1.2%
Davidson	8.1%	4.4%	12.9%	-4.0%	1.2%
Davie	9.8%	4.4%	14.9%	-4.9%	4.3%
Stokes	7.3%	6.3%	11.5%	-6.7%	0.0%
Surry	3.1%	0.0%	7.5%	-10.3%	-5.0%
Wilkes	5.8%	2.6%	10.3%	-8.6%	-2.5%
Yadkin	6.0%	2.6%	9.8%	-8.3%	0.0%

2015 Cancer Deaths

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Forsyth	734	221	52	36	60
Davidson	367	113	24	18	29
Davie	105	32	7	6	8
Stokes	113	35	8	6	9
Surry	177	54	12	9	14
Wilkes	178	55	12	9	14
Yadkin	91	28	6	5	7

2020 Projected Cancer Deaths

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Forsyth	758	211	54	36	61
Davidson	377	107	25	19	30
Davie	110	31	7	6	9
Stokes	117	33	8	6	9
Surry	174	49	12	9	14
Wilkes	182	51	12	9	15
Yadkin	92	26	6	5	7

Percent Change in Cancer Deaths 2015-2020

County	Total	Lung/Bronchus	Female Breast	Prostate	Colon/Rectum
Forsyth	3.3%	-4.5%	3.8%	0.0%	1.7%
Davidson	2.7%	-5.3%	4.2%	5.6%	3.4%
Davie	4.8%	-3.1%	0.0%	0.0%	12.5%
Stokes	3.5%	-5.7%	0.0%	0.0%	0.0%
Surry	-1.7%	-9.3%	0.0%	0.0%	0.0%
Wilkes	2.2%	-7.3%	0.0%	0.0%	7.1%
Yadkin	1.1%	-7.1%	0.0%	0.0%	0.0%

NHFMC Linear Accelerator Utilization (Page 40)

The applicant states that in FFY2019 the number of patients treated on the linear accelerator at NHFMC increased to pre-FFY2015 levels and the numbers are expected to continue to increase in the future. Because the CT simulator is a critical preparatory step to radiation therapy, the increase in linear accelerator treatments will directly correlate to an increase in the use of the CT simulator. Therefore, the applicant states that the increase in the number of linear accelerator patients supports the need to retain the existing CT simulator. Linear accelerator utilization is shown in the following table.

Linear Accelerator Patients

	FFY2015	FFY2016	FFY2017	FFY2018	FFY2019
Patients	1,246	1,204	1,160	1,196	1,266
Annual Growth		-3.4%	-3.6%	3.1%	5.9%

The information is reasonable and adequately supported based on the following:

- Population growth and aging trends for Forsyth County and the extended service area demonstrate an increase for the population most likely to use the services being proposed.
- The Forsyth County life expectancy from 1990 to 2018 has increased and supports the assumption that the services being proposed will also increase.
- The percent change for the majority of cancer types and mortality for Forsyth County and the extended service area has increased.
- Linear accelerator utilization increased to pre-FFY2015 levels in FFY2019.

Projected Utilization

In Section Q, the applicant provides historical and projected utilization, as illustrated in the following table.

Historical and Projected Utilization of Simulators at NHFMC							
	FY 2018	Prior FY 2019	Interim FY 2020	Interim FY 2021	1st FY 2022	2nd FY 2023	3rd FY 2024
# of Units	2	2	2	2	2	2	2
# of Procedures	1,707	1,827	1,742	1,803	1,866	1,931	1,999
Simulation Patients		1,454	1,340	1,387	1,435	1,485	1,538

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant states that utilization of the simulator in the first 6 months of 2020 is not an accurate representation of present simulator volumes because due to the COVID-19 pandemic, NCDHHS had initially recommended that everyone stay at home and avoid all travel thereby decreasing the number of outpatient visits and procedures. The applicant states that outpatient visits and procedures only began increasing once the stay at home recommendation was lifted during the second half of 2020. Therefore, the applicant uses volume rates from 2018 and 2019 to project future use.
- The applicant arrives at an annual change rate of 7.0% by subtracting the 2018 (previous year) volume of 1,707 from the 2019 (current year) volume of 1,827 and dividing the result by the previous year volume [$1,827 - 1,707 = 120 / 1,707 = 0.0703$ or 7.0%].
- The applicant calculates 2020 simulations by annualizing the COVID-19 affected, 2020 6-month simulation volume of 871 simulations [$871 \times 2 = 1,742$ simulations].
- The applicant projects simulations in years 2021 through 2024 by taking the calculated previous year's volume and multiplying it by 100.0% plus half the calculated change rate 3.5% ($7.0\% / 2 = 3.5\%$) or 103.5%.
- The applicant projects the number of simulation patients using the 2019 simulation to patient ratio of 1.3 simulations per patient to project the number of simulation patients for 2020 through 2024.

Projected utilization is reasonable and adequately supported based on the following reasons:

- The applicant documents projected population growth in the population groups most likely to need simulator services.
- Projected utilization is based on the applicant's historical experience with the existing simulators at NHFMC.

- The applicant uses one-half of the actual average annual change rate experienced by NHFMC simulator utilization from CY 2018 to CY 2019 to project future simulator utilization.
- The applicant provides reasonable and adequately supported information to justify retaining an existing CT simulator previously approved to be replaced.

Access to Medically Underserved Groups

In Section C, page 45, the applicant states:

“Services are available to all persons including: (a) low income persons, (b) racial and ethnic minorities, (c) women, (d) [persons with disabilities], (e) elderly, and (f) other underserved persons, including the medically indigent referred by their attending physicians.”

In Section L, page 77, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

NHFMC Projected Payor Mix – FY 3 (CY 2024)		
Payor Source	Entire Facility	Dedicated CT Simulators
Self-Pay	1.5%	1.6%
Charity Care	4.8%	**
Medicare *	54.9%	59.3%
Medicaid *	11.9%	8.0%
Insurance *	24.7%	30.1%
Other	1.9%	1.0%
Total	100.0%	100.0%

Source: NHFMC internal data

* Including any managed care plans

** Charity Care represents 1.6% of all simulation patients

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides its projected payor mix, which includes underserved groups, and states its projected payor mix is based on its historical payor mix.
- The applicant provides written statements about offering access to all residents of the service area, including underserved groups.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information 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 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 and adequately support their 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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce or eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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 retain an existing CT simulator previously approved to be replaced.

In Section E., page 56, the applicant states there are no alternative methods of meeting the needs for the proposed project. The applicant is currently using the existing CT simulator along with the new Siemens SOMATOM CT Simulator to perform simulation services at NHFMC. Another existing simulator, the Fluro-simulator was taken out of service in June 2020.

On page 56 the applicant states that there are no alternative methods of meeting the needs for this project because its proposal is the only method of maintaining service efficiency and satisfaction amongst staff and patients. Therefore, no alternatives were considered for this proposed project.

Conclusion

The Agency reviewed the:

- application
- 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. Forsyth Memorial Hospital, Inc. and Novant Health, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall retain the existing CT simulator previously approved to be replaced which shall be operated at Novant Health Forsyth Medical Center.**
- 3. Upon completion of the project, the certificate holder shall be licensed for no more than two CT simulators Novant Health Forsyth Medical Center.**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on July 1, 2021.**
- 5. The certificate holder 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.**
- 6. 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, the certificate holder 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.

7. The certificate holder 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

The applicant proposes to retain an existing CT simulator previously approved to be replaced.

Capital and Working Capital Costs

In Section F, pages 57-60, the applicant projects no capital costs, start-up or initial operating expenses associated with this project because the simulator already exists on the NHFMC campus.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full operating years of operation following completion of the project. In Section Q, Form F.2, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

NHFMC Projected Revenue & Expenses – FYs 1-3 (CYs 2022-2024)			
	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
# of Simulator procedures	1,866	1,931	1,999
Gross Revenue	\$3,039,367	\$3,239,597	\$3,454,289
Net Revenue	\$835,742	\$890,800	\$949,834
Average Net Revenue per Procedure	\$448	\$461	\$475
Operating Costs	\$688,958	\$706,196	\$724,311
Average Operating Costs per Procedure	\$369	\$366	\$362
Net Income	\$146,784	\$184,603 [\$184,604]	\$225,523

Analyst’s calculations are in [] but are not significant enough to alter the findings

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant accounts for projected operating expenses, such as salaries, consistent with projections elsewhere in the application.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (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 retain an existing CT simulator previously approved to be replaced.

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 2020 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C, pages 32-33, the applicant defines the service area for the proposed project. The applicant states that the primary service area is Forsyth County and the secondary service area includes the surrounding counties of Surry, Stokes, Davidson, Yadkin, Davie and Wilkes. Facilities may also serve residents of counties not included in the service area.

The following table summarizes the facility location and historical utilization of all simulator providers in Forsyth, Davidson and Surry counties during FFY 2019. The information was obtained from 2020 Hospital License Renewal Applications, Question 11.d. and the Registration and Inventory of Medical Equipment forms, Linear Accelerator Equipment, January 2020, Section 2.

County	Facility	Simulators	Radiation Therapy Treatment Patients*
Forsyth	Novant Health Forsyth Medical Center	2	1,266
	North Carolina Baptist Hospital	3	1,361
Davidson	Lexington Medical Center	1	178
Surry	Hugh Chatham Memorial Hospital	1	181

*The information reported does not specify which patients received CT simulation prior to treatment and therefore should be considered approximations.

In Section G, page 63, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved simulation services in Forsyth County. The applicant states its projected utilization is reasonable given the utilization at a nearby facility and that the simulator is needed to serve the projected patient census at NHFMC. Projected utilization starts with the historical patient population and grows that patient census.

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

- The applicant adequately demonstrates that retaining the existing simulator is necessary to accommodate the projected utilization.
- The applicant adequately demonstrates that the existing simulator is needed in addition to the existing simulators in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 based on the reasons stated above.

- (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

The applicant proposes to retain an existing CT simulator previously approved to be replaced.

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as summarized in the table below.

NHFMC Simulator Current and Projected Staff						
Position	Prior FFY (CY 2019)	Interim FFY 1 (CY 2020)	Interim/Partial (CY 2021)	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
Radiation Therapist	2.0	2.0	2.0	2.0	2.0	2.0
Registered Nurse	0.2	0.2	0.2	0.2	0.2	0.2
Total	2.2	2.2	2.2	2.2	2.2	2.2

The assumptions and methodology used to project staffing costs are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 65-66, the applicant states that existing staff will continue to perform CT simulations and describes its existing training and continuing education programs. In Section I, page 69, the applicant identifies the current medical director. In Exhibit I.2., the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H.3. and I.2., the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents the number of FTEs it needs to offer the proposed services.
- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3 in Section Q.
- The applicant provides adequate documentation of staff and its existing training and continuing education programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to retain an existing CT simulator previously approved to be replaced.

Ancillary and Support Services

In Section I, page 68, the applicant identifies the necessary ancillary and support services for the proposed services. On page 68, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the existing providers of the ancillary and support services.
- The applicant states the existing providers will continue to provide the necessary ancillary and support services.

Coordination

NHFMC is an existing facility. In Section I, page 68, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.1. On page 68, the applicant states that NHFMC is part of the Novant Health system and for greater than 50 years has retained established relationships with local health care and social service providers in the area. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant provides documentation that it has existing relationships with other local health care and social service providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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.

- (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.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (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 ... persons [with disabilities], 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, page 76, the applicant provides the historical payor mix during FY 2019 for the proposed services, as shown in the table below.

NHFMC Historical Payor Mix – FY 2019		
Payor Source	Entire Facility	Dedicated CT Simulators
Self-Pay	1.5%	1.6%
Charity Care	4.8%	**
Medicare *	54.9%	59.3%
Medicaid *	11.9%	8.0%
Insurance *	24.7%	30.1%
Other (Specify)**	1.9%	1.0%
Total	100.0%	100.0%

Source: NHFMC Internal Data

* Including any managed care plans

** Charity care represents 1.6% of all simulation patients

In Section L, page 75, the applicant provides the following comparison for FY 2019.

	Percentage of Total Patients Served by NHFMC	Percentage of Total Patients Served- Simulation	Percentage of the Population in the Service Area *
Female	59.6%	64.4%	52.7%
Male	40.3%	35.6%	47.3%
Unknown	0.0%	0.0%	0.0%
64 and Younger	64.5%	44.5%	83.6%
65 and Older	35.5%	55.5%	16.4%
American Indian	0.2%	0.3%	0.9%
Asian	0.5%	0.9%	2.6%
Black or African-American	23.0%	13.6%	27.5%
Native Hawaiian or Pacific Islander	0.1%	0.0%	0.1%
White or Caucasian	68.6%	83.2%	66.6%
Other Race	5.0%	1.7%	2.3%
Declined / Unavailable	2.7%	0.3%	0.0%

Sources: NHFMC internal data; *The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter the name of the county.

Conclusion

The Agency reviewed the:

- Application
- 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 the applicant's 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 ... persons [with disabilities] 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 76, the applicant states it has no such obligation.

In Section L, page 76, the applicant states that during the last five years no patient civil rights access complaints have been filed against Novant Health facilities and programs located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- 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, page 77, 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.

NHFMC Projected Payor Mix – FY 3 (CY 2024)		
Payor Source	Entire Facility	CT Simulators
Self-Pay	1.5%	1.6%
Charity Care	4.8%	**
Medicare *	54.9%	59.3%
Medicaid *	11.9%	8.0%
Insurance *	24.7%	30.1%
Other (Specify)**	1.9%	1.0%
Total	100.0%	100.0%

Source: NHFMC internal data

*Including any managed care plans

**Charity care represents 1.6% of all simulation patients

As shown in the table above, during the third full fiscal year of operation, the applicant projects 1.5 percent and 1.6 percent of total facility services and CT simulator services, respectively, will be provided to self-pay patients; 4.8 percent and 1.6 percent of total facility services and CT simulator services, respectively, will be provided to charity care patients; 54.9 percent and 59.3 percent of total facility services and CT simulator services, respectively, will be provided to Medicare patients; and 11.9 percent and 8.0 percent of total facility services and CT simulator services, respectively, will be provided to Medicaid patients.

On page 77, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected patient payor mix is consistent with the historical patient payor mix.
- The applicant does not propose to develop any services or make any changes to its facility that could foreseeably impact the projected patient payor mix in more than minor ways.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, page 79, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- 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

The applicant proposes to retain an existing CT simulator previously approved to be replaced.

In Section M, page 81, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides documentation of existing health professional training programs in the area for which it already provides access at NHFMC and other Novant facilities.
- The applicant states it will continue to provide access to NHFMC as it has in the past.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 retain an existing CT simulator previously approved to be replaced.

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 2020 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C, pages 32-33, the applicant defines the service area for the proposed project. The applicant states that the primary service area is Forsyth County and the secondary service area includes the surrounding counties of Surry, Stokes, Davidson, Yadkin, Davie and Wilkes. Facilities may also serve residents of counties not included in the service area.

The following table summarizes the facility location and historical utilization of all simulator providers in Forsyth, Davidson and Surry counties during FY 2019. The information was obtained from 2020 Hospital License Renewal Application, Question 11.d. and the Registration and Inventory of Medical Equipment forms, Linear Accelerator Equipment, January 2020, Section 2.

County	Facility	Simulators	Radiation Therapy Treatment Patients*
Forsyth	Novant Health Forsyth Medical Center	2	1,266
	North Carolina Baptist Hospital	3	1,361
Davidson	Lexington Medical Center	1	178
Surry	Hugh Chatham Memorial Hospital	1	181

*The information reported does not specify which patients received CT simulation prior to treatment and therefore should be considered approximations.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 83, the applicant states:

“NHFMC expects the retention of the Philips CT simulator to have a positive effect on competition in the service area because it will maintain the current capacity of simulation services at NHFMC and thus the service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 83, the applicant states:

“Novant Health is delivering value and quality in outcomes through its Population Health Management programs. This approach encourages wellness and preventive care and managing existing conditions to slow or reverse the progression of disease, all while lowering the overall cost of care. Ultimately this type of care provides value-safe, more affordable care with better outcomes-and is centered on our patients’ unique needs. Novant Health is collaborating with payors and partners to identify payment models that match Novant Health’s value-based care delivery. Getting the right care in the right setting at the right price is the future of healthcare. It is what makes healthcare affordable and more sustainable. It is Novant Health’s new approach to delivering remarkable healthcare, so that people can get better and stay healthy.”

See also Sections C, F, K and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 85, the applicant states:

“The Novant Health Utilization Review Plan is used at NHFMC. Utilization Review consists of interdisciplinary professionals and supporting team members providing a wide range of functions for patients and the organization. This includes the patients, their caregivers, internal and external partners, and the healthcare community. The UR team strives to ensure the achievement of quality and the most effective level(s) of care.

...

Additionally, Novant Health has twice received the prestigious Ernest A. Codman award for improving systemwide the quality and safety of care provided to patients.

...

...NHFMC will continue to strive to meet Novant Health’s high level of quality when it continues to operate the dedicated CT simulator.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 85-86, the applicant states:

“NHFMC will provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin or ability to pay. ...

...

Services are available to all persons including: (a) low income persons, (b) racial and ethnic minorities, (c) women, (d) handicapped persons, (e) elderly, and (f) other underserved persons, including the medically indigent referred by their attending physicians.”

See also Sections C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.

- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 based on 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

On Form A in Section Q, the applicant identifies the medical centers located in North Carolina which are owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of eleven facilities located in North Carolina. Based on clarifying information received, only three of the eleven facilities identified operate simulators.

In Section O, page 90, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHHS, during the 18 months immediately preceding submission of the application through the date of this decision, the facilities owned, operated, or managed by the applicant which offer simulator services are in compliance with all CMS Conditions and Participation. After reviewing and considering information provided by the applicant and considering the quality of care provided at all three 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.

G.S. 131E-183 (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 retain an existing CT simulator previously approved to be replaced. The application is conforming with all applicable Criteria and Standards for Radiation Therapy Equipment, NCAC 14C .1900. The specific criteria are discussed below.

SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT

10A NCAC 14C .1903 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met:

(1) an applicant's existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted;

(2) each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment; and

(3) an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.

-NA- The applicant does not propose to acquire a linear accelerator.

(b) A linear accelerator shall not be held to the standards in Paragraph (a) of this Rule if the applicant provides documentation that the linear accelerator has been or will be used exclusively for clinical research and teaching.

-NA- The applicant does not propose to acquire a linear accelerator.

(c) An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the following information:

(1) the number of patients who are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and

-NA- The applicant states the proposed CT simulator will not perform patient treatments.

(2) the maximum number and type of procedures that the proposed equipment is capable of performing.

-C- In Section C, page 41, the applicant projects the proposed CT simulator will have the capacity for a maximum of 5 patients per day of operation and that the equipment will be operational approximately 250 days per year for a maximum annual capacity of 1,250 patients, annually.

(d) The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.

-C- In Section C, page 45, the applicant provides the assumptions and methodology it used to project utilization of the CT simulator. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.