

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 26, 2022
Findings Date: February 2, 2022

Project Analyst: Tanya M. Saporito
Co-Signer: Gloria C. Hale

COMPETITIVE REVIEW

Project ID #: O-12110-21
Facility: Novant Health New Hanover Regional Medical Center - Scotts Hill
FID #: 200732
County: New Hanover
Applicant(s): Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC
Project: Acquire no more than one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of five linear accelerators (three at NHRMC 16th St., one in Brunswick County and one at NHRMC Scotts Hill), as part of a cancer services center

Project ID #: O-12120-21
Facility: Wilmington Health on Silver Stream Lane
FID #: 210648
County: New Hanover
Applicant(s): Wilmington Health, PLLC
Project: Acquire no more than one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

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.

C – Both Applications

Need Determination

The 2021 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed linear accelerators in North Carolina by service area. Application of the need methodology in the 2021 SMFP identified a need for one additional linear accelerator in service area 19 (linac SA-19), which consists of Brunswick, Columbus, New Hanover and Pender counties.

Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) proposing to develop a total of two new linear accelerators. However, pursuant to the need determination, only one new linear accelerator may be approved in this review.

Policies

Two policies in Chapter 4 of the 2021 SMFP are applicable to the applications received in response to the need determination.

Policy GEN-3

Policy GEN-3 on page 29 of the 2021 SMFP states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Policy GEN-3 applies to both applications in this review.

Policy GEN-4

Policy GEN-4 on page 29 of the 2021 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 is required to submit a plan of 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.”

Policy GEN-4 applies to both applications in this review.

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC (hereinafter collectively referred to as “the applicants”) propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Novant Health New Hanover Regional Medical Center-Scotts Hill (Scotts Hill) hospital campus in Wilmington. Scotts Hill is a new satellite campus of Novant Health New Hanover Regional Medical Center’s (NHNHRMC) main hospital, approved pursuant to Project ID #O-11947-20, and will be located in the northern portion of Wilmington. Following project completion, NHNHRMC would have five linacs on its license.

Need Determination. The applicants do not propose to develop more linear accelerators than are determined to be needed in linear accelerator service area 19.

Policy GEN-3. In Section B, pages 27-33 the applicants explain why they believe the application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 34-36, the applicants describe the project's plan to improve energy efficiency and conserve water. The applicants adequately demonstrate that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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 based on the following:

- The applicants do not propose to acquire more than one linear accelerator that is determined to be needed in the service area.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:
 - The applicants adequately document how the project will promote safety and quality in the delivery of radiation oncology services in linear accelerator service area 19;
 - The applicants adequately document how the project will promote equitable access to radiation oncology services in linear accelerator service area 19;
 - The applicants adequately document how the project will maximize healthcare value for the resources expended; and
 - The applicants adequately demonstrate that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

O-12120-21 Wilmington Health, PLLC (hereinafter referred to as "the applicant") proposes to acquire no more than one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator. The applicant proposes to develop the linac in renovated space in an existing physician practice, Wilmington Health on Silver Stream Lane, ("Wilmington Health") in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

Need Determination. The applicants do not propose to develop more linear accelerators than are determined to be needed in linear accelerator service area 19.

Policy GEN-3. In Section B, pages 27-30 the applicant explains why it believes the application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 31, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 based on the following:

- The applicant does not propose to acquire more than one linear accelerator that is determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of radiation oncology services in linear accelerator service area 19;
 - The applicant adequately documents how the project will promote equitable access to radiation oncology services in linear accelerator service area 19;
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended; and
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(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 – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – the applicants propose to acquire

one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington. Scotts Hill is a new satellite campus of NHRMC's main hospital, approved pursuant to Project ID #O-11947-20, and will be located in the northern portion of Wilmington. In Section C, page 37, the applicants state that NHRMC currently operates three linacs in Wilmington, co-managed by Coastal Carolina Radiation Oncology, PA (CCRO), an affiliated physician group that also provides professional and clinical services. NHRMC and CCRO jointly formed South Atlantic Radiation Oncology, LLC (SARO), which owns and operates a fourth linac in Supply, in Brunswick County. The applicant states both linac locations operate under a "Resource Services Agreement" between NHRMC and CCRO and NHRMC and SARO. On June 17, 2021, the Agency issued an exemption from CON law to NHRMC to develop a medical office building (MOB) on the Scotts Hill Campus. This application proposes to develop a comprehensive cancer center, NHRMC Cancer Services at Scotts Hill, in that MOB through the acquisition of a 5th linac that will be a joint venture between NHRMC and CCRO. The cancer center will also include one CT simulator, 14 infusion chairs and the necessary ancillary and support services, including a laboratory and pharmacy. NHRMC will operate the linac on its license and bill for the services. Following project completion, NHRMC would be licensed for a total of five linacs. In Section C, page 38, the applicants summarize the project goals:

- Fulfill NHRMC's long-term goals to enhance access to a full continuum of health care in the northern portion of linear accelerator service area 19 and surrounding areas;
- Enhance geographic access to quality cancer care services for patients in the service area, particularly those north of downtown Wilmington and charity care patients;
- Alleviate current capacity constraints on existing linacs at the hospital on 16th Street.

Patient Origin

In Chapter 17, page 324, the 2021 SMFP states, "A linear accelerator's service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology. ... Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of a linear accelerator service areas, based on proximity, utilization patterns, and patient origin data." NHRMC is located in New Hanover County. In Table 17-C4, page 333 of the 2021 SMFP, linear accelerator service area 19 consists of Brunswick, Columbus, New Hanover and Pender counties. Facilities may serve residents of counties not included in their service area.

Scotts Hill, the NHRMC campus on which the proposed linac will be developed, is not yet developed; consequently, there is no historical patient origin to report for this campus location. In Section C.2 pages 48-49, the applicants provide historical patient origin for the existing linacs on the NHRMC campus in Wilmington and the existing linac on the Brunswick County campus for the last full fiscal year (FY), as shown in the following tables:

**NHRMC – Patient Origin 16th Street Linacs for
 Last Full FY (October 1, 2019-September 30, 2020)**

COUNTY/ZIP CODE	# PATIENTS	% OF TOTAL
28401 New Hanover	75	4.9%
28405 New Hanover	80	5.2%
28411 New Hanover	101	6.6%
28429 New Hanover	30	2.0%
28480 New Hanover	6	0.4%
28425 Pender	42	2.7%
28435 Pender	8	0.5%
28443 Pender	63	4.1%
28457 Pender	27	1.8%
28445 Onslow	27	1.8%
Primary Service Area Total	458	29.9%
28398 Duplin	3	0.2%
28453 Duplin	0	0.0%
28458 Duplin	8	0.5%
28518 Duplin	2	0.1%
28521 Duplin	2	0.1%
28464 Duplin	6	0.4%
28466 Duplin	18	1.2%
28421 Pender	9	0.6%
28454 Pender	3	0.2%
28478 Pender	17	1.1%
28460 Onslow	24	1.6%
28540 Onslow	11	0.7%
28546 Onslow	5	0.3%
Secondary Service Area Total	105	6.9%
Other Duplin	4	0.3%
Other Onslow	27	1.8%
Other Pender	0	0.0%
Other New Hanover	511	33.4%
Brunswick	277	18.1%
Columbus	77	5.0%
Bladen	32	2.1%
All Other NC	36	2.4%
Tertiary Service Area Total	964	62.9%
Out of State	5	0.3%
Total Service Area	1,532	100.0%

Numbers may not sum due to rounding

**NHRMC – Brunswick Linac Patient Origin
Last Full FY (October 1, 2019-September 30, 2020)**

COUNTY/ZIP CODE	# PATIENTS	% OF TOTAL
Brunswick	351	87.3%
Columbus	33	8.2%
Bladen	3	0.7%
New Hanover	3	0.7%
Robeson	2	0.4%
Sampson	2	0.4%
Carteret	0	0.0%
Duplin	0	0.0%
Onslow	0	0.0%
Out of State	9	2.2%
Total Service Area	402	100.0%

Numbers may not sum due to rounding

In Section C.3, pages 50-53, the applicants provide projected patient origin for the first three full FYs following project completion, as illustrated in the following tables:

NHRMC – Scotts Hill Linac Projected Patient Origin Project Years 1-3

COUNTY/ZIP CODE	1 ST FULL FY (10/1/23-9/30/24)		2 ND FULL FY (10/1/24-9/30/25)		3 RD FULL FY (10/1/24-9/30/25)	
	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL
28401 New Hanover	15	4.8%	23	5.7%	24	5.7%
28405 New Hanover	25	7.7%	33	8.2%	34	8.1%
28411 New Hanover	53	16.3%	64	15.7%	65	15.8%
28429 New Hanover	17	5.2%	20	4.9%	20	4.9%
28480 New Hanover	2	0.8%	3	0.8%	3	0.8%
28425 Pender	26	8.1%	31	7.5%	31	7.5%
28435 Pender	3	1.1%	4	1.1%	4	1.1%
28443 Pender	40	12.3%	47	11.5%	48	11.6%
28457 Pender	15	4.8%	19	4.5%	19	4.5%
28445 Onslow	17	5.3%	20	4.9%	21	5.0%
Primary Service Area Total	214	66.3%	265	64.9%	269	65.0%
28398 Duplin	2	0.6%	2	0.5%	2	0.5%
28453 Duplin	0	0.0%	0	0.0%	0	0.0%
28458 Duplin	5	1.4%	5	1.3%	5	1.3%
28518 Duplin	1	0.3%	1	0.3%	1	0.3%
28521 Duplin	1	0.3%	1	0.3%	1	0.3%
28464 Duplin	4	1.1%	4	1.0%	4	1.0%
28466 Duplin	11	3.4%	13	3.1%	13	3.1%
28421 Pender	6	1.7%	7	1.6%	7	1.6%
28454 Pender	2	0.6%	2	0.5%	2	0.5%
28478 Pender	10	3.2%	12	2.9%	12	2.9%
28460 Onslow	16	5.0%	19	4.7%	19	4.7%
28540 Onslow	7	2.2%	8	2.0%	8	2.0%
28546 Onslow	3	0.9%	4	0.9%	4	0.9%
Secondary Service Area Total	67	20.7%	78	19.1%	79	19.1%
Other Duplin	2	0.5%	2	0.5%	2	0.5%
Other Onslow	11	3.5%	14	3.4%	14	3.4%
Other Pender	0	0.0%	0	0.0%	0	0.0%
Other New Hanover	16	4.9%	27	6.6%	27	6.6%
Brunswick	9	2.7%	15	3.6%	15	3.6%
Columbus	2	0.7%	4	0.9%	4	0.9%
Bladen	1	0.3%	2	0.4%	2	0.4%
All Other NC	1	0.3%	2	0.5%	2	0.5%
Tertiary Service Area Total	42	12.9%	65	15.9%	66	15.9%
Out of State	0	0.1%	0	0.1%	0	0.1%
Total Service Area	323	100.0%	409	100.0%	414	100.0%

Numbers may not sum due to rounding

In Sections C and Q, the applicants provide the assumptions and methodology used to project its patient origin, which is based on existing patient origin for linac services at the hospital.

The applicants’ assumptions are reasonable and adequately supported based on the following:

- Projected patient origin for the first three years following project completion is based on NHRMC's historical patient origin for linac services in Wilmington, because the applicant determined that a significant patient base currently served at the 16th street location would benefit from a location closer to their residence ZIP code.
- The applicant provides ZIP code detail for existing patient origin at the 16th Street location to help illustrate anticipated shift in that patient base to the Scotts Hill location following project completion.

Analysis of Need

In Section C.4, pages 53-85, the applicants explain why the population projected to utilize the proposed linac services needs the proposed services, as summarized below:

- The applicants state a cancer center is needed in the northern portion of Wilmington, where the Scotts Hill hospital campus will be developed and the previously approved MOB will be poised to offer comprehensive cancer services, including medical oncology, radiation therapy, chemotherapy and infusion services to service area residents (page 54).
- Projected population growth – the applicants state NHRMC is the only provider of linear accelerator and comprehensive cancer services in linac service area 19 (Brunswick, Columbus, Pender and New Hanover counties). Using Claritas Spotlight data for specific ZIP codes in New Hanover, Pender and Onslow counties as well as the NHRMC general service area within linac service area 19, the applicants determined that the overall population is projected to increase by 1.1% from 2021-2026, and the over 65 population group is projected to increase by 3.2% during the same time. Additionally, the over 65 age group is projected to grow by 3.7% in the primary service area alone from 2021-2026. The applicants state the National Cancer Institute reports that advancing age is the greatest risk factor for cancer overall; therefore, the applicants conclude that a projected increase in the over 65 age group, particularly in the primary service area, will drive the increased need for additional cancer services (pages 55-62).
- Cancer mortality rates in the service area – the applicants consulted the North Carolina Department of Health and Human Services age-adjusted cancer mortality rate reports for each county in the state and statewide. Those reports indicate an overall state age-adjusted cancer mortality rate of 164.1 cases per 100,000 population from 2013-2017. The applicants found that for New Hanover and Brunswick counties, each of which has comprehensive cancer services and radiation oncology services, the age-adjusted cancer mortality rates are lower than the state average. By contrast, for Columbus and Pender counties, the age-adjusted cancer mortality rates were 169.8 and 175.2 per 100,000, respectively. Furthermore, in Onslow County, a bit further to the north, the rate was 200.0 per 100,000. Those counties do not currently have access to comprehensive cancer treatment and radiation oncology services; the patients in those counties typically travel to Wilmington for those services. Thus, the applicants state

access to cancer treatment services closer to the northern areas of linac service area 19 and Onslow County is important to effectively serve the needs of the patients residing in those areas.

- Capacity constraints at Wilmington and Brunswick locations – The applicants state NHRMC is the only provider of comprehensive cancer services in the region, and its existing linacs have performed in excess of the minimum required under the performance standards set forth at 10A NCAC 14C .1903, as shown in the following table:

# LINACS	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	CAGR*
	4	4	4	4	4	4	
ESTV**	28,953	27,658	24,892	27,747	30,752	32,530	2.4%
Treatments / Linac	7,238	6,915	6,223	6,937	7,688	8,133	2.4%
Performance Standard	6,750	6,750	6,750	6,750	6,750	6,750	
% Capacity	107%	102%	92%	103%	114%	120%	

*Compound Annual Growth Rate
 **Equivalent Simple Treatment Visit

The applicants state that the COVID-19 restrictions and stay-at-home mandates formerly in place in North Carolina led many patients to forego cancer screenings. As a result, NHRMC physicians are already experiencing an increase in late-stage cancer incidence and expect to see more (pages 64-65).

- Burdensome travel distance and time – The applicants state that cancer patients who reside in the northern portion of linac SA-19 or in Onslow County to the north currently face lengthy travel to downtown Wilmington. That travel is burdensome for patients who are already dealing with cancer and its effects. Similarly, patients who reside in Columbus or Bladen counties have time consuming travel as well. See the following table from application page 66 that illustrates travel times and distances faced by cancer patients in the area:

SERVICE AREA CITY / COUNTY	PROPOSED NHRMC CANCER SERVICES AT SCOTTS HILL		NHRMC – 16 TH STREET CAMPUS	
	TIME (MINUTES)	DISTANCE (MILES)	TIME (MINUTES)	DISTANCE (MILES)
Burgaw (Pender)	35	27.6	50	31.3
Surf City (Pender)	40	18.9	70	34.4
Hampstead (Pender)	12	5.5	50	18
Kenansville (Duplin)	65	54.7	80	58.4
Sneads Ferry (Onslow)	50	28.8	80	44.4
Elizabethtown (Bladen)	80	62.1	75	51.7
Whiteville (Columbus)	70	58.7	60	48.3

Source: application page 66; applicants cite *Google Maps*[®] and state drive times were calculated assuming an 8:00 AM start time.

The applicant also cites studies that show a positive correlation between shorter drive times for cancer patients receiving radiation therapy and the effect of that therapy on

their cancer. The applicants state the studies show that mastectomies decreased by 16% when a radiation therapy provider is close to the patient’s home, compared to lengthy travel to distant facilities for treatments (pages 65-68).

- Residential development in the area – the applicants state the northern portion of Wilmington and New Hanover County is growing and residential development is increasing. The applicants describe several new multi-unit residential neighborhoods that are planned for or already under development in the area. The applicants state this will also drive the need for increased access to health care in general and cancer care in particular (pages 68-73).
- Unique benefits of the project – the applicants summarize the project and the unique benefits it will have on geographic access, financial access, continuity of care and cost effectiveness for cancer patients in the service area and in linac SA-19. The applicants provide letters of support for the project from cancer patients who have received treatment at NHRMC, family members of cancer patients, and community members in Exhibit I-2.2 (pages 73-74).

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

- There is a need determination in the 2021 SMFP for one additional linear accelerator in linear accelerator service area 19.
- Population growth statistics for the service area demonstrate an increase for the population most likely to use the services being proposed.
- Projected development in the service area and the high incidence of cancer demonstrate a need for increased access to radiation therapy in the area.
- Capacity constraints continue to exist on existing linacs at NHRMC locations.
- The applicant adequately demonstrates the need for a linear accelerator in addition to the existing linear accelerators in linear accelerator service area 19.

Projected Utilization – Scotts Hill and 16th Street

In Section Q, Form C.2a and C.2b, the applicants provide historical utilization for the linear accelerators at NHRMC and projected utilization for the linear accelerators at NHRMC and Scotts Hill, as illustrated in the following tables:

NHRMC (all campuses) Historical and Interim Utilization

LINEAR ACCELERATORS	FY 2021 (10/1/2020- 9/30/2021)	FY 2022 (10/1/2021- 9/30/2022)	FY 2023 (10/1/2022- 9/30/2023)
# Units	4	4	4
# ESTV Treatments	38,274	38,728	39,189

Source: Section Q, page 145

NHRMC (all campuses) Projected Utilization

LINEAR ACCELERATORS	FY 2024 (10/1/2023- 9/30/2024)	FY 2025 (10/1/2024- 9/30/2025)	FY 2026 (10/1/2025- 9/30/2026)
# Units	5	5	5
# ESTV Treatments	39,652	40,118	40,598

Source: Section Q, page 146

NHRMC Scotts Hill Projected Utilization

LINEAR ACCELERATORS	FY 2024 (10/1/2023- 9/30/2024)	FY 2025 (10/1/2024- 9/30/2025)	FY 2026 (10/1/2025- 9/30/2026)
# Units	1	1	1
# ESTV Treatments	6,458	8,176	8,278

Source: Section Q, page 146

The applicants state NHRMC is the sole provider of comprehensive cancer services in linac SA-19. In Section C, pages 75-85, the applicants provide the assumptions and methodology used to project utilization of the proposed and existing linacs, as summarized below:

Step 1: Establish historical linac patient origin at the existing NHRMC 16th Street location – the applicants used internal NHRMC 2020 data and annualized year to date (YTD) 2021 data to determine ZIP code level patient origin at the 16th Street location. The applicants state that all ZIP codes in the service area exhibited growth in population, as shown in the following table:

16th Street Linac Patient Origin FY 2020 and YTD FY 2021

COUNTY/ZIP CODE	FY 2020	FY 2021 YTD	FY 2021 ANNUALIZED*
28401 New Hanover	61	50	75
28405 New Hanover	77	53	80
28411 New Hanover	96	67	101
28429 New Hanover	21	20	30
28480 New Hanover	5	4	6
28425 Pender	30	28	42
28435 Pender	11	5	8
28443 Pender	50	42	63
28457 Pender	32	18	27
28445 Onslow	16	18	27
Primary Service Area Total	399	305	458
28398 Duplin	2	2	3
28453 Duplin	0	0	0
28458 Duplin	5	5	8
28518 Duplin	6	1	2
28521 Duplin	2	1	2
28464 Duplin	4	4	6
28466 Duplin	22	12	18
28421 Pender	5	6	9
28454 Pender	3	2	3
28478 Pender	13	11	17
28460 Onslow	23	16	24
28540 Onslow	7	7	11
28546 Onslow	4	3	5
Secondary Service Area Total	96	70	105
Other Duplin	2	2	4
Other Onslow	14	13	27
Other Pender	0	0	0
Other New Hanover	314	197	511
Brunswick	161	116	277
Columbus	44	33	77
Bladen	19	13	32
All Other NC	20	16	36
Tertiary Service Area Total	574	390	964
Out of State	3	2	5
Total Service Area	1,072	767	1,532

*Based on eight months of data
 Numbers may not sum due to rounding

Step 2: Project service area linac volume – the applicants project patient volume based on the ZIP code level and county population growth (i.e. Brunswick, Columbus, Bladen). The applicants calculated a population growth CAGR based on the data from FY 2020 to annualized FY 2021 for each ZIP code and county, and projected growth in linac volume for each ZIP code using that CAGR. See the following table from page 78:

Service Area Volume Projections

COUNTY/ZIP CODE	CAGR	FY 2021*	INTERIM FY 2022	INTERIM FY 2023	PY 1 FY 2024	PY 2 FY 2025	PY 3 FY 2026
28401 New Hanover	0.9%	75	76	76	77	78	78
28405 New Hanover	1.2%	80	80	81	82	83	84
28411 New Hanover	1.6%	101	102	104	105	107	109
28429 New Hanover	0.9%	30	30	31	31	31	31
28480 New Hanover	0.9%	6	6	6	6	6	6
28425 Pender	1.1%	42	42	43	43	44	44
28435 Pender	1.1%	8	8	8	8	8	8
28443 Pender	1.7%	63	64	65	66	67	69
28457 Pender	1.3%	27	27	28	28	28	29
28445 Onslow	1.7%	27	27	28	28	29	29
Primary Service Area Total		458	463	470	476	482	488
28398 Duplin	0.2%	3	3	3	3	3	3
28453 Duplin	0.6%	0	0	0	0	0	0
28458 Duplin	0.5%	8	8	8	8	8	8
28518 Duplin	0.7%	2	2	2	2	2	2
28521 Duplin	0.4%	2	2	2	2	2	2
28464 Duplin	0.1%	6	6	6	6	6	6
28466 Duplin	0.5%	18	18	18	18	18	18
28421 Pender	1.1%	9	9	9	9	9	9
28454 Pender	0.9%	3	3	3	3	3	3
28478 Pender	0.9%	17	17	17	17	17	17
28460 Onslow	1.5%	24	24	25	25	25	26
28540 Onslow	0.9%	11	11	11	11	11	11
28546 Onslow	1.1%	5	5	5	5	5	5
Secondary Service Area Total		105	106	107	108	109	110
Other Duplin	0.4%	4	4	4	4	4	4
Other Onslow	1.1%	27	27	28	28	28	28
Other Pender	2.0%	0	0	0	0	0	0
Other New Hanover	1.3%	511	517	524	530	537	544
Brunswick	1.5%	277	281	286	290	295	299
Columbus	0.1%	77	77	77	77	77	77
Bladen	-0.1%	32	32	32	32	32	32
All Other NC	1.0%	36	36	37	37	37	38
Tertiary Service Area Total		964	975	987	999	1,010	1,022
Out of State		5	5	5	5	5	5
Total Service Area		1,532	1,550	1,568	1,587	1,606	1,626

Source: Application page 78

*Annualized based on eight months of data

Numbers may not sum due to rounding

Step 3: Establish patient shift from NHRMC 16th Street to Scotts Hill – the applicants propose to develop a cancer center in an existing MOB on the Scotts Hill campus in the northern portion of New Hanover County. The applicants expect a patient shift from the NHRMC 16th Street location to Scotts Hill, in addition to new patients as previously noted. The applicants project a greater percent shift of those patients residing in ZIP codes that are closer to the Scotts Hill campus than for those patients who reside further away. During the first PY, the applicants assume a gradual ramp up for those newly diagnosed patients who will begin cancer treatment

at Scotts Hill. To account for the ramp up, the applicants assume utilization for patients residing in the primary and secondary service area ZIP codes and *Other Duplin*, *Other Onslow* and *Other Pender* would be 10% lower. For the *Other New Hanover*, Brunswick, Columbus and Bladen counties as well as *All Other NC* in the tertiary service area, the applicants project a 2% volume reduction, since patient shift from those areas to the Scotts Hill campus is projected to be small. See the following tables from pages 80 and 81 that illustrate these utilization projections following the projected patient shifts:

Projected Utilization NHRMC 16th Street and Scotts Hill Post-Shift, 2024

COUNTY/ZIP CODE	2024 TOTAL 16 TH ST. VOLUME	PROJECTED % SHIFT TO SCOTTS HILL	2024 PROJECTED SCOTTS HILL VISITS	2024 16 TH ST. VISITS POST- SHIFT
28401 New Hanover	77	20%	15	62
28405 New Hanover	82	30%	25	58
28411 New Hanover	105	50%	53	53
28429 New Hanover	31	55%	17	14
28480 New Hanover	6	40%	2	4
28425 Pender	43	60%	26	17
28435 Pender	8	45%	3	4
28443 Pender	66	60%	40	27
28457 Pender	28	55%	15	13
28445 Onslow	28	60%	17	11
Primary Service Area Total	476	45%	214	262
28398 Duplin	3	60%	2	1
28453 Duplin	0	60%	0	0
28458 Duplin	8	60%	5	3
28518 Duplin	2	60%	1	1
28521 Duplin	2	60%	1	1
28464 Duplin	6	60%	4	2
28466 Duplin	18	60%	11	7
28421 Pender	9	60%	6	4
28454 Pender	3	60%	2	1
28478 Pender	17	60%	10	7
28460 Onslow	25	65%	16	9
28540 Onslow	11	65%	7	4
28546 Onslow	5	65%	3	2
Secondary Service Area Total	108	62%	67	41
Other Duplin	4	40%	2	2
Other Onslow	28	40%	11	17
Other Pender	0	40%	0	0
Other New Hanover	530	3%	16	515
Brunswick	290	3%	9	281
Columbus	77	3%	2	75
Bladen	32	3%	1	31
All Other NC	37	3%	1	36
Tertiary Service Area Total	999	4%	42	957
Out of State	5	5%	0	5
Total Service Area	1,587	20%	323	1,264

Source: Application page 80
 Numbers may not sum due to rounding

Projected Utilization NHRMC 16th Street and Scotts Hill Post-Shift, 2025

COUNTY/ZIP CODE	2025 TOTAL 16 TH ST. VOLUME	PROJECTED % SHIFT TO SCOTTS HILL	2025 PROJECTED SCOTTS HILL VISITS	2025 16 TH ST. VISITS POST- SHIFT
28401 New Hanover	78	30%	23	54
28405 New Hanover	83	40%	33	50
28411 New Hanover	107	60%	64	43
28429 New Hanover	31	65%	20	11
28480 New Hanover	6	50%	3	3
28425 Pender	44	70%	31	13
28435 Pender	8	55%	4	4
28443 Pender	67	70%	47	20
28457 Pender	28	65%	19	10
28445 Onslow	29	70%	20	9
Primary Service Area Total	482	55%	265	217
28398 Duplin	3	70%	2	1
28453 Duplin	0	70%	0	0
28458 Duplin	8	70%	5	2
28518 Duplin	2	70%	1	0
28521 Duplin	2	70%	1	0
28464 Duplin	6	70%	4	2
28466 Duplin	18	70%	13	6
28421 Pender	9	70%	7	3
28454 Pender	3	70%	2	1
28478 Pender	17	70%	12	5
28460 Onslow	25	75%	19	6
28540 Onslow	11	75%	8	3
28546 Onslow	5	75%	4	1
Secondary Service Area Total	109	71.9%	78	31
Other Duplin	4	50%	2	2
Other Onslow	28	50%	14	14
Other Pender	0	50%	0	0
Other New Hanover	537	5%	27	510
Brunswick	295	5%	15	280
Columbus	77	5%	4	73
Bladen	32	5%	2	30
All Other NC	37	5%	2	36
Tertiary Service Area Total	1,010	6.4%	65	945
Out of State	5	5%	0	5
Total Service Area	1,606	25.4%	409	1,198

Source: Application page 80
 Numbers may not sum due to rounding

The applicants held the patient shift constant through the third project year, as shown in the following table from page 82:

Projected Utilization NHRMC 16th Street and Scotts Hill Post-Shift, 2026

COUNTY/ZIP CODE	2026 TOTAL 16 TH ST. VOLUME	PROJECTED % SHIFT TO SCOTTS HILL	2026 PROJECTED SCOTTS HILL VISITS	2026 16 TH ST. VISITS POST- SHIFT
28401 New Hanover	78	30%	24	55
28405 New Hanover	84	40%	34	51
28411 New Hanover	109	60%	65	44
28429 New Hanover	31	65%	20	11
28480 New Hanover	6	50%	3	3
28425 Pender	44	70%	31	13
28435 Pender	8	55%	4	4
28443 Pender	69	70%	48	21
28457 Pender	29	65%	19	10
28445 Onslow	29	70%	21	9
Primary Service Area Total	488	55.1%	269	219
28398 Duplin	3	70%	2	1
28453 Duplin	0	70%	0	0
28458 Duplin	8	70%	5	2
28518 Duplin	2	70%	1	0
28521 Duplin	2	70%	1	0
28464 Duplin	6	70%	4	2
28466 Duplin	18	70%	13	6
28421 Pender	9	70%	7	3
28454 Pender	3	70%	2	1
28478 Pender	17	70%	12	5
28460 Onslow	26	75%	19	6
28540 Onslow	11	75%	8	3
28546 Onslow	5	75%	4	1
Secondary Service Area Total	110	71.9%	79	31
Other Duplin	4	50%	2	2
Other Onslow	28	50%	14	14
Other Pender	0	50%	0	0
Other New Hanover	544	5%	27	517
Brunswick	299	5%	15	284
Columbus	77	5%	4	73
Bladen	32	5%	2	30
All Other NC	38	5%	2	36
Tertiary Service Area Total	1,022	6.4%	66	957
Out of State	5	5%	0	5
Total Service Area	1,626	25.5%	414	1,212

Source: Application page 80
 Numbers may not sum due to rounding

In Section Q Assumptions, pages 150-156, the applicants state they determined the number of procedures based on the number of patients multiplied by the average number of procedures beginning in FY 2019 through FY 2021 YTD. The applicants held the FY 2021 YTD average constant through all three project years. The following tables, prepared by the Project Analyst illustrates the calculations and projections of the number of procedures for the Scotts Hill and 16th Street campuses, from Sections C and Q:

Projected Number of Procedures, Scotts Hill, FY 2024-FY 2026

	FY 2024	FY 2025	FY 2026
Number of Patients	323	409	414
Average Procedure/Pt.	18.89	18.89	18.89
Total # of Procedures	6,101	7,726	7,820

Numbers may not foot due to rounding by Project Analyst

Projected Number of Procedures, 16 Street, FY 2024-FY 2026

	FY 2024	FY 2025	FY 2026
Number of Patients	1,264	1,198	1,212
Average Procedure/Pt.	18.89	18.89	18.89
Total # of Procedures	23,877	22,630	22,895

Numbers may not foot due to rounding by Project Analyst

Projected Utilization – Brunswick

Step 1: Establish historical county level linac patient origin – the applicants examined year to date data for Brunswick County to determine future utilization, since no shift is anticipated for this campus. The applicants first established a county level patient origin by annualizing year to date (YTD) data for 2021 and used it as the base volume for projected utilization, as shown in the following table:

COUNTY	FY 2020	FY 2021 YTD	FY 2021 ANNUALIZED
Brunswick	329	234	351
Columbus	27	22	33
Bladen	1	2	3
New Hanover	1	2	3
Robeson	1	1	2
Sampson	0	1	2
Carteret	1	0	0
Duplin	1	0	0
Onslow	2	0	0
Out of State	12	6	9
Total Service Area	375	268	402

Step 2: Project service area linac patient volume – the applicants projected service area patient volume based on the county level population growth and annualized YTD 2021 data presented in Step 1. The applicants projected volume through the end of the third project year, using the CAGRs of each individual ZIP code calculated in prior steps. The following table, from page 84, illustrates the volume projection:

COUNTY	POP. CAGR	FY 2021 ANNUALIZED	INTERIM FY 2022	INTERIM FY 2023	PY 1 FY 2024	PY 2 FY 2025	PY 3 FY 2026
Brunswick	1.4%	351	356	361	366	371	376
Columbus	-0.8%	33	33	32	32	32	32
Bladen	-0.5%	3	3	3	3	3	3
New Hanover	1.0%	3	3	3	3	3	3
Robeson	-0.5%	2	1	1	1	1	1
Sampson	-0.4%	2	1	1	1	1	1
Carteret	0.1%	0	0	0	0	0	0
Duplin	-0.2%	0	0	0	0	0	0
Onslow	0.8%	0	0	0	0	0	0
Out of State		9	9	9	9	9	9
Total Service Area		402	407	411	416	421	426

The applicants determined the number of procedures based on the number of patients multiplied by the average number of procedures beginning in FY 2019 through FY 2021 YTD. The applicants held the FY 2021 YTD average constant through all three project years. The following table prepared by the Project Analyst illustrates the calculations and projections of the number of procedures for the Brunswick campus, from Sections C and Q:

Projected Number of Procedures, Brunswick Campus, FY 2024-FY 2026

	FY 2024	FY 2025	FY 2026
Number of Patients	416	421	426
Average Procedure/Pt.	18.89	18.89	18.89
Total # of Procedures	7,858	7,953	8,047

Numbers may not foot due to rounding by Project Analyst

Projected Utilization – Chemotherapy and Infusion Services – As with the linac utilization projections, the applicants projected utilization for the chemotherapy and infusion therapy services it will offer at Scotts Hill based on a projected shift in patients from the northern areas of New Hanover County and linac SA-19 to the Scotts Hill location.

In Section C, page 84, the applicants provide the assumptions used to project chemotherapy and infusion services based on the cancer patients served at the 16th Street and Zimmer Cancer Center locations. The assumptions are summarized below:

1. The applicants calculated a 10.3% ratio of radiation oncology patients to total oncology based on actual patients served for all cancer related services by NHRMC in FY 2020.
2. From that base, the applicants project the number of patients who will receive infusion therapy (both chemotherapy and non-chemotherapy) based on NHRMC experience in FY 2020. The applicants determined that 14.1% of infusion therapy patients received chemotherapy and 9.1% were non-chemotherapy infusion patients. The applicants state these figures represent the total projected patients who will receive infusion therapy services.

3. The applicants projected the number of treatments per patient based on NHRMC’s historical number of treatments per patient during FY 2020, which was 7.54 treatments per patient.
4. The applicants state that, assuming a planning capacity of 260 days per year and 2.5 patients served per day per infusion chair, NHRMC projects to operate 14 infusion chairs at 77.2% capacity at NHRMC Scotts Hill.

See the following table, from Section C, page 85:

Infusion Therapy Projection and Need for Chairs, NHRMC Scotts Hill

	FY 2024 (PY 1)	FY 2025 (PY 2)	FY 2026 (PY 3)
Radiation Oncology Patients	323	409	414
Total Oncology Patients	3,134	3,968	4,017
Chemo Infusion Patients	442	559	566
Other Infusion Patients	285	361	366
Total Infusion Patients	727	921	932
Avg. Visits per Patient	7.5	7.5	7.5
Infusion Visits	5,482	6,941	7,027
Chairs Needed	8.43	10.68	10.81
Proposed Chairs	14	14	14
% of Capacity	60.2%	76.3%	77.2%

The applicants also propose to acquire a CT simulator to aid in precise delivery of radiation therapy treatments.

Access to Medically Underserved Groups

In Section C.6, page 91, the applicants state:

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

The applicants provide the estimated percentage for each medically underserved group they propose to serve during the third full fiscal year, as shown in the following table from page 92:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	3.91%
Racial and ethnic minorities	16.27%
Women	51.01%
Persons with disabilities*	N/A
The elderly	62.96%
Medicare beneficiaries	58.61%
Medicaid recipients	7.0%

*NHRMC does not currently track this information

The applicants adequately describe 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 applicants provide written statements about providing access to all residents of the service area, including underserved groups.
- The applicants provide projected payor mix, which includes underserved groups, and assumes it will remain constant for the first three years of operation.
- The applicants provide a copy of their charity care policies in Exhibit L-4.

Conclusion

The agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written comments

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

O-12120-21 Wilmington Health, PLLC – The applicant states on page 33 that Wilmington Health, PLLC is a national network of multispecialty physician practices that currently operates 19 physician practices and one telehealth practice in North Carolina. The applicant proposes to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in its existing physician practice in Wilmington from which the applicant currently provides oncology/hematology and medical oncology infusion services, as well as endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

Patient Origin

In Chapter 17, page 324, the 2021 SMFP states, *“A linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology. ...Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of a linear accelerator service areas, based on proximity, utilization patterns, and patient origin data.”* Wilmington Health is located in New Hanover County. In Table 17-C4, page 333 of the 2021 SMFP, linear accelerator service area 19 consists of Brunswick, Columbus, New Hanover and Pender counties. Facilities may serve residents of counties not included in their service area.

The applicant does not currently own or operate a linac. In Section C.2, page 37, the applicant provides historical patient origin for oncology and hematology services provided at

Wilmington Health for the last full operating year, calendar year 2020 (CY2020), as summarized in the table below:

COUNTY	# PATIENTS	% OF TOTAL
New Hanover	859	52.2%
Brunswick	387	23.5%
Pender	181	11.0%
Onslow	69	4.2%
Columbus	54	3.3%
Duplin	44	2.7%
Other*	51	3.1%
Total	1,646	100.0%

*Other includes Alamance, Bladen, Burke, Carteret, Cumberland, Dare, Gaston, Guilford, Jones, Lee, Mecklenburg, Moore, Orange, Sampson, Scotland, Wake and Wayne counties in North Carolina as well as other states.

The following table illustrates projected patient origin for the proposed linac:

COUNTY	1 ST FY (CY 2024)		2 ND FY (CY 2025)		3 RD FY (CY 2026)	
	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL
New Hanover	89	52.2%	123	52.2%	159	52.2%
Brunswick	40	23.5%	55	23.5%	72	23.5%
Pender	19	11.0%	26	11.0%	33	11.0%
Onslow	7	4.2%	10	4.2%	13	4.2%
Columbus	6	3.3%	8	3.3%	10	3.3%
Duplin	5	2.7%	6	2.7%	8	2.7%
Other*	5	3.1%	7	3.1%	9	3.1%
Total	170	100.0%	235	100.0%	304	100.0%

*Other includes Alamance, Bladen, Burke, Carteret, Cumberland, Dare, Gaston, Guilford, Jones, Lee, Mecklenburg, Moore, Orange, Sampson, Scotland, Wake and Wayne counties in North Carolina as well as other states.

In Section C, page 38, the applicant provides the assumptions and methodology used to project its patient origin which is based on the patient origin of existing oncology and hematology patients at Wilmington Health. The applicant does not anticipate any change in patient origin when the linac is added.

The applicant's assumptions are reasonable and adequately supported because they are based on actual historical patient origin for the applicant's existing oncology services at Wilmington Health.

Analysis of Need

In Section C.4, pages 40-51, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- SMFP need methodology for linacs – the applicant cites the 2021 SMFP need methodology for linacs, particularly in linac SA-19 (page 41).
- Growth of the service area population – The applicant cites population growth statistics from the North Carolina Office of State Budget and Management (OSBM) to show population growth in the linac SA-19 from 2011-2021. Using the same data, the applicant calculated a compound annual growth rate (CAGR) in the linac SA-19 population for the same time, as shown in the following table:

Linac SA-19 Historical Population Growth, 2011-2021

LINAC SA-19	2011	2021	NUMERICAL GROWTH	% GROWTH	2011-2021 CAGR
New Hanover	206,300	237,448	31,148	15.1%	1.4%
Brunswick	110,157	150,889	40,732	37.0%	3.2%
Pender	53,324	64,524	11,200	21.0%	1.9%
Columbus	58,036	55,600	-2,436	-4.2%	-0.4%
Total	427,817	508,461	80,644	18.9%	1.7%

Source: Application page 42

The applicant notes that New Hanover County was among the fastest growing counties in the area.

Using the CAGRs calculated in the previous step, the applicant projected population growth for the same area, as shown in the following table:

Linac SA-19 Projected Population Growth, 2021-2026

LINAC SA-19	2021	2026	NUMERICAL GROWTH	% OF 2026 SA POPULATION	2021-2026 CAGR
New Hanover	237,448	254,121	16,673	46.6%	1.4%
Brunswick	150,889	167,739	16,850	30.8%	3.2%
Pender	64,524	68,780	4,256	12.6%	1.9%
Columbus	55,600	54,374	-1,226	9.98%	-0.4%
Total	508,461	545,014	36,553	--	1.7%

Source: Application page 43

- Aging of the service area population – The applicant states the population of the linac SA-19 is also aging rapidly. The applicant states that since 2011, the over 65 population in SA-19 has increased by 59.4%. That same population group is projected to increase by 16% from 2021-2026, as shown in the following table:

Linac SA-19 Age 65 and Over Projected Population Growth, 2021-2026

LINAC SA-19	2011	2021	2026	2021-2026 % GROWTH
New Hanover	29,494	43,660	50,159	14.9%
Brunswick	25,185	47,515	56,761	19.5%
Pender	8,263	12,503	14,573	16.6%
Columbus	9,044	11,100	11,672	5.2%
Total SA-19	71,986	114,778	133,165	16.0%
North Carolina	1,283,233	1,842,346	2,139,783	16.1%

Source: Application page 44

The applicant states the over 65 population group has an 11-times greater chance of developing cancer compared to younger populations (pages 42-44).

- Cancer prevalence and mortality – the applicant cites the State Center for Health Statistics 2019 data (the most recent data available) and states that cancer was the second leading cause of death in New Hanover County and linac SA-19 as a whole, and accounts for approximately 19.9% and 20.8% of deaths, respectively. See the following table from page 45:

Cancer Deaths, 2015-2019

COUNTY	2015-2019 CANCER DEATHS
Mecklenburg	6,578
Wake	6,513
Guilford	4,663
Forsyth	3,568
Buncombe	2,744
Cumberland	2,660
Gaston	2,339
Durham	2,283
New Hanover	2,133
Davidson	1,989
North Carolina	97,965

The applicant states access issues such as transportation and financial issues and inadequate insurance coverage create additional hardship and access issues for cancer patients in the service area. The applicant states NHRMC is the only provider of linac services in linac SA-19, and the location of the existing linacs creates travel burdens for those patients who live further away from New Hanover County. The applicant states Onslow Memorial Hospital in Onslow County operates a linac but is over one hour drive time from New Hanover County, which underscores the reality that those patients who reside in the northern portion of linac SA-19 must travel in excess of one hour to receive treatment. For cancer patients, who are already burdened with the disease, travel compounds and exacerbates the stress. The applicant states that in 2020, 90% of oncology services provided by Wilmington Health were provided to residents of linac SA-19 (pages 45-51).

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

- There is a need determination in the 2021 SMFP for one additional linear accelerator in linear accelerator service area 19.
- Population growth statistics, particularly in the over 65 population for the service area demonstrate an increase in the population most likely to use the linac services being proposed.
- The State Center for Health Statistics 2019 data supports the applicant's demonstration of need based on cancer death rate statistics and projections in linear accelerator service area 19.
- The applicant adequately demonstrates the need for a linear accelerator in addition to the existing linear accelerators in linear accelerator service area 19.

Projected Utilization

In Section Q, Form C, Assumptions and Methodology, the applicant provides historical utilization for Wilmington Health's oncology and hematology patients for CY 2019-2021 annualized. In Section Q, Form C, page 1, the applicant states:

"...Wilmington Health does not have historical data performed on a linear accelerator it operates as a basis for determining future utilization. It does, however, have data from Wilmington Health regarding the historical number of hematology/oncology patients it has treated and patients referred to radiation therapy by its physicians."

Based on that data, the applicant determined that utilization increased by 10.6% overall from CY 2019-CY 2020 and by a CAGR of 51.2% from CY 2019-CY 2021. The applicant annualized CY 2021 year to date volume based on five months of data, noting that it treated 1,418 patients in that five month period alone. See the following table from page 1 of the Assumptions and Methodology in Form C:

	CY 2019	CY 2020	CY 2021	% GROWTH CY 2019- CY 2020	CAGR
# Oncology / Hematology Patients	1,488	1,646	3,403	10.6%	51.2%

To project oncology and hematology volume, the applicant used one-third of the historical growth from CY 2019-CY 2020, or 3.5% ($10.6 / 3 = 3.53$), as illustrated in the following table from page 2 of the Assumptions and Methodology:

Projected Oncology and Hematology Patients, CY 2020-2026

	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	CAGR
# Oncology / Hematology Patients	1,646	1,704	1,765	1,827	1,892	1,959	2,028	3.5%

The applicant used CY 2020 data as its base year and notes the growth projection for CY 2021 was lower than actual annualized utilization.

To project the number of those oncology and hematology patients who would receive radiation therapy, the applicant analyzed Wilmington Health’s historical utilization and determined that approximately 65%-75% of its oncology patients received radiation therapy during CY 2019- CY 2020. The applicant states the American Cancer Society reports a similar percentage: 66.7% of cancer patients typically receive radiation therapy. The applicant projects that 60% of the projected oncology and hematology patients will receive radiation therapy, as shown in the following table from page 2 of the Assumptions and Methodology in Form C:

Projected Radiation Therapy Patients, CY 2020-2026

	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026
# Oncology / Hematology Patients	1,704	1,765	1,827	1,892	1,959	2,028
Radiation Therapy Pts as % of Total	60%	60%	60%	60%	60%	60%
WH Potential Radiation Therapy Pts	1,023	1,059	1,096	1,135	1,175	1,217

The applicant states it does not project to serve all 60% of those patients in the service area calculated above projected to need radiation therapy. The applicant thus projects a gradual ramp up of patients, from 10% in the first project year (PY) (CY 2023) to 25% in the third PY, as shown in the following table from page 3 of the Assumptions and Methodology:

Projected Wilmington Health Radiation Therapy Patients, CY 2020-2026

	CY 2021	CY 2022	CY 2023*	CY 2024	CY 2025	CY 2026
WH Potential Radiation Therapy Pts	1,023	1,059	548	1,135	1,175	1,217
Projected Ramp Up			10%	15%	20%	25%
Projected WH Radiation Therapy Pts			55	170	235	304

*The applicant projects the proposed linac will be operational July 1, 2023. Therefore, the applicant adjusted the number of patients to reflect 6 months.

To calculate the number of projected ESTVs for its patients, the applicant analyzed the 2020 license renewal applications (LRAs) for 18 freestanding linac service providers in the state and calculated a median ratio of 23.26 ESTVs per patient. The applicant applied that ratio to the number of patients projected to be served at Wilmington Health, as shown in the following table from page 3 of the Assumptions and Methodology:

Projected Wilmington Health Radiation Therapy Patient ESTVs

	CY 2023	CY 2024	CY 2025	CY 2026
WH Potential Radiation Therapy Pts	55	170	235	304
ESTVs per Patient	23.26	23.26	23.26	23.26
Projected # ESTVs	1,275	3,960	5,467	7,076

The applicant states the Performance Standards promulgated at 10A NCAC 14C .1903 requires an applicant to demonstrate that each new proposed linac will be utilized at an annual rate of 250 patients or 6,750 ESTVs during the third project year. The applicant projects to serve 304 patients, or 7,076 ESTVs during its third project year.

The applicant explains how it converts its fiscal years to project years and the calculations used to project the number of patients to be served based on those conversions. The applicant projects the linac to be operational in July 2023, and thus provides the following calculations to determine volume in the project years:

- PY 1: July 1, 2023-June 30, 2024
 - Formula: (CY 2023) + (0.5 x CY 2024)
- PY 2: July 1, 2024-June 30, 2025
 - Formula: (0.5 x CY 2024) + (0.5 x CY 2025)
- PY 3: July 1, 2025-June 30, 2026
 - Formula: (0.5 x CY 2025 + 0.5 x CY 2026)

See the following table to illustrate these calculations, from page 5 of the Assumptions and Methodology:

Projected Wilmington Health Radiation Therapy Patients per Linac

	PY 1	PY 2	PY 3
WH Potential Radiation Therapy Pts	140	203	270
# Linacs	1	1	1
# Patients per Linac	140	203	270

The applicant also proposes a CT simulator via an operating lease to aid in precise delivery of radiation therapy treatments. The simulator will be used for radiation therapy simulations and not for diagnostic CT scans.

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

- The applicant relies on data from established and reliable sources and cites to the sources of any population growth data used.
- The applicant relies on its historical hematology and oncology patients, physician referral letters and population growth to project future growth in utilization.
- The proposed linac offers new technology that will allow Wilmington Health to serve an existing and projected patient population in linac SA 19.

Access to Medically Underserved Groups

In Section C.6, page 58, the applicant states:

“Wilmington Health provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. ...

In addition, Wilmington Health will accept various insurance plans, including Medicare and Medicaid, and will provide financial assistance to patients with financial hardships.”

The applicant provides the estimated percentage for each medically underserved group it proposes to serve during the third full fiscal year, as shown in the following table from page 59:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	--
Racial and ethnic minorities	27.4%
Women	58.8%
Persons with disabilities	--
The elderly	27.4%
Medicare beneficiaries	55.0%
Medicaid recipients	3.0%

The applicant states it does not maintain data that tracks the number of low income persons or persons with disabilities that it serves.

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 written statements about providing access to all residents of the service area, including underserved groups.
- The applicant provides projected payor mix, which includes underserved groups, and assumes it will remain constant for the first three years of operation.

Conclusion

The agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written comments
- Response to comments

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

- (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 – Both Applicants

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC: The applicants do not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

O-12120-21 Wilmington Health, PLLC: The applicant does not propose to reduce a service, 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.

C – Both Applicants

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC: In Section E.2, pages 102-103, the applicants describe the alternatives they considered and explain why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicants state maintaining the status quo is an unacceptable alternative because it would be inconsistent with NHRMC’s commitment to providing continuity of care and expanding geographic and financial access to comprehensive cancer care in the service area. In addition, maintaining the status quo would ignore the capacity issues that exist at NHRMC 16th Street and potentially create patient delays, thus impacting timely access to care for patients.
- Install the proposed linac at the NHRMC 16th Street location – The applicants state this is not an effective alternative because it would ignore the need of cancer patients who reside in the northern portion of linac SA-19 and the northern counties that comprise the NHRMC service area to have cancer services closer to their residence. In addition, the applicants state the cost of installation and space constraints at the NHRMC 16th Street location combine to make this a less effective alternative.

- Install the proposed linac at the NHRMC Brunswick location – The applicants state locating the proposed linac at the Brunswick campus would not meet the needs of patients as effectively as it would at the Scotts Hill location, because it would not improve access to radiation therapy services for those patients who reside in the northern portion of linac SA-19. The applicants state the existing linacs at the NHRMC 16th Street and Brunswick locations currently effectively serve those patients who reside closer to those two locations. The applicants state the Scotts Hill location would more effectively serve an underserved population that does not currently have access to radiation therapy services closer to home.
- Locate the proposed linac in Columbus or Pender county – The applicants state the addition of a linac within either of those two counties is not feasible because neither county has a large enough population to support the addition of a new linac; however, those populations are currently served by CCRO's medical oncology consultations through Columbus Regional Healthcare System. The applicants provide a letter of support for this project from Columbus Regional Healthcare System in Exhibit I-2.2.

On page 103, the applicants state that this proposal is the most effective alternative because it will allow NHRMC to address existing capacity constraints that exist at the 16th Street location, will expand geographic access for patients in the northern portions of linac SA-19 and will improve access to a full range of cancer treatment services, thereby ensuring continuity of care for those patients. Additionally, the applicants state the proposal will be competitively priced to maximize healthcare value for the patients.

The applicants adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicants provide reasonable information to explain why they believe the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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

O-12120-21 Wilmington Health, PLLC: In Section E.2, page 71, the applicant describes the one alternative it considered and explains why that alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternative considered was:

- Develop the proposed linac at a different location – The applicant states Wilmington Health currently offers oncology and infusion therapy services. Developing the proposed linac at another site would not save construction costs, eliminate potentially burdensome travel for its patients, nor enhance economies of scale as compared to the current location.

On page 71, the applicant states that this proposal is the most effective alternative because it will allow Wilmington Health to improve access to comprehensive cancer treatment services in a location that currently provides oncology and infusion therapy services, thereby ensuring continuity of care for those patients.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

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

- (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 – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC: the applicants propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington.

Capital and Working Capital Costs

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

Site Costs	NA
Construction / Renovation Costs	\$13,609,641
Miscellaneous Costs	\$9,325,055
Total	\$22,934,696

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit F-1, the applicants provide documentation to support projected equipment prices, including the costs associated with the delivery and installation of the proposed equipment, and these costs are included in the projected capital cost.
- In Section Q, Form F.1a, page 157, the applicants state medical equipment costs include all necessary equipment for the linac, CT simulator, pharmacy, lab, infusion and exams.
- In Section F, page 103, the applicant states that there will be no start-up or initial operating costs associated with this project.

Availability of Funds

In Section F.2, page 104, the applicants state the capital cost will be funded as shown in the following table:

TYPE	SARO	NOVANT HEALTH, INC.	TOTAL
Loans	\$4,158,261	\$0	\$4,158,261
Accumulated reserves or OE *	\$0	\$18,776,435	\$18,776,435
Bonds	\$0	\$0	\$0
Other	\$0	\$0	\$0
Total Financing	\$4,158,261	\$18,776,435	\$22,934,696

*OE = Owner's Equity

In Exhibit F-2.1, the applicants provide a July 29, 2021 letter from the Senior Vice President of Commercial Lending at First Citizens Bank documenting its intention to provide sufficient funding to SARO to finance its portion of cost of the proposed project. Exhibit F-2.1 also contains a July 29, 2021 letter from the Senior Vice President of Finance for Novant Health, Inc., confirming the ability and willingness of Novant Health, Inc. to commit sufficient funds to the project. Exhibit F-2.1 also contains the consolidated balance sheets for Novant Health, Inc. for 2019 and 2020, which show Novant Health, Inc. had total sufficient total assets and cash and cash equivalents to fund its portion of the project capital cost.

The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project based on the following:

- In Exhibit F-2.1, SARO documents that it will obtain funding in an amount sufficient to cover its portion of the project capital cost.
- Novant Health, Inc. documents that it has sufficient reserves to fund its portion of the project capital cost.
- Exhibit F-2.1 contains a copy of Novant Health, Inc.’s consolidated balance sheet for 2019 and 2020, showing cash and cash equivalents in 2020 of \$8.6 billion.

Financial Feasibility

In Section Q, the applicants provide pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicants project that revenues will exceed operating expenses in all three full fiscal years following completion of the project, as shown in the following tables:

NHRMC SCOTTS HILL RADIATION THERAPY

	1ST FFY 10/1/2023- 9/30/2024	2ND FFY 10/1/2024- 9/30/2025	3RD FFY 10/1/2025- 9/30/2026
Total Treatments	6,098	7,721	7,817
Total Gross Revenues (Charges)	\$17,202,157	\$22,435,767	\$23,391,345
Total Net Revenue	\$3,941,392	\$5,090,619	\$5,255,909
Average Net Revenue per Treatment	\$646	\$659	\$672
Total Operating Expenses (Costs)	\$3,229,775	\$4,003,948	\$4,076,291
Average Operating Expense per Treatment	\$530	\$519	\$521
Net Income	\$711,617	\$1,086,671	\$1,179,618

Numbers may not sum due to rounding

NHRMC SCOTTS HILL CANCER CENTER ENTIRE CAMPUS

	1ST FFY 10/1/2023- 9/30/2024	2ND FFY 10/1/2024- 9/30/2025	3RD FFY 10/1/2025- 9/30/2026
Total Gross Revenues (Charges)	\$122,009,684	\$159,101,217	\$165,844,245
Total Net Revenue	\$35,137,062	\$45,374,054	\$46,837,903
Average Net Revenue per Treatment	\$5,762	\$5,877	\$5,992
Total Operating Expenses (Costs)	\$23,593,891	\$30,385,997	\$31,403,828
Average Operating Expense per Treatment	\$3,869	\$3,936	\$4,017
Net Income	\$11,543,171	\$14,988,057	\$15,434,075

Numbers may not sum due to rounding

Costs and revenues in this table pertain to all of the services provided at the cancer center.

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

- The applicants base their projections on NHRMC’s and Novant Health’s historical experience and adequately account for projected operating expenses, such as salaries,

equipment maintenance and administrative support, 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
- Written comments

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

- The applicants base projections on NHRMC's historical experience in providing cancer services at both the 16th Street and the Brunswick locations.
- The applicants adequately demonstrate that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicants adequately demonstrate 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.

O-12120-21 Wilmington Health, PLLC – The applicant proposes to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in an existing physician practice in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

Capital and Working Capital Costs

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

Site Costs	\$40,308
Construction / Renovation Costs	\$4,760,533
Miscellaneous Costs	\$67,430
Total	\$4,868,271

In Section Q, the applicant provides the assumptions used to project the capital cost. Comments submitted in opposition to this proposal by Novant Health, Inc. indicate that the cost of the proposed linac should have been included as a capital cost of the project. However,

Wilmington Health states in its assumptions to Form F.1a that the proposed linac will be leased via an operating lease; therefore, the cost of the equipment is included as an operating cost in all three project years in Form F.3b. The applicant adequately accounts for the equipment cost in its operating costs.

The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit F-1.1, the applicant provides documentation from an architect projecting capital costs which are included in the projected capital cost.
- The applicant adequately accounts for project costs associated with site preparation and construction/renovation to accommodate the proposed linac.
- The applicant bases construction, furniture and equipment costs on its experience with similar projects.
- In Section F, page 74, the applicant states that there will be no start-up or initial operating costs associated with this project because Wilmington Health is an existing physician practice and infusion center.

Availability of Funds

In Section F.2, page 72, the applicant states the capital cost will be funded as shown in the following table:

Sources of Capital Cost Financing		
TYPE	WILMINGTON HEALTH, PLLC	TOTAL
Loans	\$0	\$0
Accumulated reserves or OE *	\$4,868,271	\$4,868,271
Bonds	\$0	\$0
Other	\$0	\$0
Total Financing	\$4,868,271	\$4,868,271

*OE = Owner's Equity

In Exhibit F-2.1, the applicants provide an August 16, 2021 letter from the Chief Financial Officer of Wilmington Health, PLLC which documents the availability of and commitment to dedicate the funds necessary to fund the capital cost of the project. Exhibit F-2.2 contains the consolidated balance sheets for Wilmington Health, PLLC for 2019 and 2020, which document sufficient total assets and cash and cash equivalents to fund the project capital cost.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Wilmington Health, PLLC documents its commitment to funding the project and that it has sufficient cash reserves to fund the project.
- Exhibit F-2.2 contains a copy of Wilmington Health, PLLC's consolidated balance sheets for 2019 and 2020, which show cash and cash equivalents in 2020 of \$21 million, and total current assets of \$33 million.

Financial Feasibility

In Section Q, the applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that for radiation oncology, revenues will exceed operating expenses in the third full fiscal year (CY 2026) following project completion. Regarding the total facility, the applicant projects that revenues will exceed operating expenses in the second and third full fiscal years (CY 2025 and CY 2026) following project completion, as shown in the following tables:

WILMINGTON HEALTH – RADIATION ONCOLOGY

	1ST FFY CY 2024	2ND FFY CY 2025	3RD FFY CY 2026
Total Number of ESTVs	3,960	5,467	7,076
Total Gross Revenues (Charges)	\$3,663,385	\$5,209,119	\$6,944,121
Total Net Revenue	\$1,736,360	\$2,469,003	\$3,291,354
Average Net Revenue per Treatment	\$438	\$451	\$465
Total Operating Expenses (Costs)	\$2,918,570	\$3,072,509	\$3,241,289
Average Operating Expense per Treatment	\$737	\$562	\$458
Net Income	(\$1,182,210)	(\$603,506)	\$50,065

Numbers may not sum due to rounding

WILMINGTON HEALTH – TOTAL FACILITY

	1ST FFY CY 2024	2ND FFY CY 2025	3RD FFY CY 2026
Total Gross Revenues (Charges)	\$350,635,983	\$362,590,895	\$375,047,350
Total Net Revenue	\$178,632,573	\$184,672,102	\$190,960,546
Total Operating Expenses (Costs)	\$179,005,792	\$184,442,348	\$190,052,223
Net Income	(\$373,219)	\$229,754	\$908,323

Numbers may not sum due to rounding

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 bases payor mix projections on Wilmington Health’s historical experience and does not project a shift in payor mix following the addition of the proposed linac.
- The applicant’s projection of gross revenue is based on Wilmington Health’s historical experience and research conducted by the applicant regarding similar physician practices that provide oncology and linac services.
- The applicant adequately accounts for projected operating expenses, such as salaries, equipment maintenance and administrative support, 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
- Written comments
- Response to comments

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

- The applicant bases projections on Wilmington Health's historical experience in providing oncology, infusion and hematology services at its existing facility.
- 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 the availability of sufficient funds for the capital needs of the proposal 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 – Both Applications

In Chapter 17, page 324, the 2021 SMFP states, "... a linear accelerator's service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology. Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of a linear accelerator service areas, based on proximity, utilization patterns, and patient origin data." NHRMC is located in New Hanover County. In Table 17-C4, page 333 of the 2021 SMFP, linear accelerator service area 19 consists of Brunswick, Columbus, New Hanover and Pender counties. Facilities may serve residents of counties not included in their service area. Each application proposes to locate a linac in New Hanover County, which is in linac SA-19. Thus, the service area for both proposals is linac SA-19. Facilities may also serve residents of counties not included in their service area.

The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators from 10/1/2018 – 9/30/2019, as summarized from Table 17C-1, page 328 of the 2021 SMFP:

Linear Accelerators in SA-19				
Provider	County	# of Linacs	Total Procedures* in 2018-2019	Avg. ESTVs*/Linac
NHRMC	New Hanover	4	30,752	7,688

*The 2021 SMFP equates ESTVs with procedures in Table 17C-1.

NHRMC owns and operates all four linacs in linac SA-19. Three are located at the 16th Street campus and one is located at the Brunswick campus.

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – the applicants propose propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington.

In Section G, page 113, the applicants explain why they believe the proposal would not result in the unnecessary duplication of existing linac services in linac SA-19. The applicants state:

“The proposed project will allow NHRMC to expand geographic access and extend financial access to quality radiation therapy services as part of a full continuum of cancer services for SA-19 residents and to relieve the capacity constraints that currently exist due to a high and growing demand for radiation therapy services on its existing linacs. ... NHRMC is the sole provider of linac services in SA-19 with all of its linacs being well utilized. Given the growth in demand resulting from the growing and aging service area population, the proposed linac is needed and will not result in a duplication of existing services or harm existing providers.”

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

- There is a need in the 2021 SMFP for an additional linac in linac SA-19.
- The existing linacs in linac SA-19 performed 7,688 treatments per unit in the last FFY (10/1/2019 to 9/30/2020), which exceeds the performance standard of 6,750 ESTVs per unit.
- The applicants adequately demonstrate that the proposed linac is needed in addition to the existing or approved linacs in linac SA-19.

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 all the reasons described above.

O-12120-21 Wilmington Health, PLLC – The applicant proposes to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in an existing physician practice in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

In Section G, pages 82-83, the applicant explains why it believe the proposal would not result in the unnecessary duplication of existing linac services in linac SA-19. The applicant states:

“...the proposed project is in response to a need determination for one additional linear accelerator in the 2021 SMFP for Service Area 19, which includes Brunswick, Pender, New Hanover, and Columbus counties. Currently, NHRMC is the only provider of linear accelerator services in Service Area 19, and, combined, its four existing linear accelerators are operating well above the 6,750 ESTV threshold per unit. ... Wilmington Health’s proposal will not only meet the need for additional linear accelerator services but also improve competition and access to high quality compassionate cancer services, including the proposed linear accelerator services.”

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 reasons:

- There is a need in the 2021 SMFP for an additional linac in linac SA-19.
- The applicant adequately demonstrates that the proposed linac is needed in addition to the existing or approved linacs in linac SA-19.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written comments
- Response to written comments

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

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – the applicants propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington.

In Section Q, Form H the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

NHRMC – Scotts Hill Cancer Center

POSITION	# FTEs	# FTEs	# FTEs
	1 ST FY 10/1/2023- 9/30/2024	2 ND FY 10/1/2024- 9/30/2025	3 RD FY 10/1/2025- 9/30/2026
Registered Nurse	7.00	9.50	9.50
LPN	0.90	0.90	0.90
Manager of Oncology	0.03	0.03	0.03
Nursing Coordinator	0.43	0.43*	0.43*
Radiation Therapist	3.00	4.00	4.00
Patient Access/Care Technician	3.03	3.40	3.40
Dosimetrist	1.00	1.00	1.00
Physicist	1.00	1.00	1.00
Laboratory Technician	1.00	1.00	1.00
Pharmacist	1.00	1.00	1.00
Pharmacy Technician	1.00	2.00	2.00
Medical Assistant	2.00	2.50	2.50
Phlebotomist	1.00	2.00	2.00
Clerical	3.00	3.90	3.90
Total	25.40	32.70	32.70

Numbers may not sum due to rounding

*In the excel worksheet provided by the applicant on page 166, it appears that the last digit was cut off. The Project Analyst verified the total FTEs provided by the applicants.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicants are budgeted in Form F.3, which is in Section Q. In Sections H.2 and H.3, pages 115-117 and referenced exhibits, the applicants describe the methods used to recruit or fill new positions and the existing and proposed training and continuing education programs in radiation oncology and radiation therapy services.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services, based on the applicants’ experience in staffing and operating existing hospitals and oncology and radiation therapy services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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

O-12120-21 Wilmington Health, PLLC – The applicant proposes to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in an existing physician practice in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

In Section Q, Form H the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

POSITION	# FTEs	# FTEs	# FTEs
	1 ST FY CY 2024	2 ND FY CY 2025	3 RD FY CY 2026
Radiation Oncologist	1.0	1.0	1.0
Nurse/MOA	1.0	1.0	1.0
Therapist	2.0	2.0	2.0
Clerical	1.0	1.0	1.0
Total	5.0	5.0	5.0

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicants are budgeted in Form F.3, which is in Section Q. In Sections H.2 and H.3, pages 84-85, the applicant describes the methods used to recruit or fill new positions and the proposed training and continuing education programs in radiation oncology and radiation therapy services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services, based on the applicant's experience in staffing and operating its existing physician practice and research it conducted.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – The applicants propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington.

Ancillary and Support Services

In Section I, page 119 the applicants identify the necessary ancillary and support services for the proposed services. On pages 119-120, the applicants explain how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I.1 and A-1.7. The applicants adequately demonstrate that the necessary ancillary and support services are and will continue to be made available based on the following:

- The applicants currently provide comprehensive cancer services at two hospital campuses and state the same services and providers will be available for the proposed linac services on the Scotts Hill campus.
- In Exhibit I.1, the applicants provide supporting documentation that the existing ancillary and support services will be expanded to meet the needs of the proposed additional linac services.
- In Exhibit I.1, the applicants provide a letter from the proposed Medical Director of the radiation oncology component of the proposed cancer center.
- In Exhibit I.1, the applicants provide a copy of the Routine Service Agreement (RSA) between NHRMC and SARO for the operation of the proposed linac.

Coordination

In Section I, page 120 the applicants describe the existing and proposed relationships with other local health care and social service providers and provide supporting documentation in Exhibits I.2.1 and I-2.2. The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system based on the following:

- The applicants currently provide comprehensive cancer services in New Hanover County and have established relationships with local healthcare and social services providers, which will continue to be in place in the proposed program.

- The applicants demonstrate physician support for the project in Exhibit C-4.6.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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

O-12120-21 Wilmington Health, PLLC – The applicant proposes to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in an existing physician practice in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

In Section I, pages 86-87 the applicant identifies the necessary ancillary and support services for the proposed radiation therapy service and explains how each ancillary and support service is or will be made available. The applicant 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 lists existing ancillary and support services currently in place at Wilmington Health and states these same services will be available for the proposed linac services.
- The applicant confirms the availability of ancillary and support services for the proposed project in Exhibit I-1.

Coordination

In Section I, page 87 the applicant states it has existing relationships with area healthcare providers. The applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently provides oncology, infusion therapy and hematology services in its existing facility and has established relationships with local healthcare and social services providers, which will continue to be in place following the addition of the proposed linac.
- The applicant demonstrates physician support for the project and the availability of radiologists to interpret the linac procedures in Exhibit I-1.

- The applicant provides letters from community healthcare providers expressing support for the proposed project in Exhibit I-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – The applicants propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington.

The applicants do 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 applicants do 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.

O-12120-21 Wilmington Health, PLLC – The applicant propose to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in an existing physician practice in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

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 applicants do 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 – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – The applicants propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington.

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

O-12120-21 Wilmington Health, PLLC – The applicant proposes to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in an existing physician practice in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

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

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

C – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – The applicants propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be

located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington.

In Section K, page 123 the applicants state that the project involves constructing 24,091 square feet of new space. Line drawings are provided in Exhibit K-1.

On pages 123-124, the applicants adequately explain how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicants used an architect and design team that explored cost effective, efficient design based on actual costs of similar cancer center projects.
- The applicants state the design team and architect coordinated with experienced hospital contractors as well as facility staff and clinicians to ensure development of a cost-effective and energy efficient facility design.
- The applicants state the use of the experienced design team will maximize accessibility of health care resources to the community.

On page 124, the applicants adequately explain why the proposal will not unduly increase the costs to NHRMC of providing the proposed oncology services or the costs and charges to the public for the proposed services based on the following:

- The applicants state the project will alleviate capacity constraints on existing NHRMC linacs while providing continuity of care to cancer patients who reside in linac SA-19, thereby increasing efficiencies.
- The applicants state the project will enhance patient safety and satisfaction while increasing access for patients.

On pages 124-125, the applicants identify any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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

O-12120-21 Wilmington Health, PLLC – The applicant proposes to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in an existing physician practice in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

In Section K, page 90, the applicant states that the project involves renovating 5,082 square feet of existing space. Line drawings are provided in Exhibit C-1.1.

On page 91, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states it will design the project in a resource-responsible manner by housing the proposed linac in existing space in the facility.
- The applicant states that the facility renovation and equipment installation can be completed with minimal disruption to patient care.
- The applicant states the proposed renovations are more cost-effective than new space construction.

On page 91, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states developing the project at the existing facility improves economies of scale and ultimately contains costs for the project.
- The applicant states that renovating existing space in an existing facility avoids costs associated with constructing a new facility and ensures continuity of care for its patients.

On page 91, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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 – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – Acquire one linear accelerator

The proposed project involves development of a linac and other cancer treatment services in a MOB on the Scotts Hill campus, which is not yet developed; thus, there is no historical patient information for the Scotts Hill Campus. In Section L, page 129, the applicants provide the historical payor mix during FY 2020 (10/1/2019-9/30/2020) for cancer services at the NHRMC 16th Street and Brunswick campuses, as shown in the tables below:

NHRMC 16th Street Payor Mix, FY 2020

PAYOR CATEGORY	% OF TOTAL PATIENTS SERVED
Self-Pay	1.66%
Charity Care	2.61%
Medicare*	60.27%
Medicaid*	5.69%
Insurance*	25.36%
Workers Compensation	0.08%
TRICARE	4.19%
Other	0.16%
Total	100.0%

*Includes managed care plans

NHRMC Brunswick Payor Mix, FY 2020

PAYOR CATEGORY	% OF TOTAL PATIENTS SERVED
Self-Pay	1.18%
Charity Care	1.65%
Medicare*	66.27%
Medicaid*	4.25%
Insurance*	23.58%
Workers Compensation	0.24%
TRICARE	2.59%
Other	0.24%
Total	100.0%

*Includes managed care plans

In Section L, page 130, the applicant provides the following comparison for the 16th Street location for FY 2020:

NHRMC 16th Street Cancer Services

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY, FY2020	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	50.5%	49.8%
Male	49.5%	50.2%
Unknown	0.0%	0.0%
64 and Younger	38.4%	83.7%
65 and Older	61.6%	16.3%
American Indian	0.4%	0.6%
Asian	0.5%	1.6%
Black or African-American	14.6%	18.7%
Native Hawaiian or Pacific Islander*	NA	0.1%
White or Caucasian	82.6%	70.4%
Other Race	1.3%	4.9%
Declined / Unavailable	0.4%	0.0%

*On page 130 the applicant states NHRMC does not have data on the number of native Hawaiian or Pacific Islanders treated.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the applicants adequately document the extent to which medically underserved populations currently use the applicants' existing services in comparison to the percentage of the population in the applicants' service area which is medically underserved. Therefore, the application is conforming to this criterion.

O-12120-21 Wilmington Health, PLLC – Acquire one linear accelerator

In Section L, page 94, the applicant provides the historical payor mix during CY 2020 at its existing facility, as shown in the following table:

PAYOR CATEGORY	LINAC SERVICES AS A % OF TOTAL
Self-Pay	7.5%
Charity Care^	--
Medicare*	25.6%
Medicaid*	9.7%
Insurance*	48.1%
Workers Compensation	--
TRICARE	--
Other^^	9.1%
Total	100.0%

*Includes managed care plans

^The applicant states it does not track charity care as a payor source for patients but does provide charity care to patients in any payor category.

^^The applicant states "Other" includes workers comp and TRICARE.

In Section L, page 95, the applicant provides the following comparisons:

Wilmington Health Comparison

	Percentage of Total Patients Served by the Facility in the Last Full FY, CY2020	Percentage of the Population of New Hanover County	Percentage of the Population of Brunswick County
Female	58.8%	52.4%	52.3%
Male	41.2%	47.6%	47.7%
Unknown	0.0%	0.0%	0.0%
64 and Younger	72.6%	81.6%	67.4%
65 and Older	27.4%	18.4%	32.6%
American Indian	0.2%	0.6%	0.8%
Asian	0.9%	1.6%	0.7%
Black or African-American	10.6%	13.4%	10.0%
Native Hawaiian or Pacific Islander	0.2%	0.1%	0.1%
White or Caucasian	72.6%	82.2%	86.5%
Other Race	2.2%	2.1%	1.8%
Declined / Unavailable	13.3%	0.0%	0.0%

Wilmington Health Comparison

	Percentage of the Population of Columbus County	Percentage of the Population of Pender County
Female	50.4%	50.2%
Male	49.6%	49.8%
Unknown	0.0%	0.0%
64 and Younger	79.4%	81.4%
65 and Older	20.6%	18.6%
American Indian	3.8%	0.9%
Asian	0.5%	0.7%
Black or African-American	30.6%	14.7%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	63.1%	81.5%
Other Race	1.9%	2.1%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 131, the applicants state NHRMC is under no such obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance. The applicants state on page 131 that NHRMC is a tax-exempt 501(c)(3) organization and provides charity care to the communities it serves.

In Section L, page 131, the applicants state that during the last five years no patient civil rights access complaints have been filed against any facilities owned by NHRMC or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

O-12120-21 Wilmington Health, PLLC

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 97, the applicant states it has no such obligation to provide uncompensated care. Regarding community service or access by minorities and persons with disabilities, on page 97 the applicant states it does and will continue to provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment, and provides supporting documentation in Exhibit B.20-4.

In Section L, page 97, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC

In Section L, page 132, the applicants project the following payor mix for the proposed linac at Scotts Hill and total proposed cancer services at Scotts Hill during the third full fiscal year of operation following completion of the project, as shown in the table below:

NHRMC Scotts Hill Linac Payor Mix

PAYOR SOURCE	% OF TOTAL
Self-Pay	1.66%
Charity Care	2.61%
Medicare*	60.27%
Medicaid*	5.69%
Insurance*	25.36%
Workers Compensation	0.08%
TRICARE	4.19%
Other	0.16%
Total	100.00%

*Including any managed care plans

NHRMC Scotts Hill Total Cancer Services Payor Mix

PAYOR SOURCE	% OF TOTAL
Self-Pay	2.58%
Charity Care	2.65%
Medicare*	58.61%
Medicaid*	7.00%
Insurance*	26.89%
Workers Compensation	0.03%
TRICARE	0.97%
Other	1.27%
Total	100.00%

*Including any managed care plans

As shown in the tables above, during the third full fiscal year of operation, the applicants project that for the proposed linac services at Scotts Hill, 1.66% of total services will be provided to self-pay patients, 2.61% to charity care patients, 60.27% to Medicare patients and 5.69% to Medicaid patients. For the proposed total cancer services at Scotts Hill, the applicants project that 2.58% of total services will be provided to self-pay patients, 2.65% to charity care patients, 58.61% to Medicare patients and 7.0% to Medicaid patients.

On pages 132-133, the applicants provide the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix at NHRMC 16th Street and Brunswick locations.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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

O-12120-21 Wilmington Health, PLLC

In Section L, page 98, 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:

Wilmington Health Payor Mix, CY 2026 Total Facility

PAYOR SOURCE	% OF TOTAL
Self-Pay	7.5%
Charity Care	--
Medicare*	25.6%
Medicaid*	9.7%
Insurance*	48.1%
Workers Compensation	--
TRICARE	--
Other^^	9.1%
Total	100.0%

*Includes managed care plans

^The applicant states it does not track charity care as a payor source for patients but does provide charity care to patients in any payor category.

^^The applicant states "Other" includes workers comp and TRICARE.

Wilmington Health Payor Mix, CY 2026 Radiation Therapy

PAYOR SOURCE	% OF TOTAL
Self-Pay	1.5%
Charity Care	--
Medicare*	55.0%
Medicaid*	3.0%
Insurance*	40.5%
Workers Compensation	--
TRICARE	--
Other^^	0.0%
Total	100.0%

*Includes managed care plans

^The applicant states it does not track charity care as a payor source for patients but does provide charity care to patients in any payor category.

^^The applicant states "Other" includes workers comp and TRICARE.

As shown in the table above, during the third full fiscal year of operation for the total facility, the applicant projects that 7.5% of total services will be provided to self-pay patients, 25.6% to Medicare patients and 9.7% to Medicaid patients. Regarding radiation therapy services at the facility, the applicant projects that 1.5% of total services will be provided to self-pay patients, 55% to Medicare patients and 3% to Medicaid patients

On pages 98 and 99, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects payor mix for all services based on the existing and historical payor mix at Wilmington Health in CY 2020.
- The applicant states it anticipates a payor mix shift in future years, but for the term of the project, no shift is assumed due to the uncertainty in healthcare reform, Medicaid expansion, and other policy initiatives.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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 – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC

In Section L, page 134, the applicants adequately describe the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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

O-12120-21 Wilmington Health, PLLC In Section L, page 100, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 – Both Applications

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – The applicants propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington.

In Section M, page 135, the applicants describe the extent to which health professional training programs in the area have and will continue to have access to the facility for training purposes. The applicants adequately demonstrate that health professional training programs in the area will continue to have access to the facility for training purposes based on the following:

- The applicants state both Novant Health and NHRMC maintain many health professional training programs and clinical education agreements with area health education programs.
- The applicants state NHRMC's radiation oncology sites have been long-time training sites for radiation therapy students, and most training agreements are perpetual or automatically renewed annually.
- The applicants state Novant Health, UNC Health and UNC School of Medicine have recently agreed to collaborate regarding medical education and academic and clinical training in the area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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

O-12120-21 Wilmington Health, PLLC – The applicant proposes to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in an existing physician practice in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

In Section M, page 102, the applicant describes the extent to which health professional training programs in the area have and will continue to have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will continue to have access to the facility for training purposes based on the following:

- The applicant states Wilmington Health partners with many health professional training and clinical education programs and will continue following the addition of the proposed linac.
- The applicant states it will provide clinical training opportunities that will include the linear accelerator 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 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 – Both Applications

In Chapter 17, page 324, the 2021 SMFP states, “... a linear accelerator’s service area is one of the 28 multicounty groupings described in the Assumptions of the Methodology. Patient origin data from the current reporting year forms the basis for defining service areas.... Counties are the basic units for the formation of linear accelerator service areas, based on proximity, utilization patterns, and patient origin data.” NHRMC is located in New Hanover County. In Table 17-C4, page 333 of the 2021 SMFP, linear accelerator service area 19 consists of Brunswick, Columbus, New Hanover and Pender counties. Each application proposes to locate a linac in New Hanover County, which is in linac SA-19. Thus, the service area for both proposals is linac SA-19. Facilities may also serve residents of counties not included in their service area.

The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators from 10/1/2018 – 9/30/2019, as summarized from Table 17C-1, page 328 of the 2021 SMFP:

Linear Accelerators in SA-19				
Fixed PET Scanners HSA I				
Provider	County	# of Linacs	Total Procedures* in 2018-2019	Avg. ESTVs*/Linac
NHRMC	New Hanover	4	30,752	7,688

*The 2021 SMFP equates ESTVs with procedures in Table 17C-1.

NHRMC owns and operates all four linacs in linac SA-19. Three are located at the 16th Street campus and one is located at the Brunswick campus.

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – The applicants propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 137, the applicants state:

“While there are no other existing radiation therapy providers in SA-19, the project will foster competition with surrounding facilities. NHRMC competes not only with other hospitals in the area but also with much larger systems both inside and outside of North Carolina. While the NHRMC Cancer Services at Scotts Hill will be an extension of NHRMC and primarily serve to expand access to an existing base of patients, it will also serve to enhance competition in the region. ... This project will not simply add capacity but will expand the continuum of cancer

services in the region ensuring geographic access, continuity and quality of care, as well as maximizing value.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 137, the applicants state:

“...NHRMC’s proposed project will have a positive impact on the cost-effectiveness, quality, and access by underserved groups for the proposed services. ...

Additionally, as evidenced by CMS’s ROAP, an alternative payment pilot program for radiation oncology, NHRMC provides efficient, cost-effective cancer care. ...”

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

Regarding the impact of the proposal on quality, in Section N, page 138, the applicants state:

“Because NHRMC Cancer Services at Scotts Hill will be a facility of NHRMC, it will follow and maintain the same quality and performance improvement policies and programs already established at NHRMC. NHRMC prides itself on its quality of care, and Cancer Services at Scotts Hill will serve to enhance and expand access to this level of care by addressing linac capacity constraints and increasing available access points of cancer care to SA-19 residents.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 138 the applicants state:

“...the new cancer center will also provide access to medically underserved groups at a rate that is consistent with NHRMC’s historical experience. For members of this group who reside in and around the Scotts Hill community, access to quality cancer care will be increased and the need for a lengthy commute downtown for cancer care services will be eliminated. ... Cancer Services at Scotts Hill will be a comprehensive provider to all patients without regard to race, color, religion,, creed, national origin, sex, sexual preference, disability, age, or ability to pay.”

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

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

- The proposal is cost effective – the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) the proposal would not result in an unnecessary duplication of existing and approved health services; and c) projected revenues and operating costs are reasonable.

- Quality care would be provided based on the applicants' representations regarding its commitment to quality of the proposed services, and the applicants' record of providing quality care in the past.
- Medically underserved groups will have access to the proposed services based on the applicants' representations about access by medically underserved groups and the projected payor mix.

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 all the reasons described above.

O-12120-21 Wilmington Health, PLLC – The applicant proposes to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in an existing physician practice in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 103, the applicant states:

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to linear accelerator services in Service Area 19.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 103, the applicant references the discussion of cost effectiveness provided in Section B, and states it is committed to maximizing the healthcare value for resources expended in the delivery of radiation therapy services and believes the project will have a positive impact on cost effectiveness of the proposed linac services.

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

Regarding the impact of the proposal on quality, in Section N, page 103, the applicant references the discussion regarding access and quality provided in Section B. The applicant states it is committed to promoting safety and quality in the delivery of radiation therapy services and believes the project will have a positive impact on the continued quality of those services.

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 103, the applicant references the discussion regarding access by medically underserved

groups provided in Section B, and states it is committed to providing access to radiation therapy services to medically underserved groups.

See also Sections B, L and C 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:

- 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.
- 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.
- 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
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described 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 – Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC
NA – Wilmington Health, PLLC

O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC – The applicants propose to acquire one fixed linear accelerator (linac) pursuant to the need determination in the 2021 SMFP to be located in a medical office building which will be a comprehensive cancer services center on the Scotts Hill campus in Wilmington.

In Section Q, the applicants identify the hospitals located in North Carolina owned, operated or managed by the applicants or related entities. The applicants identify a total of 24 facilities located in North Carolina.

In Section O, page 140, the applicants state that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any NHRMC or Novant Health facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care have occurred in any facility. 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 this facility, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

O-12120-21 Wilmington Health, PLLC – The applicant proposes to acquire one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator in an existing physician practice in Wilmington from which the applicant currently provides infusion therapy, endocrinology, infectious disease, internal medicine, neurology, diabetes and rheumatology services.

Neither the applicant nor any related entities own, operate, or manage an existing health service facility that owns or operates a linac located in North Carolina. Therefore, Criterion (20) is not applicable to this review.

(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 – Both Applications

The Criteria and Standards for Radiation Therapy Equipment, promulgated in 10A NCAC 14C .1900, are applicable to this review.

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;*
- C- **Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC** – In Section C, page 94 and in Section Q Form C, the applicants show that each of NHRMC’s four existing linear accelerators performed in excess of 6,750 ESTV treatments per machine in the last full fiscal year, FY2020 (July 2019-June 2020). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- NA- **Wilmington Health, PLLC** – The applicant does not own or operate a linear accelerator.
- (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*
- C- **Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC** – In Section Q, Form C, the applicant projects the proposed linac will perform 8,278 ESTV treatments during the third year of operation of the new unit. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **Wilmington Health, PLLC** – In Section C and in Section Q Form C, , the applicant shows that the proposed linear accelerator will perform 7,076 ESTV treatments and serve 304 patients in the third year of operation. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (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.*
- C- **Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC** – In Section Q, the applicants demonstrate that NHRMC’s four existing linear accelerators are projected to be utilized at an annual rate of at least 6,750 ESTV treatments per machine during the third year of operation. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- NA- **Wilmington Health, PLLC** – The applicant does not own or operate 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- **Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC** – The applicants do not propose to use the linear accelerator exclusively for clinical research and teaching. Therefore, this Rule is not applicable.
- NA- **Wilmington Health, PLLC** – The applicant does not propose to use the linear accelerator exclusively for clinical research and teaching. Therefore, this Rule is not applicable.
- (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- **Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC** – The applicants do not propose to acquire any other radiation therapy equipment as part of this project.
- NA- **Wilmington Health, PLLC** – The applicant does not propose to acquire any other radiation therapy equipment as part of this project.
 - (2) *the maximum number and type of procedures that the proposed equipment is capable of performing.*
- NA- **Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC** – The applicants do not propose to acquire any other radiation therapy equipment as part of this project.
- NA- **Wilmington Health, PLLC** – The applicant does not propose to acquire any other radiation therapy equipment as part of this project.
- (d) *The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.*
- C- **Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC** – The applicants document the assumptions and provide data supporting the methodology used to determine utilization projections in Section C, pages 54-85. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **Wilmington Health, PLLC** – The applicant documents all assumptions and provides data supporting the methodology used to determine projected utilization in Section Q, Form C *Assumptions and Methodology*. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

COMPARATIVE ANALYSIS

Pursuant to G.S. § 131E-183(a)(1) and the 2021 SMFP, no more than one linear accelerator can be approved for linear accelerator service area 19 in this review. Because the two applications in this review collectively propose to develop two additional linear accelerators, both applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review.

- **Project I.D. #O-12110-21 Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC / Acquire no more than one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of five linear accelerators (three at NHRMC 16th St., one in Brunswick County and one at NHRMC Scotts Hill), as part of a cancer services center**
- **Project I.D. #O-12120-21 Wilmington Health, PLLC / Acquire no more than one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one fixed linear accelerator**

Conformity with Statutory and Regulatory Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

Scope of Services

Each application submitted by **NHRMC and Wilmington Health** was submitted in response to the 2021 State Medical Facilities Plan (SMFP) need determination in linear accelerator service area 19 for one linear accelerator. Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor. Each application proposes to provide radiation therapy services and CT simulation services on the proposed linear accelerator. Therefore, regarding scope of services, both applications are equally effective.

Historical Utilization

NHRMC is currently the only provider of linear accelerator services in linear accelerator service area 19. **NHRMC** operates three linear accelerators at the NHRMC 16th Street hospital campus and one linear accelerator at the Brunswick hospital campus. **Wilmington Health** currently does not own or operate a linear accelerator. Generally, regarding this comparative factor, an existing provider with higher historical utilization rates is the more effective alternative based on an assumption that that provider

has a greater need for the proposed linear accelerator in order to serve its projected patients. Therefore, with regard to this comparative factor, the application submitted by **NHRMC** is the more effective alternative.

Geographical Accessibility (Location within the Service Area)

There are currently four existing linear accelerators located in linear accelerator service area 19, which is comprised of four counties: New Hanover, Brunswick, Pender and Columbus. Three of the existing linear accelerators are located in New Hanover County, and one is located in Brunswick County to the south of New Hanover County. The three existing linear accelerators located in New Hanover County are all located in downtown Wilmington. The application submitted by **NHRMC** proposes to locate the linear accelerator in a medical office building on the Scotts Hill hospital campus, located in the northern portion Wilmington in New Hanover County. The application submitted by **Wilmington Health** proposes to locate the linear accelerator in downtown Wilmington.

Therefore, with respect to this comparative factor, the application submitted by **NHRMC** is the more effective proposal and the application submitted by **Wilmington Health** application is less effective, because it proposes to locate the linear accelerator in downtown Wilmington, which already has three existing linear accelerators.

Access by Service Area Residents

Chapter 17, page 324 of the 2021 SMFP defines the service area for a linear accelerator as “*one of the 28 multicounty groupings described in the Assumptions of the Methodology.*” Linear accelerator service area 19 includes New Hanover, Brunswick, Pender and Columbus counties. Thus, the service area for this review is New Hanover, Brunswick, Pender and Columbus counties. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional linear accelerators in or in close proximity to the service area in which they live.

Both applicants propose to provide access to linear accelerator services in linear accelerator service area 19. Both applicants propose to serve patients from all counties within linear accelerator service area 19. **NHRMC** defines a primary, secondary and tertiary service area that includes all SA-19 counties and other counties and states. In addition, **NHRMC** proposes to locate the linac in a medical office building that is part of the Scotts Hill hospital campus in northern Wilmington. **Wilmington Health** also projects to serve patients from all counties within SA-19. **Wilmington Health** proposes to locate the linac in a medical office building located in Wilmington. Each applicant provides the projected number of patients to be served in each of the fiscal years following project completion. The Project Analyst totaled the number of patients to be served by each applicant in the counties that comprise Linac Service Area 19 in the third fiscal year following project completion, FY 2026. See the following table, prepared by the Project Analyst:

Projected Linac Service Area 19 Patients to be Served by Provider, FY 2026

LINAC SERVICE AREA 19 COUNTY	NHRMC SCOTTS HILL	WILMINGTON HEALTH
New Hanover	146	159
Pender	102	33
Brunswick	15	72
Columbus	4	10
Total	267	274

As shown in the table above, **Wilmington Health** proposes to serve more patients from Linac Service Area 19 in the third fiscal year following project completion. Therefore, with regard to this comparative factor, the application submitted by **Wilmington Health** is the more effective alternative.

Access by Underserved Groups

Underserved groups are defined in G.S. § 131E-183(a)(13) as follows:

“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.”

Regarding access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Projected access by each group is treated as a separate factor.

Projected Charity Care

The following table compares projected charity care in the third full fiscal year following project completion for each facility’s radiation oncology services for the proposed linac using the following metrics: charity care per ESTV treatment and charity care as a percent of net revenue. Generally, the application proposing to provide the most charity care is the more effective alternative regarding this comparative factor.

Charity Care PY 3

APPLICANT	# OF ESTV TREATMENTS	TOTAL PROJECTED CHARITY CARE	CHARITY CARE PER ESTV TREATMENT	NET REVENUE	CHARITY CARE AS A % OF NET REVENUE
NHRMC*	8,278	\$619,871	\$74.88	\$5,255,909	11.79%
WH	7,076	\$72,913	\$10.16	\$3,291,354	2.22%

*Scotts Hill campus

Source: Section Q Forms C.2b and F.2b. The Project Analyst used the F.2b forms for radiation oncology/radiation therapy services provided by each applicant.

As shown in the table above, **NHRMC** proposes to provide the most charity care in dollars, the most charity care per ESTV treatment and the highest percentage of charity care as a percentage of net revenue. Thus, regarding projected charity care, the application submitted by **NHRMC** is the more effective alternative.

Projected Medicare and Medicaid

The following table compares access by Medicare and Medicaid patients in the third full fiscal year following project completion for each facility using the following metrics: Medicare and Medicaid procedures as a percent of total gross revenue. Generally, the application proposing to provide a higher percentage of gross revenue to Medicare and/or Medicaid patients is the more effective alternative regarding this comparative factor.

Medicare, PY 3

APPLICANT	NUMBER OF ESTV TREATMENTS	GROSS REVENUE PROJECT YEAR 3	GROSS REVENUE/ESTV TREATMENT	MEDICARE REVENUE PROJECT YEAR 3	MEDICARE AS % OF GROSS REVENUE	# MEDICARE ESTV TREATMENTS
NHRMC*	8,278	\$23,391,345	\$1,731	\$14,331,916	61.3%	5,074
WH	7,076	\$6,944,121	\$540	\$3,819,267	55.0%	3,892

Source: Section Q, Forms C and Forms F.2b in each application. The Project Analyst used the F.2 forms for radiation oncology/radiation therapy provided by each applicant and calculated Medicare revenue as a percent of gross revenue.

*Scotts Hill campus radiation therapy

NHRMC proposes to provide 61.3% of gross revenue of Scotts Hill radiation therapy services to Medicare patients, which represents 5,074 ESTV treatments. **Wilmington Health** proposes to provide 55.0% of gross revenue to Medicare patients, which represents 3,892 ESTV treatments. As shown in the table above, **NHRMC** projects to serve a greater percentage of Medicare patients and provide a greater number of ESTV treatments to Medicare patients in the third full fiscal year following project completion than **Wilmington Health**. Therefore, for this comparative factor, **NHRMC** is the more effective alternative.

Medicaid, PY 3

APPLICANT	NUMBER OF ESTV TREATMENTS	GROSS REVENUE PROJECT YEAR 3	GROSS REVENUE/ESTV TREATMENT	MEDICAID REVENUE PROJECT YEAR 3	MEDICAID AS % OF GROSS REVENUE	# MEDICAID ESTV TREATMENTS
NHRMC*	8,278	\$23,391,345	\$1,731	\$1,254,983	5.4%	447
WH	7,076	\$6,944,121	\$540	\$208,324	3.0%	212

Source: Section Q, Forms C and Forms F.2b in each application. The Project Analyst used the F.2 forms for radiation oncology/radiation therapy provided by each applicant and calculated Medicaid revenue as a percent of gross revenue.

*Scotts Hill campus radiation therapy

Regarding Medicaid, as shown in the table above, **NHRMC** proposes to provide 5.4% of gross revenue to Medicaid patients, which represents 447 procedures. **Wilmington Health** proposes to provide 3.0% of gross revenue to Medicaid patients, which represents 212 procedures. Therefore, **NHRMC** projects to serve a greater percentage of Medicaid patients and provide a greater number of ESTV treatments to Medicaid patients in the third full fiscal year following project completion than **Wilmington Health**. Therefore, for this comparative factor, the application submitted by **NHRMC** is a more effective alternative.

Competition (Access to a New or Alternate Provider)

Currently, **NHRMC** is the only existing and approved radiation oncology provider located in the linear accelerator service area 19. **NHRMC** currently operates a total of four linear accelerators in the service area. **Wilmington Health** does not currently own or operate a linear accelerator in the service area. Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. Therefore, with regard to the introduction of a new provider of radiation oncology services in the service area, the application submitted by **Wilmington Health** is a more effective alternative.

Projected Average Net Revenue per ESTV Treatment

The following table compares projected average net revenue per ESTV treatment in the third full fiscal year following project completion for each facility. The Project Analyst compared the information provided by each applicant for radiation oncology/radiation therapy services in the third project year. Generally, the application proposing the lowest average net revenue per ESTV treatment is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

AVERAGE NET REVENUE PER PATIENT ESTV TREATMENT 3 RD FULL FY			
APPLICANT	TOTAL # OF ESTV TREATMENTS	NET REVENUE	AVERAGE NET REVENUE PER ESTV TREATMENT
NHRMC	8,278	\$5,255,909	\$635
Wilmington Health	7,076	\$3,291,345	\$465

Source: Applications Forms C Utilization and Form F.2b

As shown in the table above, **Wilmington Health** projects the lowest average net revenue per ESTV treatment in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **Wilmington Health** is a more effective alternative.

Projected Average Operating Expense per ESTV Treatment

The following table compares projected average operating expense per ESTV treatment in the third full fiscal year following project completion for each facility. Generally, the application proposing the lowest average operating expense per ESTV treatment is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

AVERAGE OPERATING EXPENSE PER PATIENT ESTV TREATMENT			
3RD FULL FY			
APPLICANT	TOTAL # OF ESTV TREATMENTS	OPERATING EXPENSE	AVERAGE OPERATING EXPENSE PER ESTV TREATMENT
NHRMC	8,278	\$4,076,291	\$492
Wilmington Health	7,076	\$3,241,289	\$458

Source: Applications Forms C Utilization and Form F.2b

As shown in the table above, **Wilmington Health** projects the lowest average operating expense per ESTV treatment in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **Wilmington Health** is a more effective alternative.

Summary

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance:

COMPARATIVE FACTOR	NHRMC	WILMINGTON HEALTH
Conformity with Statutory and Regulatory Review Criteria	Equally Effective	Equally Effective
Scope of Services	Equally Effective	Equally Effective
Historical Utilization	More Effective	Less Effective
Geographic Accessibility (Location within the Service Area)	More Effective	Less Effective
Access by Service Area Residents	Less Effective	More Effective
Access by Charity Care	More Effective	Less Effective
Access by Medicaid	More Effective	Less Effective
Access by Medicare	More Effective	Less Effective
Competition (Access to a New or Alternate Provider)	Less Effective	More Effective
Projected Average Net Revenue per Treatment	Less Effective	More Effective
Projected Average Operating Expense per Treatment	Less Effective	More Effective

Both applications are conforming to all applicable statutory and regulatory review criteria, and thus both applications are approvable standing alone. However, collectively they propose a total of two linear accelerators in linear accelerator service area 19, and the need determination in the 2021 SMFP is for only one linear accelerator. Therefore, only one application for one linear accelerator can be approved.

As shown in the table above, **New Hanover Regional Medical Center** was determined to be a more effective alternative for the following factors:

- Historical Utilization
- Geographic Accessibility
- Access by Charity Care
- Access by Medicaid

- Access by Medicare

As shown in the table above, **Wilmington Health** was determined to be a more effective alternative for the following two factors:

- Access by service area residents
- Competition (access to a new or alternate provider)
- Projected Average Net Revenue per ESTV Treatment
- Projected Average Operating Expense per ESTV Treatment

DECISION

Each application is individually conforming to the need determination in the 2021 SMFP for one additional linear accelerator as well as individually conforming to all statutory and regulatory review criteria. However, G.S. § 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of linear accelerators that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the following application is approved as submitted:

- **Project I.D. #O-12110-21 / Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC / Acquire no more than one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of five linear accelerators (three at NHRMC 16th St., one at Brunswick, and one at Scotts Hill), as part of a new cancer services center**

And the following application is denied:

- **Project ID#O-12120-21/ Wilmington Health, PLLC / Acquire no more than one linear accelerator pursuant to the need determination in the 2021 SMFP for a total of one linear accelerator**

Project ID# #O-12110-21 is approved subject to the following conditions.

1. **Novant Health, Inc., South Atlantic Radiation Oncology, LLC and Novant Health New Hanover Regional Medical Center, LLC (herein after “the certificate holders”) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holders shall acquire no more than one linear accelerator pursuant to the need determination in the 2021 SMFP to be located on the Scotts Hill Hospital campus for a total of no more than five linear accelerators: three on the 16th Street hospital campus, one on the Brunswick hospital campus and one on the Scotts Hill hospital campus.**

- 3. The certificate holders shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 4. The certificate holders shall 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.**
- 5. Progress Reports:**
 - a. Pursuant to G.S. § 131E-189(a), the certificate holders 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 holders shall complete all sections of the Progress Report form.**
 - c. The certificate holders 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. Progress reports shall be due on the first day of every third month. The first progress report shall be due on March 1, 2022. The second progress report shall be due on June 1, 2022 and so forth.**
- 6. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holders 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 holders shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**