

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 13, 2021

Findings Date: September 13, 2021

Project Analyst: Julie M. Faenza

Co-Signer: Fatimah Wilson

Project ID #: G-12090-21

Facility: Novant Health Kernersville Medical Center

FID #: 060620

County: Forsyth

Applicants: Forsyth Memorial Hospital, Inc.

Novant Health, Inc.

Project: Replace an existing linear accelerator

### 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

Forsyth Memorial Hospital, Inc. and Novant Health, Inc. (hereinafter collectively referred to as “Novant” or “the applicant”) propose to replace an existing linear accelerator (LINAC) at Novant Health Kernersville Medical Center (NH Kernersville), a satellite campus of Novant Health Forsyth Medical Center (NH Forsyth).

#### **Need Determination**

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

## **Policies**

There is one policy in the 2021 SMFP which is applicable to this review.

**Policy GEN-4: Energy Efficiency and Sustainability for Health Services Facilities**, 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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 27, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant states there are no proposed renovations to water fixtures and it will utilize construction recycling and lighting control systems that provide energy savings and reduce costs.

## **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 based on the following reasons:

- The applicant does not propose to develop any beds, services, or equipment for which there is a need determination in the 2021 SMFP.
  - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because 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

The applicant proposes to replace an existing LINAC at NH Kernersville, a satellite campus of NH Forsyth.

**Patient Origin**

On page 324, the 2021 SMFP states, “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....” NH Kernersville is in Forsyth County. Table 17C-4 on page 332 of the 2021 SMFP shows Forsyth County is part of Service Area 10, along with Alleghany, Davie, Stokes, Surry, Wilkes, and Yadkin counties. Thus, the service area for this facility is Service Area 10, comprised of Alleghany, Davie, Forsyth, Stokes, Surry, Wilkes, and Yadkin counties. Facilities may also serve residents of counties not included in their service area.

The following table shows current and projected patient origin.

<b>NH Kernersville LINAC – Current (CY 2020) and Projected (CYs 2024-2026) Patient Origin</b>								
	<b>Current</b>		<b>Projected</b>					
	<b>CY 2020</b>		<b>FY 1 – CY 2024</b>		<b>FY 2 – CY 2025</b>		<b>FY 3 – CY 2026</b>	
<b>County</b>	<b># Patients</b>	<b>% of Total</b>	<b># Patients</b>	<b>% of Total</b>	<b># Patients</b>	<b>% of Total</b>	<b># Patients</b>	<b>% of Total</b>
Forsyth	144	52.4%	131	52.4%	154	52.4%	176	52.4%
Guilford	71	25.8%	65	25.8%	76	25.8%	87	25.8%
Davidson	18	6.5%	16	6.5%	19	6.5%	22	6.5%
Rockingham	14	5.1%	13	5.1%	15	5.1%	17	5.1%
Stokes	12	4.4%	11	4.4%	13	4.4%	15	4.4%
Other	16	5.8%	15	5.8%	17	5.8%	20	5.8%
<b>Total</b>	<b>275</b>	<b>100.0%</b>	<b>251</b>	<b>100.0%</b>	<b>294</b>	<b>100.0%</b>	<b>337</b>	<b>100.0%</b>

Source: Section C, pages 38-39

In Section C, page 39, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant projected patient origin based on its historical patient origin.
- The applicant provides the details of how it calculated the number of patients and treatment for projected patient origin.

### **Analysis of Need**

In Section C, pages 42-48, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- **Population Growth in Forsyth County:** the applicant states 52.4 percent of its LINAC patients originate in Forsyth County. The applicant states that, based on data and projections from the North Carolina Office of State Budget and Management (NC OSBM), the population of Forsyth County grew by 3.6 percent between 2016 and 2021 and is projected to grow by another 4.1 percent between 2021 and 2026. The applicant states the population of people age 65 and older in Forsyth County increased by 15.7 percent between 2016 and 2021 and is projected to increase by another 15.1 percent between 2021 and 2026.
- **Population Growth in Extended Service Area:** the applicant defines "Extended Service Area" as Guilford, Davidson, Rockingham, and Stokes counties, and states 41.8 percent of its LINAC patients originate from the Extended Service Area. The applicant states that, based on data and projections from NC OSBM, the population of the Extended Service Area grew by 3.1 percent between 2016 and 2021 and is projected to grow by another 3.6 percent between 2021 and 2026. The applicant states the population of people age 65 and older in the Extended Service Area increased by 18.6 percent between 2016 and 2021 and is projected to increase by another 14.2 percent between 2021 and 2026.
- **Impact of Population Increases in People Age 65 and Older:** the applicant states that while the population age 65 and older is a relatively small percentage of the total population, the population age 65 and older is projected to comprise more than 52 percent of radiation therapy patients at NH Kernersville. The applicant further states that, based on data from the North Carolina Central Cancer Registry, the incidence of cancer increases with age.
- **Increases in Life Expectancy and Cancer Cases/Death Trends:** the applicant states that, based on data from the North Carolina State Center for Health Statistics, the life expectancy of Forsyth County residents has increased across all age and demographic groups compared to 27 years ago. The applicant also cites data from the North Carolina Central Cancer Registry showing that, in Forsyth, Guilford, and Davidson counties, the incidence of most types of cancer are projected to increase and the number of deaths will also increase for most types of cancer. On page 47, the applicant states: *"The increase in the number of cases has a direct relationship to the need for radiation therapy services."*

- Age of the Existing LINAC: the applicant states that due to the age of the existing LINAC, the ability to update both the software and the hardware is limited. The applicant states the age of the LINAC has forced many cases to go to NH Forsyth, where they have the most up-to-date equipment and software, and the applicant has not been able to serve as many patients at NH Kernersville.

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

- The applicant provides data to support its assertions about population increases (both countywide and by age groups), changes in life expectancy, and changes in cancer incidence.
- The applicant uses data and information from reliable sources and provides those sources.

Projected Utilization

On Form C.2a and Tab C in Section Q, the applicant provides historical and projected utilization, as illustrated in the table below.

<b>NH Kernersville LINAC – Historical &amp; Projected Utilization</b>				
	<b>Historical</b>	<b>Projected</b>		
	<b>FFY 2020</b>	<b>FY 1 – CY 2024</b>	<b>FY 2 – CY 2025</b>	<b>FY 3 – CY 2026</b>
# of LINACs	1	1	1	1
# 1.0 ESTV Treatments	3,073	2,912	3,367	3,821
# 0.5 ESTV Treatments	1,165	948	1,160	1,371
Total # ESTV Treatments	4,238	3,860	4,527	5,192
Total # of ESTVs	3,655.5	3,386.0	3,947.0	4,506.5

In the Utilization Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant projected FFY 2021 LINAC utilization by annualizing its October 2020 – March 2021 LINAC utilization data.
- The applicant made the following assumptions:
  - FFY 2022 LINAC utilization would be the same as FFY 2021 utilization.
  - The LINAC would be out of service between October 2022 and June 2023 and would begin offering services again in July 2023.
  - July – December 2023 LINAC utilization would be 50 percent of the FFY 2022 LINAC utilization.
  - CY 2024 LINAC utilization would be the same as FFY 2022 utilization.

- CY 2026 LINAC utilization would equal historical FFY 2018 LINAC utilization. The applicant states utilization began declining after FFY 2018 due to the age limitations of the LINAC and subsequently due to the COVID-19 pandemic.
- CY 2025 LINAC utilization would be equivalent to 150 percent of the CY 2024 LINAC utilization.

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

- The applicant relied on its historical utilization as the starting point for projecting future utilization.
- The applicant excluded time periods the LINAC would be out of service.
- The applicant made reasonable assumptions about how utilization would increase after the replacement LINAC is offering services.

### **Access to Medically Underserved Groups**

In Section C, page 54, the applicant states:

*“Novant Health does not exclude from participation, deny benefits to, or otherwise discriminate against patients, students, or visitors on the basis of race; color; religion; national origin; culture; language; physical or mental disability; age; sex, including pregnancy, childbirth or related medical conditions; marital status; sexual orientation; gender identity or expression; socioeconomic status; source of payment; or any other protected status in admission to, participation in, or receipt of the services and benefits of any of its programs and activities, whether carried out by Novant Health directly or through a contractor or other entity with whom Novant Health arranges to carry out its programs and activities.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>% of Total Patients</b>
Low income persons	10.2%
Racial and ethnic minorities	27.5%
Women	64.3%
Persons with disabilities	6.8%
Persons 65 and older	52.7%
Medicare beneficiaries	52.7%
Medicaid recipients	3.6%

**Source:** Section C, page 55

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 a statement saying that it will provide access to all underserved groups.
- The applicant provides supporting documentation of the access it provides and programs to assist the underserved in Exhibit C.6.

### **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.

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

NA

The applicant does not propose to reduce 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.

CA

The applicant proposes to replace an existing LINAC at NH Kernersville, a satellite campus of NH Forsyth.

In Section E, page 67, the applicant states there is no alternative method available to meet the need for the proposed project. The applicant states:

*“..., the existing linear accelerator at NHKMC was a used unit when it was relocated from NHFMC to NHKMC in 2011. Since beginning operation at NHKMC in 2012, the linear accelerator has reached the end of its useful life. Replacing the existing linear accelerator is the only alternative available to maintain the linear accelerator unit inventory in Linear Accelerator Service Area 10 and to continue providing radiation therapy at NHKMC and within the Kernersville community.”*

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

- The applicant provides reasonable and adequately supported 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. Therefore, the application can be approved.

### **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. Therefore, the application is approved subject to the following conditions:

- 1. Forsyth Memorial Hospital, Inc. and Novant Health, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire no more than one replacement linear accelerator to be located at Novant Health Kernersville Medical Center.**
- 3. Upon completion of the project, Novant Health Kernersville Medical Center shall have no more than one linear accelerator and Novant Health Forsyth Medical Center shall have a combined total of no more than five linear accelerators.**
- 4. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**





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 applicant provides a quote for the replacement LINAC which shows a quotation total matching the total from Form F.1a.
- In Exhibit F.1, the applicant provides a renovation cost estimate signed by an architect which includes a cost breakdown and which matches the construction cost listed on Form F.1a.

In Section F, page 70, the applicant states there will be no working capital costs because radiation therapy is an existing service at NH Kernersville.

### **Availability of Funds**

In Section F, page 68, the applicant states the capital cost will be funded through the accumulated reserves of Novant Health, Inc.

Exhibit F.2 contains a letter dated June 10, 2021, signed by the Senior Vice President of Operational Finance & Revenue Cycle, which commits to funding the capital cost from the accumulated reserves of Novant Health, Inc. Exhibit F.2 also contains the Novant Health, Inc. and Affiliates Consolidated Financial Statements and Supplemental Information for the years ending December 31, 2020 and 2019. The Consolidated Financial Statements show that as of December 30, 2020, Novant Health, Inc. had adequate cash and assets to fund the proposed project.

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

- The applicant provides documentation of the commitment to use the necessary funding toward development of the proposed project.
- The applicant provides documentation of the availability of sufficient financial resources to fund the proposed capital cost.

### **Financial Feasibility**

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

<b>NH Kernersville LINAC Projected Revenue &amp; Expenses – FYs 1-3 (CYs 2024-2026)</b>			
	<b>FY 1 (CY 2024)</b>	<b>FY 2 (CY 2025)</b>	<b>FY 3 (CY 2026)</b>
# of ESTVs	3,386.0	3,947.0	4,506.5
Gross Revenue	\$5,274,179	\$6,371,113	\$7,526,217
Net Revenue	\$1,710,944	\$2,066,789	\$2,441,505
Average Net Revenue per ESTV	\$505	\$524	\$542
Operating Costs	\$1,449,343	\$1,603,113	\$1,782,571
Average Operating Costs per ESTV	\$428	\$406	\$396
<b>Net Profit/(Loss)</b>	<b>\$261,600</b>	<b>\$463,676</b>	<b>\$658,933</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in the Form F.2b Assumptions and Calculations subsection of Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant accounts for projected operating expenses and clearly explains the revenue projections.
- Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to replace an existing LINAC at NH Kernersville, a satellite campus of NH Forsyth.

On page 324, the 2021 SMFP states, “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....” NH Kernersville is in Forsyth County. Table 17C-4 on page 332 of the 2021 SMFP shows Forsyth County is part of Service Area 10, along with Alleghany, Davie, Stokes, Surry, Wilkes, and Yadkin counties. Thus, the service area for this facility is Service Area 10, comprised of Alleghany, Davie, Forsyth, Stokes, Surry, Wilkes, and Yadkin counties. Facilities may also serve residents of counties not included in their service area.

There are 10 LINACs in Linear Accelerator Service Area 10. The following table identifies the provider, number of LINACs, and average utilization of each LINAC during FFY 2019.

<b>Linear Accelerator Service Area 10 Utilization</b>				
<b>Facility</b>	<b>County</b>	<b># of LINACs</b>	<b>Total # of Procedures</b>	<b>Average # of Procedures/Unit</b>
North Carolina Baptist Hospital	Forsyth	4	25,469	6,367
Novant Health Forsyth Medical Center	Forsyth	5*	20,291	4,058
Hugh Chatham Memorial Hospital	Surry	1	5,034	5,034
<b>Total</b>		<b>10</b>	<b>50,794</b>	<b>5,079</b>

Source: Table 17C-1, page 327, 2021 SMFP

\*Includes the LINAC at NH Kernersville

In Section G, page 78, the applicant explains why the proposal would not result in the unnecessary duplication of existing or approved LINAC services in LINAC Service Area 10. The applicant states that, based on the performance standard in the Criteria and Standards for Radiation Therapy Equipment promulgated in 10A NCAC 14C .1900 (which is not applicable to this review) and each provider’s 2021 License Renewal Application, each of the three LINAC providers is performing enough ESTV procedures per unit to justify all of the units they currently have.

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

- The applicant uses current and publicly available information from each facility with LINACs in the service area and utilizes a performance standard to support its belief that the replacement LINAC is not unnecessarily duplicative.
- The applicant does not propose to increase the number of LINACs in LINAC Service Area 10.

**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.

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

C

The applicant proposes to replace an existing LINAC at NH Kernersville, a satellite campus of NH Forsyth.

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

<b>NH Kernersville LINAC FTE Staffing – Current and Projected</b>				
	<b>Current</b>	<b>Projected</b>		
	<b>5/15/2021</b>	<b>FY 1 – CY 2024</b>	<b>FY 2 – CY 2025</b>	<b>FY 3 – CY 2026</b>
Patient Services Coordinator IV	0.94	0.94	1.08	1.24
Registered Nurse OP	0.81	0.81	0.93	1.07
RN Team Leader – OP	0.04	0.04	0.05	0.05
Radiation Therapist	2.00	2.00	2.30	2.65
Supervisor, Radiation Therapy	0.66	0.66	0.76	0.87
Certified Medical Assistant/RMA	0.02	0.02	0.02	0.03
Clinical Services Navigator	0.81	0.81	0.93	1.07
<b>Total</b>	<b>5.28</b>	<b>5.28</b>	<b>6.07</b>	<b>6.98</b>

The assumptions and methodology used to project staffing are provided on Form H and in the Form H Staffing Assumptions subsection of Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, page 80, the applicant describes its existing training and continuing education programs and states its existing radiation therapy staff will be able to perform LINAC procedures.

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

- The applicant currently has sufficient staff to operate the replacement LINAC once it is operational.
- The applicant provides supporting documentation of its existing training and continuing education programs in Exhibit H.3.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to replace an existing LINAC at NH Kernersville, a satellite campus of NH Forsyth.

### **Ancillary and Support Services**

In Section I, page 83, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 84-85, the applicant explains how each ancillary and support service is made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because it is already providing all of the necessary ancillary and support services necessary for the proposed replacement LINAC

### **Coordination**

In Section I, page 85, 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 because the applicant is already coordinating with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

C

The applicant proposes to replace an existing LINAC at NH Kernersville, a satellite campus of NH Forsyth.

In Section K, page 88, the applicant states that the project involves renovating 1,135 square feet of existing space. Line drawings are provided in Exhibit C.1.

In Section K, page 89, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal. The applicant states both the project architect and construction company have reviewed the renovations proposed and estimated the necessary renovation costs.

In Section K, page 89, 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. The applicant states the project architect has determined based on expertise that the proposed renovations are necessary to provide LINAC services and to be in compliance with federal, local, and state codes.

On page 89, 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

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

In Section L, page 92, the applicant provides the historical payor mix during CY 2020 at NH Kernersville, as shown in the table below.



<b>NH Kernersville Historical Payor Mix – CY 2020</b>	
<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	2.4%
Charity Care	9.6%
Medicare*	34.4%
Medicaid*	10.3%
Insurance*	38.0%
Other (Governmental)	5.3%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

In Section L, page 93, the applicant provides the following comparison.

	<b>% of Total Patients Served by NH Kernersville During CY 2020</b>	<b>% of the Population of the Service Area</b>
Female	64.3%	52.7%
Male	35.7%	47.3%
Unknown	0.0%	0.0%
64 and Younger	69.0%	83.6%
65 and Older	31.0%	16.4%
American Indian	0.2%	0.9%
Asian	0.6%	2.6%
Black or African-American	21.5%	27.5%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	72.5%	66.6%
Other Race	4.7%	2.3%
Declined / Unavailable	0.4%	0.0%

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 94, the applicant states it has no such obligation.

In Section L, page 94, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 95, 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.

<b>NH Kernersville Projected Payor Mix – CY 2026</b>		
<b>Payor Category</b>	<b>Percent of Total Patients Served</b>	
	<b>Entire Facility</b>	<b>LINAC</b>
Self-Pay	2.4%	0.0%
Charity Care	9.6%	1.1%
Medicare*	34.4%	52.7%
Medicaid*	10.3%	3.6%
Insurance*	38.0%	37.1%
Other (Governmental)	5.3%	5.5%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.4 percent of total services will be provided to self-pay patients, 9.6 percent of total services and 1.1 percent of LINAC services will be provided to charity care patients, 34.4 percent of total services and 52.7 percent of LINAC services will be

provided to Medicare patients, and 10.3 percent of total services and 3.6 percent of LINAC services will be provided to Medicaid patients.

On page 95, 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 because it is based on the applicant's historical payor mix from CY 2020.

**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.

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

C

In Section L, page 96, the applicant adequately describes the range of means by which patients will have access to the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to replace an existing LINAC at NH Kernersville, a satellite campus of NH Forsyth.

In Section M, page 98, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting

documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes because the applicant currently provides access to the facility for training purposes for health professional training programs in the area.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

### C

The applicant proposes to replace an existing LINAC at NH Kernersville, a satellite campus of NH Forsyth.

On page 324, the 2021 SMFP states, “*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....*” NH Kernersville is in Forsyth County. Table 17C-4 on page 332 of the 2021 SMFP shows Forsyth County is part of Service Area 10, along with Alleghany, Davie, Stokes, Surry, Wilkes, and Yadkin counties. Thus, the service area for this facility is Service Area 10, comprised of Alleghany, Davie, Forsyth, Stokes, Surry, Wilkes, and Yadkin counties. Facilities may also serve residents of counties not included in their service area.

There are 10 LINACs in Linear Accelerator Service Area 10. The following table identifies the provider, number of LINACs, and average utilization of each LINAC during FFY 2019.

<b>Linear Accelerator Service Area 10 Utilization</b>				
Facility	County	# of LINACs	Total # of Procedures	Average # of Procedures/Unit
North Carolina Baptist Hospital	Forsyth	4	25,469	6,367
Novant Health Forsyth Medical Center	Forsyth	5*	20,291	4,058
Hugh Chatham Memorial Hospital	Surry	1	5,034	5,034
<b>Total</b>		<b>10</b>	<b>50,794</b>	<b>5,079</b>

Source: Table 17C-1, page 327, 2021 SMFP

\*Includes the LINAC at NH Kernersville

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 100, the applicant states:

*“NHKMC expects the replacement of the existing linear accelerator to have a positive effect on competition in the service area because it will maintain the current capacity of linear accelerator services at NHKMC and thus the service area.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 100, the applicant states:

*“Novant Health is delivering value and quality in outcomes through its Population Health Management programs. This approach encourages wellness and preventive care and managing existing conditions to slow or reverse the progression of disease, all while lowering the overall cost of care. The key to the Population Health Management approach is coordinated care, with physicians, nurses, pharmacists, dietitians, social workers referral coordinators, and others working together to give patients the customized care they want and need. Ultimately this type of care provides value-safe, more affordable care with better outcomes-and is centered on our patients’ unique needs. With a focus on keeping people healthy, some traditional fee-for service payments will be replaced by newly negotiated agreements focusing on value, where quality and outcomes factor into how much providers and facilities are paid.*

*Novant Health is collaborating with payors and partners to identify payment models that match Novant Health’s value-based care delivery. Getting the right care in the right setting at the right price is the future of healthcare. It is what makes healthcare affordable and more sustainable. It is Novant Health’s new approach to delivering remarkable healthcare, so that people can get better and stay healthy.”*

On pages 101-102, the applicant describes how it has implemented its value-based care delivery through revenue cycle process improvements, value-based care programs, and other ways to save money that would not impact patients.

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

Regarding the impact of the proposal on quality, in Section N, page 103, the applicant states:

*“The Novant Health Utilization Review Plan is used at NHKMC. Utilization Review consists of interdisciplinary professionals and supporting team members providing a*

*wide range of functions for patients and the organization. .... The UR team strives to ensure the achievement of quality and the most effective level(s) of care. ...*

*The Novant Health Risk Management Plan is used at NHKMC. The Risk Management program covers Novant Health entities and team members, including medical staff, licensed independent practitioners, volunteers, students, and contracted workers. Risk Management identifies and presents risk exposures and assures proactive risk assessments are conducted. .... Risk Management also serves as a resource to physicians, staff and executive leadership on current risk and safety issues.*

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

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 104, the applicant states:

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

*Services are available to all persons including: (a) low-income persons, (b) racial and ethnic minorities, (c) women, (d) [disabled] persons, (e) elderly, and (f) other underserved persons, including the medically indigent referred by their attending physicians. Novant Health facilities and programs do not discriminate against the listed persons, or other medically underserved persons, regardless of their ability to pay.*

...

*NHKMC conforms to all requirements of the Americans with Disabilities Act, so that access to patients and their families are available for wheelchair patients and other patients with limited mobility. ...., NHKMC meets all North Carolina [accessibility] requirements and all federal ADA requirements...”*

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

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

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

- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and & the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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.

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

### C

The applicant proposes to replace an existing LINAC at NH Kernersville, a satellite campus of NH Forsyth.

On Form O in Section Q, the applicant identifies the hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 16 hospitals located in North Carolina.

In Section O, page 109, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy at any of these hospitals. 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, incidents related to quality of care occurred in one of these hospitals. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 16 hospitals, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to replace an existing LINAC. The Criteria and Standards for Radiation Therapy Equipment, which are promulgated in 10A NCAC 14C .1900, are not applicable to this review because they do not apply to proposals to replace existing LINACs.