

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 26, 2023

Findings Date: January 26, 2023

Project Analyst: Julie M. Faenza

Co-Signer: Micheala Mitchell

Project ID #: F-12257-22

Facility: Atrium Health Pineville

FID #: 110878

County: Mecklenburg

Applicant: The Charlotte-Mecklenburg Hospital Authority

Project: Acquire no more than one additional linear accelerator pursuant to the need determination in the 2022 SMFP for a total of no more than two linear accelerators

### 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

The Charlotte-Mecklenburg Hospital Authority (hereinafter referred to as “CMHA,” “Atrium,” or “the applicant) proposes to add a second fixed linear accelerator (LINAC) on the campus of Atrium Health Pineville (AH Pineville).

#### **Need Determination**

Chapter 17 of the 2022 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional LINAC equipment in North Carolina by service area. Application of the need methodology in the 2022 SMFP showed a need for one additional LINAC in Service Area 7. Service Area 7 is comprised of Anson, Mecklenburg, and Union counties.

The applicant does not propose to acquire more LINACs than are determined to be needed in Service Area 7 and proposes to develop the LINAC in Mecklenburg County. Therefore, the application is consistent with the need determination.

### **Policies**

There are two policies in the 2022 SMFP applicable to this review: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

*Policy GEN-3: Basic Principles*, on page 30 of the 2022 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.”*

In Section B, pages 27-30, the applicant explains why it believes its proposal is consistent with Policy GEN-3. On page 30, the applicant states:

*“The increased number of patients served, including the medically underserved, will have access to the safe, high quality linear accelerator services provided at Atrium Health Pineville, and the proposed project will be developed in such a way as to maximize healthcare value.”*

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on pages 30-31 of the 2022 SMFP, states:

*“Any person proposing a capital expenditure greater than \$4 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 capital expenditure of the project is greater than \$5 million. In Section B, pages 30-31, the applicant describes its plan to assure improved energy efficiency and water conservation.

### **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:

- The applicant does not propose to develop more LINACs than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of LINAC services in Mecklenburg County.
  - The applicant adequately documents how the project will promote equitable access to LINAC services in Mecklenburg County.
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- 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 acquire and add an additional LINAC on the campus of AH Pineville.

**Patient Origin**

In Chapter 17, page 321, the 2022 SMFP defines a LINAC’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 329 shows Service Area 7 is comprised of Anson, Mecklenburg, and Union counties. Thus, the service area for this project consists of those three counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

<b>Current &amp; Projected Patient Origin – AH Pineville LINAC</b>								
	<b>Current – CY 2021</b>		<b>FY 1 – CY 2025</b>		<b>FY 2 – CY 2026</b>		<b>FY 3 – CY 2027</b>	
	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Mecklenburg	668	56.8%	697	56.8%	721	56.8%	746	56.8%
York (SC)	234	19.9%	244	19.9%	253	19.9%	261	19.9%
Lancaster (SC)	164	13.9%	171	13.9%	177	13.9%	183	13.9%
Union	83	7.1%	87	7.1%	90	7.1%	93	7.1%
Other*	28	2.4%	29	2.4%	30	2.4%	31	2.4%
<b>Total</b>	<b>1,177</b>	<b>100.0%</b>	<b>1,228</b>	<b>100.0%</b>	<b>1,270</b>	<b>100.0%</b>	<b>1,314</b>	<b>100.0%</b>

Source: Section C, pages 34 and 36

\*Other: Other counties in North Carolina as well as other states

In Section C, page 36, the applicant provides the assumptions and methodology used to project its patient origin. The applicant projects no changes in patient origin because it is an expansion to existing services AH Pineville already provides. The applicant’s assumptions and methodology used to project patient origin are reasonable and adequately supported because they are based on the current patient origin for the same services already being offered at the same location.

**Analysis of Need**

In Section C, pages 39-45, the applicant explains the reasons why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below.

- There is a need determination in the 2022 SMFP for one LINAC in Service Area 7 because the population of the service area is greater than 120,000 persons per LINAC and the

existing LINACs are performing a total combined average of 6,932 Equivalent Simple Treatment Visits (ESTVs) per LINAC. (page 39)

- AH Pineville's LINAC utilization grew at a compound annual growth rate (CAGR) of 6.2% between FFY 2019 and FFY 2021. AH Pineville's LINAC also has the highest utilization of any LINAC in the state. (pages 40-42)
- The applicant is recruiting more medical and surgical oncology staff at AH Pineville and expects that to result in more demand for LINAC services. (page 42)
- According to the NC Office of State Budget and Management (NC OSBM), the population of Service Area 7 grew at a CAGR of 1.8% between 2012 and 2022. One of the counties in Service Area 7, Mecklenburg County, is one of the fastest growing counties with one of the largest populations in North Carolina. Further, according to NC OSBM, the population aged 65 and older in Service Area 7 will increase by a total of 24.5% between 2022 and 2027. The applicant states people aged 65 and older are eleven times more likely to develop cancer than younger patients. (pages 43-44)
- The North Carolina Central Cancer Registry lists cancer as the leading cause of death in Service Area 7 and cancer comprises approximately 21% of total deaths in Service Area 7. According to the American Cancer Society, two-thirds of cancer patients receive radiation therapy, and due to a number of significant side effects, the applicant states patients should be able to access care at the provider they choose and one that is close to home because of the effect of those side effects. (pages 44-45)

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

- There is a need determination in the 2022 SMFP for one additional linear accelerator in Service Area 7.
- The growth in utilization at AH Pineville is higher than any other utilization growth in Service Area 7.
- Publicly available data shows AH Pineville has the highest utilization of any LINAC in the state of North Carolina.

### *Projected Utilization*

On Forms C.2a and C.2b in Section Q, the applicant provides historical and projected utilization, as illustrated in the following table.

<b>AH Pineville LINAC – Historical and Projected Utilization</b>				
	<b>Historical CY 2021</b>	<b>FY 1 CY 2025</b>	<b>FY 2 CY 2026</b>	<b>FY 3 CY 2027</b>
# of Units	1	2	2	2
# of ESTV Treatments*	12,122	12,648	13,084	13,536

\*ESTV = Equivalent Simple Treatment Visits

In the Form C 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’s LINAC utilization increased at AH Pineville by a 6.9% CAGR between CY 2019 and CY 2021 and increased by 5.1% between CY 2020 and CY 2021.
- The applicant assumes that, due to capacity constraints from operating at nearly twice the recommended volume, there will be no increase in utilization at AH Pineville between now and October 2024, when the second LINAC is projected to be operational.
- The applicant then projects utilization growth at an annual rate of 3.4%, or half of the CY 2019 to CY 2021 CAGR.

The applicant’s assumptions and methodology are summarized in the table below.

<b>AH Pineville LINAC – Historical and Projected Utilization</b>							
	<b>Historical</b>	<b>Interim</b>			<b>Projected</b>		
	<b>CY 2021</b>	<b>CY 2022</b>	<b>CY 2023</b>	<b>CY 2024*</b>	<b>FY 1 – CY 2025</b>	<b>FY 2 – CY 2026</b>	<b>FY 3 – CY 2027</b>
# of Units	1	1	1	2*	2	2	2
# of ESTV Treatments	12,122	12,122	12,122	12,227	12,648	13,084	13,536
% Growth – Utilization		0.0%	0.0%	3.4%*	3.4%	3.4%	3.4%

\*CY 2024 will remain the same as previous years until October 1, 2024, when the second LINAC is projected to be operational and utilization growth is projected to begin.

Atrium Health System – Service Area 7

Pursuant to 10A NCAC 14C .1903(e), an applicant proposing to add a LINAC must project that all LINACs in the service area owned or operated by the applicant or a related entity will perform at least 6,750 ESTVs per LINAC in the third full fiscal year following project completion.

In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all Atrium LINACs in Service Area 7, which are summarized below.

- The applicant calculated ESTVs per LINAC for each facility where it has LINACs and calculated growth rates, as shown in the table below.

Atrium Health System Historical LINAC Utilization – Service Area 7						
Facility	# of LINACs	CY19 ESTVs	CY20 ESTVs	CY21 ESTVs	CY19-21 CAGR	CY20-21 Growth
AH Pineville	1	10,608	11,529	12,122	6.9%	5.1%
AH University City	1	8,605	7,891	8,046	-3.3%	2.0%
AH Union	1	8,473	7,878	7,551	-5.6%	-4.2%
Carolinas Medical Center	3	18,363	18,075	18,474	0.3%	2.2%

- For Atrium Health University City (AH University City), the applicant projected growth at an annual rate of 1.8%, equivalent to NC OSBM’s projected CAGR for Mecklenburg County’s population growth between CY 2022 and CY 2027. The applicant states that despite having a negative CAGR for CY 2019 to CY 2021, growth increased from CY 2020 to CY 2021.
- For Atrium Health Union (AH Union), the applicant projected no growth in utilization. The applicant states that declines in utilization at AH Union’s LINAC are due to the pandemic and that the declines have not reversed like they have in other locations. The applicant states that it projects utilization will stabilize due to initiatives such as the opening of a branch of Levine Cancer Institute on AH Union West’s campus (those patients will be referred to AH Union for LINAC services).
- For Carolinas Medical Center (CMC), the applicant projected growth at an annual rate of 1.8%, equivalent to NC OSBM’s projected CAGR for Mecklenburg County’s population growth between CY 2022 and CY 2027. The applicant states that while there was a decline in LINAC utilization at CMC during CY 2020, there was a rebound during CY 2021, with growth higher than the 1.8% projected population growth rate.

The applicant’s assumptions and methodology are summarized in the table below.

Atrium Health System LINAC Utilization – Service Area 7									
Facility	ESTVs							# LINACs	ESTVs /LINAC
	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	CY 2027		
AH Pineville (0.0%/3.4%)	12,222	12,222	12,222	12,227	12,648	13,084	13,536	2	6,768
AH University City (1.8%)	8,046	8,189	8,334	8,481	8,632	8,785	8,940	1	8,940
AH Union (0.0%)	7,551	7,551	7,551	7,551	7,551	7,551	7,551	1	7,551
Carolinas Medical Center (1.8%)	18,474	18,801	19,134	19,473	19,818	20,172	20,529	3	6,843
<b>Total</b>	<b>46,293</b>	<b>46,763</b>	<b>47,241</b>	<b>47,732</b>	<b>48,649</b>	<b>49,592</b>	<b>50,556</b>	<b>7</b>	<b>7,222</b>

As shown in the table above, each individual LINAC as well as the average utilization across all LINACs owned and operated by Atrium in Service Area 7 are projected to exceed 6,750 ESTVs per LINAC during the third full fiscal year following project completion. This meets the performance standard required by 10A NCAC 14C .1903(e).

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

- The applicant relies on data from its own operating experience and other reliable sources for its assumptions.

- The applicant relies on historical linear accelerator utilization at AH Pineville to project future utilization.
- The applicant provides reasonable explanations for the utilization growth rates it used for each facility and provides support for the utilization growth rates chosen.

**Access to Medically Underserved Groups**

In Section C, page 52, the applicant states:

*“Atrium Health Pineville provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. .... As noted in CMHA’s Non-Discrimination Policy Statement, “[n]o individual shall be subject to discrimination or denied the benefits of the services, programs, or activities of the Carolinas HealthCare System<sup>12</sup> on the basis of race, color, religion, national origin, sex, age, disability or source of payment.” CMHA will continue to serve this population as dictated by the mission of CMHA, which is the foundation for every action taken. The mission is simple, but unique: To improve health, elevate hope, and advance healing – for all. This includes the medically underserved.”*

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

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Racial and ethnic minorities	27.6%
Women	57.6%
Persons 65 and older	29.1%
Medicare beneficiaries	33.0%
Medicaid recipients	13.0%

**Source:** Section C, page 53

On page 53, the applicant states it does not maintain data on the number of low-income or disabled people it serves but that neither low-income nor disabled people are denied access to services.

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 it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for LINAC services.
- The applicant provides documentation of its existing policies regarding non-discrimination in Exhibit B.20-4 and its financial policies in Exhibit L.4-1.



## **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 acquire and add an additional LINAC on the campus of AH Pineville.

In Section E, page 64, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – The applicant states that maintaining the status quo would force AH Pineville to operate extended hours, divert patients to other facilities, and continue to experience unsustainable utilization, particularly with the risk of equipment failure, and with no options for future growth; therefore, this was not an effective alternative.
- Develop the LINAC at a Different Facility – The applicant states developing the LINAC at a different facility would not meet the overwhelming demand for LINAC services at AH Pineville, and would not be as cost-effective, because the location at AH Pineville includes enough space for an additional LINAC; therefore, this was not an effective alternative.

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. 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 the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. The Charlotte-Mecklenburg Hospital Authority (herein after “the 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 fixed linear accelerator, pursuant to the need determination in the 2022 SMFP, to be located in the Pineville Medical Plaza II building on the campus of Atrium Health Pineville, for a total of no more than two fixed linear accelerators.**
- 3. The certificate holder shall not acquire as part of this project any equipment that is not included in the project’s proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 4. The certificate holder 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 holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. The first progress report shall be due on July 1, 2023.**

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 holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. **Payor mix for the services authorized in this certificate of need.**
    - b. **Utilization of the services authorized in this certificate of need.**
    - c. **Revenues and operating costs for the services authorized in this certificate of need.**
    - d. **Average gross revenue per unit of service.**
    - e. **Average net revenue per unit of service.**
    - f. **Average operating cost per unit of service.**
  7. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire and add an additional LINAC on the campus of AH Pineville.

**Capital and Working Capital Costs**

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

Construction/Renovation Contracts	\$5,055,000
Architect/Engineering/CON/Legal Fees	\$352,000
Medical Equipment	\$4,843,000
Non-Medical Equipment/Furniture	\$90,000
Other (IS, Security, Internal Allocation)	\$1,514,000
<b>Total</b>	<b>\$11,854,000</b>

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1a in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides assumptions about costs included in the calculation of each line item in the projected capital cost.

- The applicant states much of the projections are based on the applicant's history or the project architect's history in developing similar projects.
- In Exhibit F.1, the applicant provides a registered architect's certification dated June 15, 2022 stating the construction costs listed (which match those listed in Form F.1a) are accurate.
- The applicant provides a quote for the proposed LINAC in Exhibit C.1-2.

In Section F, page 68, the applicant states that there are no projected start-up expenses or initial operating expenses because the project does not involve a new service. This information is reasonable and adequately supported because AH Pineville is an existing and licensed facility currently offering the existing services and will continue to offer the existing services during and after development of the proposed project.

### **Availability of Funds**

In Section F, pages 66-67, the applicant states the entire projected capital expenditure of \$11,854,000 will be funded with CMHA's accumulated reserves.

In Exhibit F.2-1, the applicant provides a letter dated August 15, 2022 from the Executive Vice President and Chief Financial Officer for CMHA, stating that CMHA has sufficient accumulated reserves to fund the projected capital cost and committing to providing that funding to develop the proposed project.

Exhibit F.2-2 contains a copy of Atrium's Combined Financial Statements and Other Financial Information for the year ending December 31, 2021. According to the Combined Financial Statements, as of December 31, 2021, Atrium had adequate cash and assets to fund all the capital needs of 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 a letter from the appropriate Atrium official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

### **Financial Feasibility**

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

<b>Revenues and Operating Expenses – AH Pineville LINAC Services</b>			
	<b>FY 1 (CY 2025)</b>	<b>FY 2 (CY 2026)</b>	<b>FY 3 (CY 2027)</b>
Total ESTVs	12,648	13,084	13,536
Total Gross Revenues (Charges)	\$63,114,190	\$67,249,793	\$71,656,384
Total Net Revenue	\$14,464,241	\$15,412,021	\$16,421,905
Total Net Revenue per ESTV	\$1,144	\$1,178	\$1,213
Total Operating Expenses (Costs)	\$7,546,138	\$7,773,930	\$8,386,747
Total Operating Expenses per ESTV	\$597	\$594	\$620
<b>Net Profit/(Loss)</b>	<b>\$6,918,103</b>	<b>\$7,638,091</b>	<b>\$8,035,157</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.3b 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 clearly details the sources of data used to project revenues and expenses.
- The applicant bases projections on its own historical experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 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 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

The applicant proposes to acquire and add an additional LINAC on the campus of AH Pineville.

In Chapter 17, page 321, the 2022 SMFP defines a LINAC’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 329 shows Service Area 7 is comprised of Anson, Mecklenburg, and Union counties. Thus, the service area for this project consists of those three counties. Facilities may also serve residents of counties not included in their service area.

There are a total of 11 LINACs in seven different facilities in Service Area 7. Information about each of the facilities and utilization of the LINACs in Service Area 7 during FFY 2020 is provided in the table below.

Service Area 7 LINACs				
Facility	County	# of LINACs	# of Procedures /ESTVs	Average # of Procedures /ESTVs per LINAC
Atrium Health Pineville	Mecklenburg	1	11,170	11,170
Atrium Health Union	Union	1	7,811	7,811
Atrium Health University City	Mecklenburg	1	8,166	8,166
Carolinas Medical Center	Mecklenburg	3	19,170	6,390
Matthews Radiation Oncology Center	Mecklenburg	2	10,249	5,124
Novant Health Huntersville Medical Center	Mecklenburg	1	8,227	8,227
Novant Health Presbyterian Medical Center	Mecklenburg	2	11,457	5,729
<b>Total</b>		<b>11</b>	<b>76,250</b>	<b>6,932</b>

Source: Table 17C-1, 2022 SMFP

In Section G, page 76, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Service Area 7. The applicant states:

*“The 2022 SMFP includes a need determination for an additional linear accelerator in Service Area 7. ..., CMHA is the only system in Service Area 7 with any volume in excess of the per unit planning threshold. To meet the identified need, CMHA is proposing to develop an additional linear accelerator at Atrium Health Pineville. ..., Atrium Health Pineville operates the busiest linear accelerator in North Carolina by a wide margin. Further, Atrium Health Pineville’s existing linear accelerator has operated for many years well above the threshold of 6,750 ESTVs defined in the special rules for linear accelerators, indicating a consistent need for additional capacity at Atrium Health Pineville. Finally, volume has increased over the last few years despite significant capacity constraints; demand is expected to continue growing, absent capacity constraints.”*

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:

- There is a need determination in the 2022 SMFP for the proposed linear accelerator in Service Area 7.
- The applicant adequately demonstrates that the proposed linear accelerator is needed in addition to the existing or approved linear accelerators in Service Area 7.

**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 acquire and add an additional LINAC on the campus of AH Pineville.

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

<b>AH Pineville LINAC – Current &amp; Projected FTEs</b>		
	<b>Current (12/31/2021)</b>	<b>Projected FY 3 (CY 2027)</b>
Registered Nurses	2.0	3.0
Care Coordinator/Scheduler	1.0	1.5
Advance Authorization Specialist	1.0	1.0
Clerical Team Lead	1.0	1.0
Radiation Therapist	4.6	7.0
Physicist	1.0	3.0
Dosimetry	0.0	2.0
Chief Radiation Therapist	1.0	1.0
Admin. Director	0.5	0.5
<b>Total</b>	<b>12.1</b>	<b>20.0</b>

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 applicant are budgeted in Form F.3b. In Section H, pages 78-80, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.
- The applicant accounts for projected salaries and other costs of employment for FTEs in its projected operating expenses found on Form F.3b in Section Q.

### **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.

- (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 acquire and add an additional LINAC on the campus of AH Pineville.

### **Ancillary and Support Services**

In Section I, page 81, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 81-82, 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 based on the following:

- The applicant is currently providing the necessary ancillary and support services at the same facility where it proposes to develop the additional LINAC.
- In Exhibit I.1, the applicant provides a letter from an administrator at AH Pineville, attesting to the existence of the necessary ancillary and support services and committing to continue to provide the necessary ancillary and support services for the proposed project.



## **Coordination**

In Section I, page 82, the applicant describes AH Pineville's existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 1.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- AH Pineville is an existing facility and thus has established many relationships with area healthcare providers.
- The applicant provides letters of support from local physicians and healthcare providers documenting their support for AH Pineville and the proposed project.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 acquire and add an additional LINAC on the campus of AH Pineville.

In Section K, page 85, the applicant states that the project involves renovating 1,850 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

In Section K, pages 85-86, 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 plans to develop the LINAC in existing space which requires only renovation instead of in newly constructed space.
- The applicant plans to develop the LINAC adjacent to the existing LINAC at the same location, which the applicant states will provide operational efficiencies.

In Section K, page 86, 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 describes its “conservative fiscal management” that has allowed it to pay for projects such as the project proposed in this application.
- The applicant states that, because of its “conservative fiscal management,” it does not plan to increase costs or charges to pay for the proposed project.

In Section B, pages 30-31, 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 89, the applicant provides the historical payor mix during the last full fiscal year for all services at AH Pineville, as shown in the table below.

<b>AH Pineville Historical Payor Mix – CY 2021</b>	
<b>Payor Category</b>	<b>% of Total Patients Served</b>
Self-Pay	10.2%
Medicare*	33.0%
Medicaid*	13.0%
Insurance*	40.8%
Other**	3.0%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

\*\*Includes Workers Compensation and TRICARE.

**Source:** Atrium Health internal data

**Note:** The applicant states charity care is provided to patients in any payor category and that its internal data does not include charity care as a payor source.

In Section L, page 90, the applicant provides the following comparison.

AH Pineville	% of Total Patients Served During CY 2021	% of Population of Mecklenburg County	% of Population of Union County	% of Population of Anson County
Female	57.6%	51.7%	50.4%	49.2%
Male	42.4%	48.3%	49.6%	50.8%
Unknown	0.0%	0.0%	0.0%	0.0%
64 and Younger	70.9%	88.1%	86.8%	80.3%
65 and Older	29.1%	11.9%	13.2%	19.7%
American Indian	0.6%	0.9%	0.7%	1.0%
Asian	1.8%	6.5%	4.3%	1.6%
Black or African-American	24.3%	33.3%	12.6%	47.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%	0.1%	0.1%
White or Caucasian	57.3%	56.6%	80.2%	47.8%
Other Race	0.8%	2.6%	2.1%	2.5%
Declined / Unavailable	15.1%	0.0%	0.0%	0.0%

Source: Atrium Health internal data

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the 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 91, the applicant states it has no such obligation.

In Section L, page 92, the applicant states that no patient civil rights access complaints have been filed against AH Pineville or other affiliated entity during the 18 months immediately prior to submission of the application.

**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, pages 92-93, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>AH Pineville Projected Payor Mix – CY 2027</b>		
<b>Payor Category</b>	<b>% of Total Patients Served</b>	<b>% of LINAC Patients Served</b>
Self-Pay	10.2%	1.5%
Medicare*	33.0%	53.9%
Medicaid*	13.0%	3.3%
Insurance*	40.8%	38.5%
Other**	3.0%	2.8%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

\*Including any managed care plans.

\*\*Includes Workers Compensation and TRICARE.

**Source:** Atrium Health internal data

**Note:** The applicant states charity care is provided to patients in any payor category and that its internal data does not include charity care as a payor source.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 10.2% of all services and 1.5% of LINAC services will be provided to self-pay patients, 33.0% of all services and 53.9% of LINAC services to Medicare patients, and 13.0% of all services and 3.3% of LINAC services to Medicaid patients.

On page 92, 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 the projected payor mix is based on the historical 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 the reasons stated above.

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

C

In Section L, page 94, 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 acquire and add an additional LINAC on the campus of AH Pineville.

In Section M, page 96, 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 will have access to the facility for training purposes based on the following:

- The applicant provides documentation of existing health professional training programs in the area which already have access to AH Pineville.
- The applicant describes the clinical education training programs it provides access for and identifies numerous clinical education training programs it partners with to offer both training and access to its facilities.

### **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 acquire and add an additional LINAC on the campus of AH Pineville.

In Chapter 17, page 321, the 2022 SMFP defines a LINAC’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 329 shows Service Area 7 is comprised of Anson, Mecklenburg, and Union counties. Thus, the service area for this project consists of those three counties. Facilities may also serve residents of counties not included in their service area.

There are a total of 11 LINACs in seven different facilities in Service Area 7. Information about each of the facilities and utilization of the LINACs in Service Area 7 during FFY 2020 is provided in the table below.

Service Area 7 LINACs				
Facility	County	# of LINACs	# of Procedures /ESTVs	Average # of Procedures /ESTVs per LINAC
Atrium Health Pineville	Mecklenburg	1	11,170	11,170
Atrium Health Union	Union	1	7,811	7,811
Atrium Health University City	Mecklenburg	1	8,166	8,166
Carolinas Medical Center	Mecklenburg	3	19,170	6,390
Matthews Radiation Oncology Center	Mecklenburg	2	10,249	5,124
Novant Health Huntersville Medical Center	Mecklenburg	1	8,227	8,227
Novant Health Presbyterian Medical Center	Mecklenburg	2	11,457	5,729
<b>Total</b>		<b>11</b>	<b>76,250</b>	<b>6,932</b>

Source: Table 17C-1, 2022 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 98, 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.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 98, the applicant discusses its “...*commitment to promoting safety and quality in the delivery of radiation therapy services and the positive impact that its proposed project will have on the cost effectiveness of the proposed services.*”

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 98, the applicant discusses its “...*commitment to promoting safety and quality in the delivery of radiation therapy services and the positive impact that its proposed project will have on the quality of the proposed services.*”

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 98, the applicant discusses its “...*commitment to promoting equitable access in the provision of radiation therapy services and the positive impact its proposed project will have on access by medically underserved groups to the proposed to services.*”

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 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

The applicant proposes to acquire and add an additional LINAC on the campus of AH Pineville.

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 11 hospitals with LINACs located in North Carolina.

In Section O, page 102, the applicant states that during the 18 months immediately preceding the submittal of the application there were no incidents resulting in findings of immediate jeopardy at any of the 11 hospitals identified in Form O. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 11 hospitals with LINACs, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

The application conforming with all applicable Criteria and Standards for Radiation Therapy Equipment, promulgated in 10A NCAC 14C .1900. The specific criteria are discussed below.

**SECTION .1900 - CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT**

**10A NCAC 14C .1903                      PERFORMANCE STANDARDS**

*An applicant proposing to acquire a LINAC pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- (1) identify the existing LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;*
- C- On Forms C.2a and C.2b in Section Q, the applicant identifies the existing LINACs owned or operated by the applicant or a related entity and located in Service Area 7.
- (2) identify the approved LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;*
- C- On Forms C.2a and C.2b in Section Q, the applicant identifies the approved LINACs owned or operated by the applicant or a related entity and located in Service Area 7. The applicant does not have any LINACs which are approved but not yet operational in Service Area 7.
- (3) provide projected utilization of the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC during each of the first three full fiscal years of operation following completion of the project;*
- C- On Forms C.2a and C.2b in Section Q, the applicant provides projected utilization of all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 7 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (4) provide the assumptions and methodology used for the projected utilization required by Item (3) of this Rule;*
- C- In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 7 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (5) project that the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC shall perform during the third full fiscal year of operation following completion of the project either:*
  - (a) 6,750 or more ESTVs per LINAC; or*
  - (b) serve 250 or more patients per LINAC.*
- C- On Form C.2b in Section Q, the applicant projected that all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 7 and the

proposed LINAC will perform 6,750 or more ESTVs per LINAC. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.