ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: April 24, 2020
Findings Date: April 24, 2020

Project Analyst: Tanya M. Saporito
Team Leader: Fatimah Wilson

Project ID #: F-11823-19
Facility: Carolinas Medical Center
FID #: 943070
County: Mecklenburg
Applicant: The Charlotte-Mecklenburg Hospital Authority
Project: Acquire one unit of proton therapy equipment

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

In October 2019, the Agency issued an exemption (Record # 3090) for The Charlotte-Mecklenburg Hospital Authority (CMHA) or "the applicant" to develop a medical office building (MOB) at the Levine Cancer Institute (LCI) on the Carolinas Medical Center (CMC) main hospital campus in Charlotte. In this application, the applicant proposes to acquire one unit of proton therapy equipment and install it in the previously approved MOB. CMHA also does business as Atrium Health (AH), formerly known as Carolinas HealthCare System (CHS).

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 2019 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2019 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-4, on page 31 of the 2019 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 $5 million. In Section B.11, pages 22 - 23, the applicant describes its plans to ensure energy efficiency and water conservation with regard to the proposed project. The applicant adequately demonstrates that the application includes a written statement describing the applicant's plans to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to acquire one unit of proton therapy equipment and install it in a MOB at the Levine Cancer Institute on the Carolinas Medical Center hospital campus in Charlotte.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) defines "service area" as: *"… the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility."* The 2019 SMFP does not specifically define a service area for proton therapy equipment, nor are there any applicable rules adopted by the Department that define the service area for proton therapy equipment. Thus, the service area for this review is as defined by the applicant. In Section C, page 50, the applicant states the service area for its proton therapy services includes the following counties: Anson, Cabarrus, Cleveland, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Rutherford, Stanly and Union. Facilities may also serve residents of counties not included in the service area.

In Section C.2, page 27, the applicant states it has no historical patient origin because it does not currently own or operate proton therapy equipment. In Section C.3, page 28, the applicant projects the following patient origin for the proposed proton therapy equipment for the first three operating years (OY) following project completion:

CMC Proton Therapy Service Projected Patient Origin, First Three OYs

County	1ST OY (CY 2023)		2ND OY (CY 2024)		3RD OY (CY 2025)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Mecklenburg	51	40.2%	83	40.2%	100	40.2%
Cabarrus	19	15.2%	31	15.2%	38	15.2%
Union	14	10.7%	22	10.7%	27	10.7%
Stanly	8	6.5%	13	6.5%	16	6.5%
Cleveland	6	4.4%	9	4.4%	11	4.4%
York, SC	5	4.0%	8	4.0%	10	4.0%
Rowan	4	3.5%	7	3.5%	9	3.5%
Gaston	4	3.1%	6	3.1%	8	3.1%
Lancaster, SC	4	2.9%	6	2.9%	7	2.9%
Anson	3	2.2%	4	2.2%	5	2.2%
Chesterfield, SC	2	1.3%	3	1.3%	3	1.3%
Iredell	1	1.0%	2	1.0%	2	1.0%
Other*	6	4.9%	10	4.9%	12	4.9%
Total	**126**	**100.0%**	**207**	**100.0%**	**248**	**100.0%**

Source: Section C, Table on page 28.
*On page 28, the applicant states "other" is less than 1% from the remaining counties in Health Service Areas I and II, and other states.
Numbers may not sum due to rounding.

In Section C, page 29, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 30 - 59, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- Clinical advantages of proton therapy treatment – the applicant explains how proton therapy effectively and precisely treats cancer while limiting patients' exposure to the harmful side effects of radiation therapy. The applicant states research indicates that proton therapy substantially improves patient outcomes while reducing cost to patients. The applicant provides specific information on specific types of cancer and the cost and outcome efficiencies of proton therapy versus other types of radiation therapy (pages 30 – 34).

- Types of cancers treated with proton therapy – citing information from the National Association for Proton Therapy, the applicant describes the types of cancers that are most effectively and safely treated with proton therapy, and states that for these types of cancers, proton therapy is superior to traditional methods of radiation therapy (pages 34 – 36).

- Need for local access to proton therapy – the applicant states that, until recently, proton therapy was only available in very limited facilities, most of which were academic

medical centers. The applicant states that there are currently 57 proton therapy treatment centers in the world, concentrated primarily in the United States, Germany and Japan. In North Carolina, there are two approved but not developed proton therapy centers:

- A certificate of need was issued effective November 3, 2017 to UNC Hospitals to install a proton therapy machine on the Chapel Hill hospital campus. This facility is approximately 141 miles from the location in this proposal and is projected to be operational in 2022.

- A certificate of need was issued effective January 3, 2018 to Duke University Health System, Inc. to install two proton therapy machines in the Duke-Provision Proton Therapy Center in Durham. This facility is approximately 144 miles from the location in this proposal and is projected to be operational in October 2021.

The applicant states that neither of the approved proton therapy centers projected to serve a significant number of patients from Mecklenburg County; therefore, development of a proton therapy center on the CMC campus is vital to providing access to effective cancer treatment for Atrium Health's service area residents (pages 36 – 38).

- Atrium Health Levine Cancer Institute radiation therapy services – the applicant states the Levine Cancer Institute (LCI), which is part of Atrium Health's hospital network in Mecklenburg County, is one of the nation's leading oncology institutes and provides pediatric cancer care as well. The applicant states that in 2018, LCI provided oncology services to 18,000 new patients. In addition, the applicant states that Atrium Health's inpatient market share of cancer patients has increased since 2016. See the following table that compares area oncology service providers, from page 40 of the application:

Inpatient Market Share, Cancer Patients

PROVIDER	2016	2017	2018
Atrium Health	54.9%	55.6%	56.8%
Novant Health	23.6%	23.1%	22.7%
CaroMont	4.7%	5.2%	5.3%
"Other"	16.8%	16.1%	15.2%

The applicant further describes the types of radiation currently provided to its cancer patients and how proton therapy differs from traditional radiation therapy. The applicant states the proton therapy will significantly advance the treatment services it is able to provide to its adult and pediatric cancer patients (pages 39 – 43).

- Cancer cases in North Carolina and the applicant's service area – the applicant states that, according to the State Center for Health Statistics, cancer is the leading cause of death in the state and has been since 2009. The applicant provides information from the North Carolina Central Cancer Registry that shows the number of new cancer cases throughout the state increased by a compound annual growth rate (CAGR) of 1.7%

from 2014 to 2019, while the number of new cancer cases in the proposed service area increased by 2.4% during the same time period (pages 44 – 47).

- Statewide demand for proton therapy – the applicant explains how several national and international studies show the percentage of overall cancer cases that are appropriate for proton therapy. In addition, the applicant looked at data from the North Carolina Central Cancer Registry and population growth statistics in the state to project the types of cancer in the proposed service area that would be appropriate for proton therapy services. The applicant determined that approximately 18% of all cancer cases in the state are appropriate for proton therapy. To be conservative, the applicant calculated a percentage of total cancer cases in the state that would be appropriate for proton therapy based on an analysis presented by Duke University Health System in its application for proton therapy services that was approved by the Agency in January 2018. Under that analysis, the applicant determined that 11.6% of all cancer cases in the state would be appropriate for proton therapy (pages 47 – 51).

- Service area demand for proton therapy – the applicant used the analysis from the statewide proton therapy demand as a basis for determining the percentage of cancer that would be appropriate for proton therapy treatment in the proposed service area for the proposed proton therapy center (pages 52 – 54).

- Growth and aging of the proposed service area – the applicant utilized data from the North Carolina State Office of Budget and Management (NCSOBM) to determine the historical and projected population growth in all age groups in those counties which comprise the proposed service area. The applicant determined the number of cancer cases across all age groups that would be appropriate for proton therapy services from 2019 – 2025 (pages 55 – 58).

- Physician and community support – the applicant provides letters of support from area physicians, community members, and cancer survivors whose treatment regimen was performed at LCI to demonstrate support for the proposed proton therapy center in CMC (pages 58 – 59).

The information is reasonable and adequately supported for the following reasons:

- The types of cancer nationally that are appropriate for proton therapy treatment represent approximately 30% of all cancer types, according to the data submitted by the applicant.

- The types of cancer within the state that are appropriate for proton therapy treatment represent approximately 18% of all cancer types; however, the applicant used a Duke University Health System analysis that more conservatively indicates that 11.6% of all cancer types in North Carolina are appropriate for proton therapy treatment.

- The only two approved proton therapy treatment centers in the state are in Durham and Orange counties, which are over 140 miles east of the CMC hospital campus. The

applicant's project represents the only other proposal for this type of service in North Carolina.

- Population growth projections and cancer incidence projections in the state and in the proposed service area indicate a need in the applicant's service area for the proposed proton therapy services.

Projected Utilization

In Section Q, the applicant provides projected utilization, as illustrated in the following table:

Projected Proton Therapy Procedures: CMC/LCI

	FY2021	FY2022	FY2023	FY2024
# Procedures	1,219	3,381	5,528	6,638

Source: Section Q, page 117.

In Section Q, pages 118 - 130, the applicant provides the assumptions and methodology used to project utilization, in 11 steps, which is summarized below.

Step 1: Identify Atrium Health Potential Proton Therapy Patient Base:

The applicant examined its historical radiation therapy patient utilization by cancer types to determine which types would be appropriate for proton therapy treatment. The applicant also calculated a compound annual growth rate (CAGR) of the incidence of those cancers. See the following table, from page 119:

CANCER PROGRAM	CY 2016	CY 2017	CY 2018	CY 2019*	3-YEAR CAGR
Breast	754	869	922	1,013	10.3%
GI Colorectal	128	117	130	111	-4.6%
GI Other	198	240	233	267	10.5%
Gynecology	112	106	101	101	-3.4%
Head & Neck	219	210	247	237	2.7%
Lymphoma	86	83	68	91	1.9%
Musculoskeletal	43	55	58	69	17.1%
Neurology	358	391	439	468	9.3%
Prostate	332	340	402	525	16.5%
Thoracic	550	483	513	564	0.8%
Urology Other	68	43	46	53	-8.0%
All Other Cancers	546	635	602	691	8.2%
Total Unique Patients	**3,394**	**3,572**	**3,761**	**4,190**	**7.3%**

*the applicant annualized this data based on seven months, from January to July 2019.

The applicant acknowledges that not all cancer types are appropriate for proton therapy. The applicant consulted a radiation oncologist at LCI, several studies that assessed a percentage of cancer types that are appropriate for proton therapy, and other LCI staff members, to determine that between 15% to 46% of radiation therapy patients may be appropriate for proton therapy. The applicant determined the following numbers of adult radiation therapy patients would be candidates for proton therapy:

Atrium Health Adult Radiation Therapy Patients Appropriate for Proton Therapy

CANCER PROGRAM	% APPROPRIATE FOR PROTON THERAPY	CY 2016	CY 2017	CY 2018	CY 2019*
Breast	5.0%	38	43	46	51
GI Colorectal	10.0%	13	12	13	11
GI Other	10.0%	20	24	23	27
Gynecology	10.0%	11	11	10	10
Head & Neck	20.0%	44	42	49	47
Lymphoma	15.0%	13	12	10	14
Musculoskeletal	15.0%	6	8	9	10
Neurology	20.0%	72	78	88	94
Prostate	5.0%	17	17	20	26
Thoracic	15.0%	83	72	77	85
Urology Other	15.0%	10	6	7	8
All Other Cancers	15.0%	82	95	90	104
Total Unique Patients		**407**	**422**	**443**	**486**

*the applicant annualized this data based on seven months, from January to July 2019.

The applicant states it has a growing base of over 480 adults who are appropriate candidates for proton therapy as of July 2019.

The applicant performed the same analysis on its pediatric cancer patients, as shown in the following table, from page 121:

Atrium Health Pediatric Radiation Therapy Patients Appropriate for Proton Therapy

CANCER PROGRAM	CY 2016	CY 2017	CY 2018	CY 2019*
GI	1	1	0	2
Head & Neck	0	0	0	2
Lymphoma	1	0	3	0
Musculoskeletal	6	4	5	2
Neurology	11	10	6	5
Thoracic	1	3	5	2
Urology	3	3	4	2
All Other Cancers**	9	7	7	15
Total Unique Patients	**32**	**28**	**30**	**29**

*the applicant annualized this data based on seven months, from January to July 2019.

The applicant determined it has a growing base of adult and pediatric cancer patients who currently receive radiation therapy treatment, who would be candidates for proton therapy treatment.

Step 2: Projected Atrium Health Potential Proton Therapy Base

To project the future Atrium Health patient base that would be appropriate for proton therapy, the applicant assumes that the number of adult cancer patients appropriate for proton therapy determined in Step 1 will increase by 4% annually, which the applicant states is conservative, given that the CAGR of those patients from 2016 to 2019 was 7.3%. The following table, from

page 123, illustrates projected growth in adult cancer types that are appropriate for proton therapy:

Atrium Health Adult Potential Proton Therapy Patient Base

CANCER PROGRAM	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025
Breast	53	55	57	59	62	64
GI Colorectal	12	12	12	13	14	14
GI Other	28	29	30	31	32	34
Gynecology	11	11	11	12	12	13
Head & Neck	49	51	53	55	58	60
Lymphoma	14	15	15	16	17	17
Musculoskeletal	11	11	12	12	13	13
Neurology	97	101	105	109	114	118
Prostate	27	28	30	31	32	33
Thoracic	88	92	95	99	103	107
Urology Other	8	9	9	9	10	10
All Other Cancers	108	112	117	121	126	131
Total Potential Proton Therapy Pts.	**505**	**526**	**547**	**569**	**591**	**615**

The applicant projects the number of cancer cases that would be appropriate, based on the 11.6% rate it determined was reasonable. The following table, from page 123, illustrates Atrium Health's projected potential proton therapy patients as a percentage of statewide proton therapy demand (discussed in Section C.4):

Atrium Health Potential Proton Therapy Patients as a Percent of Statewide Proton Therapy Demand

	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025
Statewide Cancer Cases*	63,547	64,653	65,778	66,922	68,087	69,272
Proton Therapy-Appropriate Cases (11.6%)	7,359	7,487	7,618	7,750	7,884	8,022
Atrium Health Potential PT** Patients	505	526	547	569	591	615
Atrium Health Potential PT Pts. As % of Statewide Demand	6.9%	7.0%	7.2%	7.3%	7.5%	7.7%

*Projected by State Center for Health Statistics
**PT = Proton Therapy

Thus, the applicant states it projected patient base represents a small fraction of the projected base of patients who would be appropriate candidates for proton therapy treatment.

Step 3: Determine Project Years

The applicant projects the facility will be operational by April 2022, and the proposed proton therapy services offered by July 2022. The applicant states its fiscal years are consistent with calendar years; therefore, it projects an interim year from July 2022 through December 2022. The first three operating years are therefore CYs 2023 – 2025.

Step 4: Project Proton Therapy Patients from Atrium Health's Patient Base

Based on Step 2, the applicant states it has an existing radiation therapy base of over 600 patients who are appropriate for proton therapy. Citing issues with insurance coverage of proton therapy treatment and limited capacity of proton therapy equipment, the applicant

projects that its proton therapy patients will increase gradually. The applicant states that in the interim period (July 2022 – December 2022), Atrium Health will provide proton therapy services to 15% of the total Atrium Health potential proton therapy patients, and then will increase by 5% per year thereafter. See the following table, from page 124:

Atrium Health Adult Proton Therapy Patients

	PARTIAL YEAR 7/22 – 12/22	OY 1 (CY 2023)	OY 2 (CY 2024)	OY 3 (OY 2025)
Atrium Health Potential PT Patients (Step 2)	273	569	591	615
% of Potential Atrium Health PT Patients	15%	20%	25%	30%
Proton Therapy Patients (Adult)	**41**	**114**	**148**	**184**

The applicant compares its projected adult proton therapy patients to the more conservative projected total statewide percentage of cases that are appropriate for proton therapy (11.6%), as illustrated in the following table from page 125:

Atrium Health Projected PT Patients as Percent of Statewide Demand

	PARTIAL YEAR 7/22 – 12/22	OY 1 (CY 2023)	OY 2 (CY 2024)	OY 3 (OY 2025)
Statewide Cancer Cases*	65,778	66,922	68,087	69,272
Statewide PT-appropriate Cases	7,617	7,750	7,884	8,022
Atrium Health Projected PT Patients	41	114	148	184
Atrium Health Projected PT Patients as % of Total Statewide PT-appropriate Cases	**0.5%**	**1.5%**	**1.9%**	**2.3%**

*Projected by State Center for Health Statistics

The applicant states its projections of proton therapy patients therefore conservatively represent a small percentage of the statewide cancer patient population that would be appropriate for proton therapy treatment.

Step 5: Determine Incremental Patient Volume (Non-Atrium Existing Patients)

Noting that the two approved proton therapy centers are located over 140 miles east of CMC and most of CMC's patient base, the applicant states it is reasonable to assume patients from outside its existing patient base will choose to receive proton therapy services at CMC. The applicant projects a 0.5% increase in its market share that represents those patients who are not part of its existing patient base in the second and third operating years, as shown in the following table, from page 126:

Incremental Patient Volume Outside Existing Atrium Patient Base

	PARTIAL YEAR 7/22 – 12/22	OY 1 (CY 2023)	OY 2 (CY 2024)	OY 3 (OY 2025)
Statewide Cancer Cases*	65,778	66,922	68,087	69,272
Statewide PT-appropriate Cases	7,617	7,750	7,884	8,022
Incremental Market Share	0.0%	0.0%	0.5%	0.5%
Incremental PT Patients	**0**	**0**	**38**	**39**

Step 6: Total Adult Atrium Health Proton Therapy Patients

The applicant combines the numbers of patients from Steps 4 and 5:

Atrium Health Adult Proton Therapy Patients

	PARTIAL YEAR 7/22 – 12/22	OY 1 (CY 2023)	OY 2 (CY 2024)	OY 3 (OY 2025)
Adult PT Patients	41	114	186	223

Source: application page 126

Step 7: Determine Projected Pediatric Proton Therapy Patients

The applicant states Atrium Health's Levine Children's Hospital provides an additional base of pediatric patients. These pediatric patients are receiving radiation therapy and could be appropriate for proton therapy, as calculated by the applicant in Step 1. The following table, from page 126, shows the projected pediatric cancer patients who would be appropriate candidates for proton therapy treatment:

Atrium Health Pediatric Radiation Therapy Patients Appropriate for Proton Therapy

	CY 2016	CY 2017	CY 2018	CY 2019*
Pediatric PT-Appropriate Patients	32	28	30	29

*the applicant annualized this data based on seven months, from January to July 2019.

The applicant states those numbers of pediatric proton therapy-appropriate patients are conservative, because they exclude pediatric cancer patients who are not candidates for radiation therapy and those pediatric cancer patients who travel out of state for their treatment. The applicant projects that actual pediatric cancer patients who are appropriate for proton therapy at Atrium Health will represent approximately 10% of total cancer patients who are appropriate for proton therapy treatment, based on projected population growth in the service area, pediatric cancer incidence rates, the expansion of LCI and integration of LCI with the Levine Children's Hospital, and numerous letters of support that were submitted with the application.

Step 8: Total Atrium Health Proton Therapy Patients (Adult and Pediatric)

The following table, from page 127, illustrates the total projected adult and pediatric patients who are projected to utilize the applicant's proposed proton therapy services:

Total Projected Adult and Pediatric PT Patients

	PARTIAL YEAR 7/22 – 12/22	OY 1 (CY 2023)	OY 2 (CY 2024)	OY 3 (OY 2025)
Adult PT Patients	41	114	186	223
Pediatric PT Patients (10% of total)	5	13	21	25
Total PT Patients	**46**	**126**	**207**	**248**

Step 9: Determine Atrium Health PT Patients by Cancer Program

Based on the information in Step 2 of the assumptions, and the assumption that pediatric cancer patients comprise 10% of total cancer patients, the applicant projects the total number of Atrium Health proton therapy patients, as shown in the table from page 128:

Total Projected Adult and Pediatric PT Patients by Cancer Program

CANCER PROGRAM	% DISTRIBUTION	7/22 – 12/22	CY 2023	CY 2024	CY 2025
Breast	9%	4	12	19	23
GI Colorectal	2%	1	3	4	5
GI Other	5%	2	6	10	12
Gynecology	2%	1	2	4	5
Head & Neck	9%	4	11	18	22
Lymphoma	3%	1	3	5	6
Musculoskeletal	2%	1	2	4	5
Neurology	17%	8	22	36	43
Prostate	5%	2	6	10	12
Thoracic	16%	7	20	32	39
Urology Other	1%	1	2	3	4
All Other Cancers	19%	9	24	40	48
Pediatric	10%	5	13	21	25
Total Potential Proton Therapy Pts.	**100%**	**46**	**126**	**207**	**248**

Step 10: Determine the Average Number of Proton Therapy Treatments by Cancer Type

The applicant states the number of proton therapy treatments a patient will undergo depend on the type of cancer and can range from 25 to 46. The applicant consulted a radiation oncologist and other medical staff from LCI to determine an average number of projected proton therapy treatments by type per patient, as shown in the following table from page 129:

Atrium Health Projected # of PT Treatments by Type

CANCER PROGRAM	AVG. # TREATMENTS PER PATIENT
Breast	25
GI Colorectal	25
GI Other	25
Gynecology	25
Head & Neck	30
Lymphoma	25
Musculoskeletal	25
Neurology	28
Prostate	40
Thoracic	25
Urology Other	30
All Other Cancers	25
Pediatric	25

Step 11: Determine Atrium Health Total Projected PT Treatments

The applicant applied the projected average number of proton therapy treatments per patient to the number of projected proton therapy patients by cancer program (from Step 9) to project the number of Atrium Health's proton therapy treatments by type, as shown in the following table from page 129:

Atrium Health Projected Proton Therapy Treatments by Type

CANCER PROGRAM	7/22 – 12/22	CY 2023	CY 2024	CY 2025
Breast	107	296	484	582
GI Colorectal	23	65	106	127
GI Other	56	156	255	307
Gynecology	21	59	97	116
Head & Neck	120	333	544	653
Lymphoma	29	80	131	157
Musculoskeletal	22	61	99	119
Neurology	221	613	1,003	1,204
Prostate	89	246	402	482
Thoracic	178	495	809	971
Urology Other	20	56	91	110
All Other Cancers	219	606	991	1,190
Pediatric	114	316	516	620
Total PT Treatments	**1,219**	**3,381**	**5,528**	**6,638**
Weighted Avg. Treatment / Patient	**26.8**	**26.8**	**26.8**	**26.8**

The applicant does not explain the weighting factor that it used to calculate the "weighted average treatment per patient"; however, the average of the projected number of treatments by type is 27.1. Therefore, the use of 26.8 as a weighted average with which to project proton therapy treatments by type is reasonable.

On page 130, the applicant provides a table that summarizes Atrium Health's projected proton therapy patients and treatments, as follows:

Atrium Health Projected Proton Therapy Treatments by Type

CANCER PROGRAM	7/22 – 12/22	CY 2023	CY 2024	CY 2025
Proton Therapy Patients	46	126	207	248
Proton Therapy Treatments	1,219	3,381	5,528	6,638

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant's utilization projections are supported by population growth projections, adult and pediatric cancer incidence projections and its own radiation therapy patient experience.
- The applicant projects the number of proton therapy appropriate patients using conservative growth factors that are less than the historical and projected growth calculated by the applicant based on research.
- The applicant utilizes research from national and local sources to support its growth projections.
- The applicant provides 208 letters of support from physicians, community members, and family members of LCI patients in Exhibit I.1 to demonstrate support for the project.

Access

In Section C, page 64, the applicant states *"CMC provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment."* In Section L, page 101, 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.

Projected Payor Mix, Third Full Federal Fiscal Year (CY 2025)

PAYOR CATEGORY	ENTIRE FACILITY: % OF TOTAL	RADIATION ONCOLOGY: % OF TOTAL
Self-Pay	14.1%	1.5%
Medicare*	26.1%	45.8%
Medicaid*	24.5%	7.5%
Insurance*	33.4%	38.6%
Other (specify)	1.9%	6.6%
Total	**100.0%**	**100.0%**

*Including any managed care plans.
The applicant states "other" includes TRICARE and Workers Compensation

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

NA

The applicant does not propose a reduction or elimination of a service, or the relocation of a facility or a 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 proton therapy equipment and install it in a MOB at the Levine Cancer Institute on the Carolinas Medical Center hospital campus in Charlotte.

In Section E, pages 75 - 76, 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:

- Develop the proton therapy center in another location – the applicant states the CMC campus in Charlotte is the flagship hospital of Atrium Health, is an Academic Medical Center Teaching Hospital, and has a substantial base of existing radiation therapy patients to be treated with the proton therapy equipment. Additionally, LCI is the region's largest network of cancer care. Therefore, developing the center in a different location is not an effective alternative.

- Acquire different proton therapy equipment – the applicant considered acquiring different equipment from a different vendor; however, the costs and performance associated with the proposed equipment will most efficiently and effectively serve the applicant's patient base. In addition, the applicant states that each of the other proton therapy centers (Duke University Health System and UNC Chapel Hill) has different equipment and the applicant's choice will provide an additional vendor to contribute to research in the region.

- Acquire a different quantity of proton therapy equipment – the applicant states this is not an effective alternative because it would result in substantially greater capital cost.

On page 76, the applicant states that its proposal is the most effective alternative because it represents the most reasonable and cost-effective alternative to meet the need for existing and projected cancer patients in the CMC service area.

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

Conclusion

The Agency reviewed the:

- Application
- Remarks made at the public hearing
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

1. **The Charlotte-Mecklenburg Hospital Authority shall materially comply with all representations made in the certificate of need application.**

2. **The Charlotte-Mecklenburg Hospital Authority shall acquire no more than one unit of proton therapy equipment to be located at the Levine Cancer Institute on the Carolinas Medical Center hospital campus.**

3. **The Charlotte-Mecklenburg Hospital Authority 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 Charlotte-Mecklenburg Hospital Authority 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. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, The Charlotte-Mecklenburg Hospital Authority 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.**

6. **The Charlotte-Mecklenburg Hospital Authority 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 proton therapy equipment and install it in a MOB at the Levine Cancer Institute on the Carolinas Medical Center hospital campus in Charlotte.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 131, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	$1,350,630
Construction Costs	$13,627,755
Miscellaneous Costs*	$40,928,545
Total	**$55,906,930**

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 80 - 81, the applicant projects that start-up costs will be $550,000 and initial operating expenses will be $1,110,000 for a total working capital of $1,660,000. On

pages 80 - 81, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2, page 79, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

TYPE	CMC	TOTAL
Loans	$0	$0
Accumulated reserves or OE *	$55,990,930	$55,990,930
Bonds	$0	$0
Other (Specify)	$0	$0
Total Financing	**$55,990,930**	**$55,990,930**

* OE = Owner's Equity

The applicant states on page 79 that it projects to fund the entire project with accumulated reserves; however, it has included financing costs of $245,056 in the event the project is funded with bond financing.

In Section F.3(e), page 81, the applicant states that the working capital needs of the project will be funded as shown in the table below.

	SOURCES OF FINANCING FOR WORKING CAPITAL – CMC/LCI	AMOUNT
(a)	Loans	$0
(b)	Accumulated Reserves or Owner's Equity	$1,660,000
(c)	Lines of credit	$0
(d)	Bonds	$0
(e)	**Total**	**$1,660,000**

In Exhibit F-2.1 the applicant provides a letter dated November 15, 2019 from Atrium Health's Chief Financial Officer documenting that the funds will be available for the capital cost and working capital cost of the project. Exhibit F-2.2 contains the most recent audited financial statements for The Charlotte-Mecklenburg Hospital Authority, d/b/a Atrium Health which indicate on page 18 that the hospital had $82,900,000 in cash and cash equivalents as of December 31, 2018.

Financial Feasibility

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

	INTERIM YEAR (7/1/2022 – 12/31/2022)	1ST FULL FISCAL YEAR (CY 2023)	2ND FULL FISCAL YEAR (CY 2024)	3RD FULL FISCAL YEAR (CY 2025)
Total Procedures	1,219	3,381	5,528	6,638
Total Gross Revenues (Charges)	$5,963,230	$17,034,164	$28,685,216	$35,477,367
Total Net Revenue	$1,410,269	$4,028,480	$6,783,886	$8,390,190
Average Net Revenue per Procedure	$1,156.91	$1,191.51	$1,219.05	$1,263.96
Total Operating Expenses (Costs)	$2,657,372	$5,542,437	$6,792,231	$6,953,574
Average Operating Expense per IR Case	$2,180.18	$1,639.29	$1,228.70	$1,047.54
Net Income (loss)*	($1,247,372)	($1,513,957)	($8,345)	$1,436,616

*The applicant provides two sources of Net Income, one of which includes depreciation and one of which does not. The project analyst is using the net income calculated including depreciation.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working 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 acquire proton therapy equipment and install it in a MOB at the Levine Cancer Institute on the Carolinas Medical Center hospital campus in Charlotte.

N.C. Gen. Stat. §131E-176(24a) states, *"Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives*

services from a health service facility." The 2019 SMFP does not define a service area for a proton therapy services, nor are there any applicable rules adopted by the Department that define the service area for proton therapy services. Thus, the service area for this review is as defined by the applicant.

In Section C, page 50, the applicant states the service area for its proton therapy services includes the following counties: Anson, Cabarrus, Cleveland, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Rutherford, Stanly and Union. Facilities may also serve residents of counties not included in the service area.

In Section G, page 85, the applicant states there are no other providers of proton therapy services in the service area. The applicant states Duke and UNC provide proton therapy services in centers that are over 140 miles from the proposed location of this center, and neither facility projects to serve a significant portion of Mecklenburg County residents. The applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved proton therapy services in the service area. On pages 85 – 86, the applicant states:

> *"The approved Duke and UNC facilities will each provide needed access for residents of central and eastern North Carolina; however, residents of Mecklenburg County and the surrounding area do not have effective access to the approved facilities. …Given the typical treatment regimen for proton therapy is a total of 25 – 30 treatments per patient…, service area residents will either be foreclosed from utilizing proton therapy treatment, or they will have to travel significant distances and stay for an extended duration of time to receive care. …*
>
> *Furthermore, the approved UNC and Duke proton therapy facilities did not represent that residents of Mecklenburg County and the surrounding area would be served…. Consequently, the approved proton therapy facilities will not provide material access for Atrium Health's service area residents."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed proton therapy center is needed in the service area. Furthermore, the proposed proton therapy center would be the only one in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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

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

C

The applicant proposes to acquire proton therapy equipment and install it in a MOB at the Levine Cancer Institute on the Carolinas Medical Center hospital campus in Charlotte.

In Section Q, Form H, page 135, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services for all three project years, as illustrated in the following table.

Proton Therapy Services Projected Staff

POSITION	NUMBER OF FTES
Physicist	3.0
Radiation Therapist	4.5
Dosimetrist	2.0
Registered Nurse	1.5
Patient Service Specialist	2.0
Medical Assistant	1.5
Total	**14.5**

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 87 - 89, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.2, page 91, the applicant identifies the current medical director. In Exhibit I.3, the applicant provides a letter from the medical director which confirms his intent to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated 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 proton therapy equipment and install it in a MOB at the Levine Cancer Institute on the Carolinas Medical Center hospital campus in Charlotte.

In Section I, page 90, the applicant states that the following ancillary and support services will be available for the proposed services:

- Laboratory
- Radiology
- Pharmacy
- Emergency Services
- Pastoral Care
- Nutrition and Food Services
- Physical Therapy
- Patient Relations
- Information Systems
- Fiscal Services
- Social Services
- Environmental Services
- Materials Management
- Plant Maintenance

In Exhibit I.1, the applicant provides a letter from the vice president and chief operating officer of CMC which confirms the availability of the above ancillary and support services.

In Section I, page 91, the applicant describes its efforts to develop 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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 proton therapy equipment and install it in a MOB at the Levine Cancer Institute on the Carolinas Medical Center hospital campus in Charlotte.

In Section K, page 94, the applicant states that the project involves renovating 17,607 total square feet of existing space in the previously approved MOB. Line drawings are provided in Exhibit C.1-1.

In Section K, page 94, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 95, 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 and provides supporting documentation in Exhibit F.1.

In Section K.3(c), pages 95 - 96, 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
- Remarks made at the public hearing

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

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The applicant does not currently provide proton therapy services. In Section L, page 100, the applicant provides the historical payor mix during calendar year (CY) 2018 for the entire CMC hospital and for radiation oncology services at the hospital, as shown in the following table:

PAYOR CATEGORY	ENTIRE FACILITY: % OF TOTAL	RADIATION ONCOLOGY: % OF TOTAL
Self-Pay	14.1%	1.5%
Medicare*	26.1%	45.8%
Medicaid*	24.5%	7.5%
Insurance*	33.4%	38.6%
Other (specify)	1.9%	6.6%
Total	**100.0%**	**100.0%**

*Including any managed care plans.
The applicant states "other" includes TRICARE and Workers Compensation

In Section L, page 99, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	59.6%	51.9%
Male	40.4%	48.1%
Unknown	0.0%	0.0%
64 and Younger	78.5%	88.8%
65 and Older	21.5%	11.2%
American Indian	0.9%	0.8%
Asian	1.6%	6.4%
Black or African-American	33.0%	32.9%
Native Hawaiian or Pacific Islander	0.2%	0.1%
White or Caucasian	46.0%	57.5%
Other Race	5.6%	2.4%
Declined / Unavailable	12.8%	0.0%

Source: Table on page 83 of the application.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 handicapped persons 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, pages 100 - 101, the applicant states,

> *"CMC has had no obligation to provide a specific uncompensated care amount, community service, or access to care by medically underserved, minorities, or handicapped persons. However, as stated earlier, CMC*

provides and will continue to provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment."

In Section L, page 101, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility nor any related hospital located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 101, 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.

Projected Payor Mix, Third Full Federal Fiscal Year (CY 2025)

PAYOR CATEGORY	ENTIRE FACILITY: % OF TOTAL	RADIATION ONCOLOGY: % OF TOTAL
Self-Pay	14.1%	1.5%
Medicare*	26.1%	45.8%
Medicaid*	24.5%	7.5%
Insurance*	33.4%	38.6%
Other (specify)	1.9%	6.6%
Total	**100.0%**	**100.0%**

*Including any managed care plans.
The applicant states "other" includes TRICARE and Workers Compensation

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.5% of its proton therapy services will be provided to self-pay patients, 45.8% to Medicare patients and 7.5% to Medicaid patients.

On pages 101 - 102, 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 historical payor mix of current radiation oncology patients at CMC.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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

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

C

In Section L, page 102, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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

In Section M, page 104, 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

The applicant proposes to acquire proton therapy equipment and install it in a MOB at the Levine Cancer Institute on the Carolinas Medical Center hospital campus in Charlotte.

N.C. Gen. Stat. §131E-176(24a) states, *"Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility."* The 2019 SMFP does not define a service area for a proton therapy services, nor are there any applicable rules adopted by the Department that define the service area for proton therapy services. Thus, the service area for this review is as defined by the applicant.

In Section C, page 50, the applicant states the service area for its proton therapy services includes the following counties: Anson, Cabarrus, Cleveland, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Rutherford, Stanly and Union. Facilities may also serve residents of counties not included in the service area.

There are currently no providers of proton therapy services in Mecklenburg County or the surrounding area; the two approved proton therapy centers are over 140 miles to the east, in Durham and Orange Counties.

In Section N, pages 106 - 108, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 106, the applicant states: *"The proposed application is indicative of Atrium health's commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended. The proposed Mevion proton therapy system integrates patented technology at the very forefront of proton therapy to delivery exceptional beam quality…."*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency

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

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form A, pages 115 – 116, the applicant provides a list of 31 facilities that are owned or operated by the applicant or a related entity.

In Section O.3, page 111, the applicant states that on September 12, 2018, one of those facilities was found to be out of compliance with Medicare Conditions of Participation. On October 4, 2018, the facility was found to be back in compliance. The applicant provides supporting documentation in Exhibit O.3:

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 resulting in a finding of immediate jeopardy have not occurred in any of these facilities. 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 of the facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The application is conforming with all applicable Criteria and Standards for Radiation Therapy Equipment. The specific criteria are discussed below.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

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

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

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

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

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

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

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

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

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

-C- In Section C.12, page 69, the applicants provide the number of patients who are projected to receive treatment with the proposed proton therapy equipment by diagnosis and treatment procedure. The applicants provide number of patients who are projected to receive treatment with the proposed proton therapy equipment by county of residence in Section C.3(a), page 28.

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

-C- The applicant provides the projected maximum number and types of procedures that the proton therapy equipment is capable of performing in Section C.12, page 70.

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

-C- The applicants document the assumptions and methodology supporting utilization of the proton therapy equipment in Section Q, Form C.