

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 23, 2020

Findings Date: July 23, 2020

Project Analyst: Julie M. Faenza

Chief: Martha J. Frisone

Project ID #: F-11898-20

Facility: Carolinas Medical Center

FID #: 943070

County: Mecklenburg

Applicant: The Charlotte-Mecklenburg Hospital Authority

Project: Acquire a gamma knife pursuant to the adjusted need determination in the 2020 SMFP

### 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

The Charlotte-Mecklenburg Hospital Authority (hereinafter referred to as “Atrium” or “the applicant”) proposes to acquire a gamma knife pursuant to the adjusted need determination in the 2020 State Medical Facilities Plan (SMFP), which will be located at Carolinas Medical Center (CMC) in Charlotte.

#### **Need Determination**

Chapter 17 of the 2020 State Medical Facilities Plan (SMFP) does not include a methodology for determining the need for additional gamma knives by planning regions or Health Service Areas (HSAs). Page 399 of the 2020 SMFP states:

*“The SMFP does not have a methodology to project need for additional gamma knives. A summer petition is required to place a need in the upcoming SMFP. If the need determination is approved, any person may apply for a certificate of need to acquire the gamma knife.”*

Table 17B-1 on page 399 of the 2020 SMFP shows there is an adjusted need determination for one gamma knife in HSA III. The applicant proposes to acquire one gamma knife to be located at CMC in Charlotte, in Mecklenburg County. Mecklenburg County is part of HSA III. The applicant does not propose to add more gamma knives than are determined to be needed in HSA III.

### **Policies**

There are two policies in the 2020 SMFP applicable to this review.

Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 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 21-25, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant adequately documents how the project will promote safety and quality in the delivery of gamma knife services in HSA III, will promote equitable access to gamma knife services in HSA III, and will maximize healthcare value for resources expended. The applicant documents how projected volumes incorporate these concepts in meeting the need.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2020 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, pages 26-27, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant does not propose to develop more gamma knives than are determined to be needed in HSA III.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of gamma knife services in HSA III.
  - The applicant adequately documents how the project will promote equitable access to gamma knife services in HSA III.
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - The applicant adequately documents how projected volumes will incorporate the concepts above in meeting the need.

- 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

### C

The applicant proposes to acquire a gamma knife, pursuant to the adjusted need determination in the 2020 SMFP, to be located at CMC in Charlotte.

In Section C, page 28, the applicant states it petitioned the State Health Coordinating Council (SHCC) in July 2019 for an adjusted need determination of one gamma knife for the western gamma knife planning region (HSAs I, II, and III). The SHCC ultimately approved an adjusted need determination in the 2020 SMFP for one gamma knife in HSA III. See Exhibits C.1-1 and C.1-2 for the petition and the Agency Report in response to the petition, respectively. The applicant states it will locate the gamma knife in a medical office building under development on CMC's campus. The medical office building is adjacent to and will be connected to the Levine Cancer Institute (LCI).

#### **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." On page 399, the 2020 SMFP states: "North Carolina has two gamma knife planning regions (service areas) - the western region (Health Service Areas [HSA] I, II, and III) and the eastern region (HSAs IV, V, and VI)..." In Table 17B-1 on page 399 of the 2020 SMFP, the adjusted need determination identifies the service area for the proposed gamma knife as HSA III. Facilities may also serve residents of counties not included in the service area.

The applicant does not currently own or operate a gamma knife. The following table illustrates projected patient origin.

<b>CMC Gamma Knife – Projected Patient Origin – FYs 1-3 (CYs 2023-2025)</b>						
<b>County</b>	<b>FY 1 – CY 2023</b>		<b>FY 2 – CY 2024</b>		<b>FY 3 – CY 2025</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Mecklenburg	183	33.9%	233	33.9%	237	33.9%
Cabarrus	65	12.1%	83	12.1%	84	12.1%
Union	51	9.4%	65	9.4%	66	9.4%
York (SC)	41	7.6%	52	7.6%	53	7.6%
Gaston	25	4.7%	32	4.7%	33	4.7%
Lancaster (SC)	23	4.3%	30	4.3%	30	4.3%
Stanly	23	4.2%	29	4.2%	29	4.2%
Lincoln	20	3.7%	26	3.7%	26	3.7%
Rowan	20	3.7%	25	3.7%	26	3.7%
Cleveland	13	2.3%	16	2.3%	16	2.3%
Catawba	12	2.3%	16	2.3%	16	2.3%
Iredell	10	1.8%	13	1.8%	13	1.8%
Other*	54	10.0%	68	10.0%	70	10.0%
<b>Total</b>	<b>540</b>	<b>100.0%</b>	<b>687</b>	<b>100.0%</b>	<b>698</b>	<b>100.0%</b>

Source: Section C, page 32

\*Other includes Alamance, Anson, Avery, Brunswick, Buncombe, Burke, Caldwell, Cherokee, Cumberland, Davidson, Forsyth, Franklin, Guilford, Henderson, Lee, Madison, McDowell, Montgomery, Moore, New Hanover, Polk, Randolph, Richmond, Robeson, Rockingham, Rutherford, Scotland, Stokes, Swain, Transylvania, Wake, and Watauga counties in North Carolina and Anderson, Charleston, Chester, Chesterfield, Colleton, Dorchester, Florence, Greenville, Horry, Lexington, Marlboro, Newberry, Orangeburg, Pickens, and Spartanburg counties in South Carolina, as well as other states.

In Section C, page 33, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported by historical patient origin for patients with gamma knife eligible conditions served by Atrium facilities in HSA III.

**Analysis of Need**

In Section C, pages 33-45, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

Clinical Advantages in Stereotactic Radiosurgery (pages 33-37): Stereotactic radiosurgery (SRS) is an advanced type of radiation therapy procedure used to treat tumors and diseases of the brain, neck, lungs, and other parts of the body. SRS is incisionless and can be performed with a linear accelerator, a CyberKnife (a lightweight linear accelerator mounted on a robotic arm), and a gamma knife. The applicant states gamma knives are considered the gold standard for brain and head disorders because of the extremely precise ability to target the radiation to the diseased area while minimizing impact to healthy surrounding tissue, something that a linear accelerator and a CyberKnife cannot do as precisely. The applicant cites numerous studies which show the clinical superiority of gamma knives and states more scientific articles about patient outcomes with gamma knives are published than any other kind of SRS modality.

2020 SMFP Adjusted Need Determination (pages 37-38): The applicant cites data from previous SMFPs and license renewal applications which show utilization of the two existing

gamma knives in North Carolina has been steadily increasing between FFY 2011-2019. The applicant states the combined Compound Annual Growth Rate (CAGR) for utilization of the two gamma knives in North Carolina between FFY 2011 and FFY 2019 is 7.87 percent. The applicant states that, since the SMFP does not include a methodology to determine the need for additional gamma knives, it submitted a petition to the SHCC for an adjusted need determination for one additional gamma knife which was approved and added to the 2020 SMFP.

Need for a Gamma Knife in HSA III (pages 38-42): There are two existing gamma knives in North Carolina – one at North Carolina Baptist Hospital in Forsyth County (western gamma knife planning region) and one at Vidant Medical Center in Pitt County (eastern gamma knife planning region). The applicant cites data from the North Carolina Office of State Budget and Management (NC OSBM) which projects some of the counties in HSA III will have some of the highest growth rates in the state between 2020 and 2030. The applicant also cites data from NC OSBM projecting the population of people age 65 and older will comprise 13.8 percent of the total population of Mecklenburg County in 2025, which the applicant states is significant because people age 65 and older utilize healthcare services more than people younger than 65. The applicant cites data from ESRI projecting increasing population growth for counties in South Carolina adjacent to HSA III. Finally, the applicant states it treats many radiation therapy patients in Mecklenburg County, particularly at CMC, and CMC is one of the five Academic Medical Center Teaching Hospitals (as defined by the SMFP) in North Carolina.

Need for a Gamma Knife at CMC (pages 42-45): The applicant states CMC has the largest population of radiation therapy patients at any of Atrium's hospitals in the state. The applicant discusses LCI, its recent growth, and the extensive cancer treatments for both common and unique cases provided by LCI. The applicant states LCI is a world-renowned research and academic institution and its headquarters at CMC has recently undergone extensive investments and renovations to increase the number and type of cancer patients that can be seen at LCI. The applicant states the physicians at LCI and local neurosurgeons provide state of the art treatment, participate in advanced research trials, and coordinate patient support, while also developing new techniques for treatment of brain cancer that become worldwide treatment standards. The applicant states locating the gamma knife at CMC and LCI will further assist not only cancer treatment but development of new research on cancer.

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

- The applicant uses reliable data sources to demonstrate projected population growth in HSA III and surrounding areas.
- The applicant adequately supports its assertion that gamma knives are better than other types of SRS procedures for brain and head disorders.
- The applicant adequately demonstrates why the gamma knife is needed as part of LCI on the campus of CMC.

*Projected Utilization*

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

<b>Projected Utilization – CMC/LCI Gamma Knife</b>				
	<b>Partial Interim Year</b>	<b>Project Years</b>		
	<b>July – December 2022</b>	<b>CY 2023</b>	<b>CY 2024</b>	<b>CY 2025</b>
Units	1	1	1	1
Procedures	199	540	687	698

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 identified 12 gamma knife eligible conditions by diagnosis.
- The applicant identified the number of new patients with gamma knife eligible conditions during CY 2019 using the following parameters:
  - Only patients seen at Atrium facilities in HSA III were included.
  - A patient was considered a new patient if the patient was seen at an Atrium facility in HSA III during CY 2019 but not during CY 2018 or CY 2017.
  - Each patient was counted only once regardless of the number of encounters and number of Atrium facilities utilized.
  - Patients were considered to have a gamma knife eligible condition if the diagnosis code for one of the 12 eligible conditions appeared within the first five diagnosis codes in the patient’s record.
- The applicant assumed the number of patients with gamma knife eligible conditions would grow at a CAGR of 1.6 percent through CY 2025, equal to NC OSBM’s projected CAGR for the population of HSA III.
- The applicant consulted with Atrium physicians with experience in SRS and gamma knife treatment to determine the percentage of patients with one of the 12 gamma knife eligible conditions that could be optimally treated with a gamma knife procedure.
- The applicant projected 70 percent of patients who could be optimally treated with a gamma knife procedure would undergo a gamma knife procedure. The applicant states it bases this estimate on an anecdotal understanding of patient choice. The applicant states that, although about half of patients with multiple brain tumors would likely need further gamma knife procedures within one year, the applicant assumes each patient will only receive one gamma knife treatment and no further treatments.

- The applicant projects a ramp-up in gamma knife utilization over the first two and a half years of operation. The applicant projects a ramp-up percentage of 60 percent beginning on July 1, 2022; 80 percent beginning January 1, 2023; and 100 percent beginning January 1, 2024.
- The annual utilization capacity of the gamma knife is 1,020 procedures per year or four procedures per day for 255 days per year.
- The applicant projects to offer services beginning on July 1, 2022. The first three full fiscal years of operation will be CYs 2023-2025.

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

<b>CMC – Gamma Knife Utilization Projections Summarized – July 1, 2022 – December 31, 2025</b>				
	<b>7/1/2022 – 12/31/2022*</b>	<b>FY 1 – CY 2023</b>	<b>FY 2 – CY 2024</b>	<b>FY 3 – CY 2025</b>
# Potential Gamma Knife Patients	1,140	2,318	2,356	2,394
Annual Growth Rate	1.6%	1.6%	1.6%	1.6%
# of Optimal Gamma Knife Patients	475	965	981	997
70% of Optimal Gamma Knife Patients	333	676	687	698
Ramp-up Percentage	60%	80%	100%	100%
Projected Gamma Knife Patients	199	540	687	698
Gamma Knife Capacity (# procedures)	510	1,020	1,020	1,020
Utilization %	39%	53%	67%	68%

\*The number of patients listed for the partial interim year between July 1, 2022 – December 31, 2022 is one-half of the patients listed for CY 2022 in the applicant’s assumptions and methodology.

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

- Historical utilization of the two existing gamma knives in North Carolina grew at a CAGR of 7.87 percent between FFY 2011 and FFY 2019.
- The applicant projected growth of potential gamma knife patients at a rate approximately five times lower than the actual historical CAGR for gamma knife procedures in North Carolina.
- The applicant limited its historical calculations of eligible patients to those with specific diagnoses and to patients seen at Atrium facilities in HSA III.
- Despite physician estimates that approximately half of patients with metastatic brain cancer would require more than one gamma knife treatment, the applicant projected each patient would only receive one gamma knife procedure.
- The applicant consulted with physicians that have experience in SRS treatment to form utilization projections.



- The applicant accounted for patients who would be optimal for gamma knife treatment but who would choose not to pursue the treatment.

### Access

In Section C, page 50, 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. .... As noted in Atrium Health’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 on the basis of race, color, religion, national origin, sex, age, disability or source of payment.’ Atrium Health will continue to serve this population as dictated by the mission of Atrium Health, 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.”*

In Section L, page 88, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>Projected Payor Mix – FY 3 (CY 2025)</b>		
<b>Payor Source</b>	<b>CMC</b>	<b>Gamma Knife</b>
Self-Pay	15.7%	6.7%
Medicare*	27.1%	44.2%
Medicaid*	22.8%	10.9%
Insurance*	32.2%	36.3%
Other**	2.2%	1.8%
Total	100.0%	100.0%

\*Includes Charity Care

\*\*Includes Workers Compensation and TRICARE

The projected payor mix is reasonable and adequately supported because it is based on historical patient origin for the facility and for patients eligible for gamma knife treatment.

### Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.

- The applicant adequately explains why the population to be served needs the services proposed in this application.
  - Projected utilization is reasonable and adequately supported.
  - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (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 the reduction, elimination, or relocation of 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.

C

The applicant proposes to acquire a gamma knife, pursuant to the adjusted need determination in the 2020 SMFP, to be located at CMC in Charlotte.

In Section E, pages 63-64, 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 maintaining the status quo would not address the need for dedicated gamma knife services for patients in HSA III and surrounding areas who wish to receive treatment closer to home and would not address the need for the most current radiation therapy services for the physicians and patients at LCI. Therefore, maintaining the status quo is not an effective alternative.

Develop the Gamma Knife in a Different Location: The applicant states LCI is based on the campus of CMC and hosts LCI's academic and research headquarters. The applicant states CMC has the largest complement of radiation therapy patients out of all Atrium facilities, and states CMC is one of only five Academic Medical Center Teaching Hospitals in North Carolina. Therefore, developing the gamma knife in a different location is not an effective alternative.

On pages 63-64, the applicant states developing the gamma knife on CMC's campus provides HSA III patients access to dedicated gamma knife services closer to home than are currently available, will enable further access to comprehensive cancer care at LCI, and will allow for medical students and residents to train on gamma knife services.

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 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
- 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 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 gamma knife to be located on the campus of Carolinas Medical Center.**
- 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 Sections F and 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 it-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 a gamma knife, pursuant to the adjusted need determination in the 2020 SMFP, to be located at CMC in Charlotte.

**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 Contract(s)	\$2,981,095
Medical Equipment	\$6,858,016
Furniture	\$100,000
A&E/Consultant Fees	\$456,804
Interest during Construction/Financing	\$629,207
Other	\$889,993
<b>Total</b>	<b>\$11,915,115</b>

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

In Section F, page 67, the applicant projects one month of startup expenses in the amount of \$176,754 and 1.5 months of initial operating expenses in the amount of \$265,131 for a total projected working capital cost of \$441,885. On page 67, the applicant provides the assumptions used to project the working capital cost.

**Availability of Funds**

In Section F, pages 66 and 68, the applicant states that the capital cost and the working capital cost, respectively, will be funded via accumulated reserves. On page 66, the applicant states it conservatively included financing costs and costs for interest during construction in the event the applicant decides to fund the project via bond financing.

Exhibit F.2-1 contains a letter from the Executive Vice President and Chief Financial Officer of Atrium Health, stating it will fund the capital cost of \$11,915,115 and working capital costs up to \$750,000 through accumulated reserves. Exhibit F.2-2 contains Atrium Health's Basic Financial Statements and Other Financial Information, which shows that as of December 31, 2018, Atrium Health had adequate cash and assets to fund the capital and working capital costs of the proposed project.

### **Financial Feasibility**

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

<b>Revenues/Operating Expenses – CMC Gamma Knife – FYs 1-3 (CYs 2023-2025)</b>			
	<b>FY 1 (CY 2023)</b>	<b>FY 2 (CY 2024)</b>	<b>FY 3 (CY 2025)</b>
Total Procedures	540	687	698
Total Gross Revenues (Charges)	\$32,322,677	\$42,296,876	\$44,279,147
Total Net Revenue	\$8,899,799	\$11,646,118	\$12,191,921
Average Net Revenue per Procedure	\$16,481	\$16,952	\$17,467
Total Operating Expenses (Costs)	\$3,734,072	\$4,216,615	\$4,311,430
Average Operating Expense per Procedure	\$6,915	\$6,138	\$6,177
Net Income/(Loss)	\$5,165,727	\$7,429,503	\$7,880,491

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

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

- The applicant adequately demonstrates that the capital 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 a gamma knife, pursuant to the adjusted need determination in the 2020 SMFP, to be located at CMC in Charlotte.

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.” On page 399, the 2020 SMFP states: “North Carolina has two gamma knife planning regions (service areas) - the western region (Health Service Areas [HSA] I, II, and III) and the eastern region (HSAs IV, V, and VI)...” In Table 17B-1 on page 399 of the 2020 SMFP, the adjusted need determination identifies the service area for the proposed gamma knife as HSA III. Facilities may also serve residents of counties not included in the service area.

There is currently one gamma knife in the western gamma knife planning region and no gamma knives in HSA III. In Section G, page 72, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved gamma knife services in HSA III. The applicant states:

*“..., North Carolina currently has only two operational gamma knives – one in Forsyth County and one in Pitt County. As such, residents of HSA III, including Mecklenburg County, do not have proximate access to gamma knife services. Given the limited availability of gamma knives in North Carolina, the addition of a gamma knife to HSA III, and more specifically, Mecklenburg County, will not result in any unnecessary duplication of services, but rather, will serve to improve access to the leading treatment for tumors and other disorders of the brain and will offer an opportunity to advance both the research and patient care abilities in the service area.”*

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 an adjusted need determination in the 2020 SMFP for one gamma knife in HSA III.
- The applicant adequately demonstrates the need for a gamma knife at CMC. The discussion regarding need found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

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

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

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

C

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

<b>CMC Gamma Knife Services Projected Staffing</b>	
<b>Position</b>	<b>FYs 1-3 (CYs 2023-2025)</b>
Registered Nurses (RNs)	1.0
Clerical Staff	3.0
Radiation Therapists	2.5
Chief Gamma Knife Physicist	1.0
Dosimetrist	1.0
<b>Total</b>	<b>8.5</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 74-75, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibit H.3. In Section I, page 77, the applicant identifies the proposed co-medical directors. In Exhibit I-3, the applicant provides letters from each of the proposed co-medical directors, stating their intent to serve as co-medical directors 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

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

In Section I, page 76, the applicant states gamma knife patients may utilize any of CMC's ancillary and support services and provides a list of the ancillary and support services that may be necessary for gamma knife patients, including physicist, dosimetry, laboratory, radiology, and pharmacy services, among others.

On page 76, the applicant adequately explains how each ancillary and support service is or will be made available. The applicant provides supporting documentation in Exhibit I.1.

In Section I, pages 76-77, the applicant describes its existing 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

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

In Section K, page 80, the applicant states that the project involves renovating 12,183 square feet of existing space. Line drawings are provided in Exhibit C.1-3.

On October 24, 2019, the Agency determined that a proposal from Atrium to construct a new medical office building on the campus of CMC was exempt from review, pursuant to N.C. Gen. Stat. §131E-184(a)(9). In that request, Atrium proposed to construct and operate a 24,500 square foot medical office building adjacent to and connected to LCI.

In Section C, pages 28-29, the applicant states that it included in the capital expenditures the total cost to develop the space for gamma knife services, including the cost of the core, shell, and upfit for support space and the portions of the building shell and core that are attributable to development of gamma knife services. Thus, while the applicant states that the space will be renovated, it can also be considered new construction.

In Section K, page 80, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

On page 81, 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.

On pages 81-82, 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
- 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.

(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

Atrium does not currently own, operate, or manage any gamma knives anywhere in the state. In Section L, page 87, the applicant provides the historical payor mix for CMC, as shown in the table below.

<b>Historical Payor Mix – CY 2019</b>	
<b>Payor Source</b>	<b>CMC</b>
Self-Pay	15.7%
Medicare*	27.1%
Medicaid*	22.8%
Insurance*	32.2%
Other**	2.2%
Total	100.0%

\*Includes Charity Care

\*\*Includes Workers Compensation and TRICARE

In Section L, page 86, the applicant provides the following comparison.

<b>CMC – CY 2019</b>	<b>% of Total Patients Served at CMC</b>	<b>% of the Population of the Service Area</b>
Female	59.4%	51.9%
Male	40.4%	48.1%
Unknown	0.2%	0.0%
64 and Younger	77.3%	88.8%
65 and Older	22.7%	11.2%
American Indian	0.8%	0.8%
Asian	1.5%	6.4%
Black or African-American	33.8%	32.9%
Native Hawaiian or Pacific Islander	0.2%	0.1%
White or Caucasian	49.1%	57.5%
Other Race	2.2%	2.3%
Declined / Unavailable	12.4%	0.0%

**Sources:** Atrium Health Internal Data, US Census Bureau

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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, page 87, the applicant states that it has no such obligation.

In Section L, page 87, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 88, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>Projected Payor Mix – FY 3 (CY 2025)</b>		
<b>Payor Source</b>	<b>CMC</b>	<b>Gamma Knife</b>
Self-Pay	15.7%	6.7%
Medicare*	27.1%	44.2%
Medicaid*	22.8%	10.9%
Insurance*	32.2%	36.3%
Other**	2.2%	1.8%
Total	100.0%	100.0%

\*Includes Charity Care

\*\*Includes Workers Compensation and TRICARE

As shown in the table above, during the third full fiscal year of operation, the applicant projects 6.7 percent of gamma knife services will be provided to self-pay patients, 44.2 percent to Medicare patients, and 10.9 percent to Medicaid patients.

On page 88, 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 historical patient origin for the facility and for patients eligible for gamma knife treatment.

**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 89, 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

In Section M, page 91, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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 a gamma knife, pursuant to the adjusted need determination in the 2020 SMFP, to be located at CMC in Charlotte.

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.” On page 399, the 2020 SMFP states: “North Carolina has two gamma knife planning regions (service areas) - the western region (Health Service Areas [HSA] I, II, and III) and the eastern region (HSAs IV, V, and VI)...” In Table 17B-1 on page 399 of the 2020 SMFP, the adjusted need determination identifies the service area for the proposed gamma knife as HSA III. Facilities may also serve residents of counties not included in the service area.

There is currently one gamma knife in the western gamma knife planning region and no gamma knives in HSA III.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 93, the applicant states:

*“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to gamma knife services.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 93, the applicant states:

*“Atrium Health intends to develop the proposed gamma knife equipment in space within an MOB that is being developed on the campus of CMC. This represents an efficient use of planned space for development of the proposed services that can be accomplished in a timely and resource-responsible manner. Moreover, Atrium Health believes that there will be long-term financial savings, quality of care benefits, and mortality improvements for patients that will outweigh the capital outlay associated with the acquisition of the gamma knife equipment.”*

Regarding the impact of the proposal on quality, in Section N, page 93, the applicant states:

*“CMC believes that the proposed project will promote safety and quality in the delivery of healthcare services. CMC is known for providing high quality services and expects the proposed project to provide patients significant benefits in terms of safety/quality,*

*access, and value through expanded service offerings while bolstering its high quality standard of care.”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 96, the applicant states:

*“..., there are only two providers of gamma knife services in North Carolina – located in Forsyth County and Pitt County. As such, residents of HSA III, including Mecklenburg County, do not have proximate access to gamma knife services. The proposed project will give residents of HSA III an alternate, more convenient site of care. As such, the proposed project will improve access to gamma knife services by providing patients with local access...”*

*Atrium Health has long-promoted economic access to its services as it historically has provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, [disability], or ability to pay.... The proposed gamma knife service will continue to serve this population...”*

Considering all the information in the application, 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 (see Sections C, F, K, N, and Q of the application and any exhibits)
- Quality (see Sections C, N, and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L, and N of the application and any exhibits)

### **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 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, the applicant identifies the acute care hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 14 acute care hospitals located in North Carolina.

In Section O, page 100, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents of immediate jeopardy occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care 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 14 acute care hospitals, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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 Criteria and Standards for Radiation Therapy Equipment promulgated in 10A NCAC 14C .1900 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

**10 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. Therefore, this Rule is not applicable to this review.
- (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. Therefore, this Rule is not applicable to this review.
- (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, pages 53-54, the applicant provides the number of patients projected to receive gamma knife treatment on gamma knife equipment classified by diagnosis, treatment procedure, and by county of residence.
  - (2) *the maximum number and type of procedures that the proposed equipment is capable of performing.*
  - C- In Section C, page 55, the applicant provides the maximum number and type of procedures the proposed gamma knife is capable of performing. The applicant states the proposed gamma knife has a maximum annual capacity of 1,000 procedures per year, or four procedures per day when used 255 days per year.
- (d) *The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.*
- C- In Section C, pages 53-55, and in Section Q, the applicant documents all assumptions and provides all data supporting the methodology used to determine projected utilization as required in this Rule.