# REQUIRED STATE AGENCY FINDINGS

Decision Date: December 21, 2022 Findings Date: December 21, 2022

Project Analyst: Ena Lightbourne Co-Signer: Micheala Mitchell

Project ID #: F-12272-22

Facility: Atrium Health Union

FID #: 923515 County: Union

Applicant(s): The Charlotte-Mecklenburg Hospital Authority

Project: Acquire a Dedicated CT Simulator

# **REVIEW CRITERIA**

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

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

#### NA

The Charlotte-Mecklenburg Hospital Authority ("applicant" or "CMHA") proposes to acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services.

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 2022 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

### **Policies**

There are no policies in the 2022 SMFP which are applicable to this project.

# 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 Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services.

# **Patient Origin**

N.C.G.S. §131E-176(24a) states: "Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility." The 2022 SMFP does not define a service area for simulators, nor are there any applicable rules adopted by the Department that define the service area for simulators. In Section C, pages 29-31, the applicant defines the primary service area as Union County and the secondary service area as Anson County and the State of South Carolina. Providers may serve residents of counties not included in their service area. According to the 2022 SMFP, there are no other providers of radiation therapy in the primary service area.

The following tables illustrate historical and projected patient origin.

| County           | Atrium Health Union CT Simulator Historical Patient Origin Last Full FY |        |  |  |
|------------------|---|--------|--|--|
| -                | 01/01/2021-12/31/2021<br>Patients % of Total                            |        |  |  |
| Union            | 241   | 71.6%  |  |  |
| Anson            | 42  | 12.4%  |  |  |
| Chesterfield, SC | 31  | 9.3%   |  |  |
| Mecklenburg      | 8   | 2.4%   |  |  |
| Other*           | 14  | 4.3%   |  |  |
| Total            | 336   | 100.0% |  |  |

Source: Section C, page 29

<sup>\*</sup>Other includes Cabarrus, Davidson, Montgomery, Richmond, and Stanly counties and other State counties.

|                  | Atrium Health Union<br>CT Simulator<br>Projected Patient Origin |        |                    |       |                    |        |  |
|------------------|---|--------|--------------------|-------|--------------------|--------|--|
|                  | 1 <sup>st</sup> Fu  |        | 2 <sup>nd</sup> Fi |       | 3 <sup>rd</sup> Fu | ıll FY |  |
| Country          | CY2   | 024    | CY2                | 025   | CY2                | 026    |  |
| County           | Patients  | % of   | Patients           | % of  | Patients           | % of   |  |
|                  | Patients  | Total  | Patients           | Total | Patients           | Total  |  |
| Union            | 288   | 71.6%  | 290                | 71.6% | 292                | 71.6%  |  |
| Anson            | 50  | 12.4%  | 50                 | 12.4% | 50                 | 12.4%  |  |
| Chesterfield, SC | 37  | 9.3%   | 38                 | 9.3%  | 38                 | 9.3%   |  |
| Mecklenburg      | 10  | 2.4%   | 10                 | 2.4%  | 10                 | 2.4%   |  |
| Other *          | 17  | 4.3%   | 17                 | 4.3%  | 18                 | 4.3%   |  |
| Total            | 403   | 100.0% | 405                | 71.6% | 408                | 100.0% |  |

Source: Section C, page 31

In Section C, page 31, the applicant provides the assumptions and methodology used to project its patient origin. The applicant projects patient origin based on the historical patient origin of simulator encounters at Atrium Health Union and does not anticipate an impact on future patient origin. The applicant assumes that one simulation per patient will be performed. The applicant's assumptions are reasonable and adequately supported.

#### **Analysis of Need**

In Section C, pages 33-36, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

• The need for a dedicated CT simulator equipment with specialized features will allow for greater flexibility in patient positioning, provide sharper imaging, and free-up the existing PET-CT scanner, which will allow for flexibility in scheduling CT simulations and accommodating patients in the radiation oncology department. (pages 33-34)

<sup>\*</sup>Other includes Cabarrus, Davidson, Montgomery, Richmond, and Stanly counties and other State counties.

- CMHA's development of new cancer services in Union County, supports the need for the CT simulator. (pages 34-35)
- Population growth in Union County over the last decade has driven increased utilization of oncology services in the county and is projected to continue to increase over the next five years. (pages 35-36)

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

- The growth in cancer cases and the development of new cancer-related services in Union County drives the need for the proposed CT simulator.
- The applicant adequately demonstrates the proposed CT simulator will improve performance and the delivery of radiation therapy services.

# Projected Utilization

In Section Q, Form C.2b, page 2, the applicant provides historical and projected utilization, as illustrated in the following table.

| Atrium Health Union Historical and Interim Utilization |        |        |        |  |  |
|--|--------|--------|--------|--|--|
| 1st 2 <sup>nd</sup> 3rd<br>Full FY Full FY Full F      |        |        |        |  |  |
|  | CY2024 | CY2025 | CY2026 |  |  |
| Linear Accelerators                                    |        |        |        |  |  |
| # of Units   | 1      | 1      | 1      |  |  |
| # of ESTV* Treatments                                  | 7,551  | 7,551  | 7,551  |  |  |
|  |        |        |        |  |  |
| CT Simulator   |        |        |        |  |  |
| # of Units   | 1      | 1      | 1      |  |  |
| # of Procedures  |        |        |        |  |  |
| (Simulations)  | 403    | 405    | 408    |  |  |

<sup>\*</sup>Equivalent Simple Treatment Visit

In Section Q, Form C Utilization-Assumption and Methodology, pages 1-2, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The proposed project is projected to become operational on January 1, 2024. The first three full fiscal years of the project is CY 2024, CY 2025, and CY 2026.
- The applicant states that Atrium Health Union began using its diagnostic PET-CT scanner for all of its radiation therapy simulation approximately four and a half years ago. The applicant begins with the historical simulations performed on the existing PET-CT scanner, as illustrated in the table below.

| Atrium Health Union                                      |     |     |     |     |      |
|--|-----|-----|-----|-----|------|
| Historical Simulations on PET-CT Scanner                 |     |     |     |     |      |
| CY 2019 CY 2020 CY 2021 CY 2022* CY 2019 – CY 2022 CAGR^ |     |     |     |     |      |
| Simulations on   |     |     |     |     |      |
| PET-CT Scanner   | 391 | 345 | 336 | 398 | 0.6% |

Source: Section Q, Form C Utilization-Assumptions and Methodology, page 1; CMHA Internal data \*Annualized based on January to June data.

According to the CMHA internal data, the simulation utilization grew annually 0.6% from CY 2019 to CY 2022. The applicant states that although the facility saw a decline in CY 2020 and CY 2022 due to the pandemic, simulation volume rebounded 18.5% from CY 2021 to CY 2022. The applicant states that this demonstrates that simulation volumes will return to consistent growth in the future.

• The applicant states that upon project completion, 100% of simulation volume will shift from the PET-CT scanner to the proposed CT simulator. The applicant conservatively projects that CT simulation volume will continue to grow at the historical growth rate of 0.6%.

| Atrium Health Union Projected CT Simulations    |     |     |     |     |     |                               |
|---|-----|-----|-----|-----|-----|-------------------------------|
| CY 2022* CY 2023 CY 2024 CY 2025 CY 2026 CY 202 |     |     |     |     |     | CY 2022 –<br>CY 2026<br>CAGR^ |
| CT Simulations                                  | 398 | 400 | 403 | 405 | 408 | 0.6%                          |

Source: Section Q, Form C Utilization-Assumptions and Methodology, page 1; CMHA Internal data

• The applicant states that CT simulation supports radiation therapy services and includes the historical and projected linear accelerator utilization at Atrium Health Union. The applicant project that volumes will remain consistent with CY 2021 volume.

|   | Atrium Health Union                                   |       |       |       |      |  |
|---|---|-------|-------|-------|------|--|
|   | Historical ESTVs (Equivalent Simple Treatment Visits) |       |       |       |      |  |
| CY 2019 CY 2020 CY 2021 CY 2022* CY 2021 – CY 2022 Growth |   |       |       |       |      |  |
| ESTVs   | 8,473   | 7,878 | 7,551 | 8,032 | 6.4% |  |

Source: Section Q, Form C Utilization-Assumptions and Methodology, page 2; CMHA Internal data \*Annualized based on January to June data.

<sup>^</sup>Compound Annual Growth Rate

<sup>\*</sup>Annualized based on January to June data.

<sup>^</sup>Compound Annual Growth Rate

| Atrium Health Union<br>Historical ESTVs |       |       |       |       |      |
|---|-------|-------|-------|-------|------|
| CY 2023                                 |       |       |       |       |      |
| ESTVs                                   | 7,551 | 7,551 | 7,551 | 7,551 | 6.4% |

Source: Section Q, Form C Utilization-Assumptions and Methodology, page 2; CMHA Internal data \*Annualized based on January to June data.

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

- The applicant's projections are supported by the historical growth of simulation volume at Atrium Health Union.
- The applicant's projected growth rate is conservative and supported by the rebound of simulation volume despite the impacted by the pandemic.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

#### NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

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The applicant proposes to acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services.

In Section E, page 54, the applicant describes the alternative it considered and explains why the alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternative considered was:

Maintain the Status Quo-The applicant states that Atrium Health union is currently performing all simulations on its existing diagnostic PET CT scanner. However, the PET-CT scanner is not designed for radiation therapy simulations. Patients are required to travel outside of the county to receive services at Atrium Health Pineville's busy radiation therapy program. The applicant states that scheduling simulations is difficult because the existing PET-CT scanner needs to be available for inpatient and outpatient PET procedures. Therefore, this alternative was dismissed.

On page 54, the applicant states that its proposal is the most effective alternative because the proposed CT simulator will provide essential features for simulation, full capacity for 4D imaging, and the flexibility to schedule and accommodate patients.

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

- The proposed CT simulator will allow the facility to enhance radiation therapy services without having to rely on its PET-CT scanner and will relieve patients of the burden of traveling outside of the county to received services.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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 certificate holder shall acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union.
- 3. Upon completion of the project, Atrium Health Union shall be licensed for no more than one CT simulator.

### 4. Progress Reports:

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
- b. The certificate holder shall complete all sections of the Progress Report form.

- c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
- d. The first progress report shall be due on June 1, 2023.
- 5. The certificate holder shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Sections F and Q of the application and that would otherwise require a certificate of need.
- 6. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
  - a. Payor mix for the services authorized in this certificate of need.
  - b. Utilization of the services authorized in this certificate of need.
  - c. Revenues and operating costs for the services authorized in this certificate of need.
  - d. Average gross revenue per unit of service.
  - e. Average net revenue per unit of service.
  - f. Average operating cost per unit of service.
- 7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

 $\mathbf{C}$ 

The applicant proposes to acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services.

In Section Q, Form F.1a, page 4, the applicant projects the total capital cost of the project, as shown in the table below.

| Atrium Health Union                       |             |  |  |  |
|---|-------------|--|--|--|
| Capital Costs                             |             |  |  |  |
| Construction/Renovation Contract(s)       | \$578,400   |  |  |  |
| Architecture/Engineering Fees             | \$59,600    |  |  |  |
| Medical Equipment                         | \$360,200   |  |  |  |
| Consultant Fees (CON and Legal)           | \$85,000    |  |  |  |
| Other (IS, Security, Internal Allocation) | \$202,600   |  |  |  |
| Total                                     | \$1,285,800 |  |  |  |

In Section Q, Form F.1a, page 5, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is derived from reasonable and adequately supported assumptions that are based on the applicant's and the architecture's experience with similar projects.

In Section F, page 57, the applicant states that there will be no start-up or initial operating costs because the proposal involves installing the equipment in an existing, renovated space, that is part of ongoing operations.

### **Availability of Funds**

In Section F, page 55, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing** 

| Туре                             | СМНА        | Total       |
|----------------------------------|-------------|-------------|
| Loans                            | \$0         | \$0         |
| Accumulated reserves or OE *     | \$1,285,800 | \$1,285,800 |
| Bonds                            | \$0         | \$0         |
| Other (\$100 per square foot up- |             |             |
| fit allowance within the lease)  | \$0         | \$0         |
| Total Financing                  | \$1,285,800 | \$1,285,800 |

<sup>\*</sup> OE = Owner's Equity

Exhibit F.2 contains a letter dated September 25, 2022, from the Executive Vice-President and Chief Financial Officer of the CMHA, stating that the project will be funded using CMHA's accumulated reserves. Exhibit F-2 also contains a copy of the December 31, 2021 Consolidated Balance Sheets from Atrium Health Enterprises, stating that CMHA had over \$7 million in cash and equivalents and over \$2 billion in total net assets available to fund the project. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that

revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

| Atrium Health Union               | 1 <sup>st</sup> FFY<br>CY 2024 | 2 <sup>nd</sup> FFY<br>CY 2025 | 3 <sup>rd</sup> FFY<br>CY 2026 |
|-----------------------------------|--------------------------------|--------------------------------|--------------------------------|
| Total Procedures and ESTV         |                                |                                |                                |
| Treatments                        | 7,954                          | 7,956                          | 7,959                          |
| Total Gross Revenues (Charges)    | \$39,454,063                   | \$40,637,685                   | \$41,856,816                   |
| Total Net Revenue                 | \$8,834,106                    | \$9,099,130                    | \$9,372,104                    |
| Average Net Revenue per Treatment | \$1,111                        | \$1,144                        | \$1,178                        |
| Total Operating Expenses (Costs)  | \$3,250,478                    | \$3,368,602                    | \$3,491,854                    |
| Average Operating Expense per     |                                |                                |                                |
| Treatment                         | \$409                          | \$423                          | \$439                          |
| Net Income                        | \$5,583,628                    | \$5,730,528                    | \$5,880,250                    |

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

- The applicant projects patient services gross revenue based on the projected payor mix for each project year and projected payor mix is based on Atrium Health Union's CY2021 actual payor mix.
- Projected average charge is based on CY 2021 average charge per treatment for linear accelerator services (including CT simulations) inflated 3.0% per year.
- Adjustments to gross revenue such as charity care, contractual adjustments and bad debts are based on Atrium Health Union's CY2021 actual experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

#### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

 $\mathbf{C}$ 

The applicant proposes to acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services.

N.C.G.S. §131E-176(24a) states: "Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility." The 2022 SMFP does not define a service area for simulators, nor are there any applicable rules adopted by the Department that define the service area for simulators. In Section C, pages 29-31 the applicant defines the primary service area as Union County and the secondary service area includes Anson County and the state of South Carolina. Providers may serve residents of counties not included in their service area. According to the 2022 SMFP, there are no other providers of radiation therapy in the primary service area.

In Section G, page 65, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved CT simulation services in Union County. The applicant states:

"Atrium Health is the only facility in Union County that offers CT simulation. It is also the only facility with a linear accelerator...diagnostic CT scanners, such as the CT component of the existing PET-CT scanner at Atrium Health Union, and CT simulators offer distinct features and address different clinical needs despite using the same underlying technology."

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:

- Atrium Health Union is the only facility in Union County that offers CT simulation.
- The applicant's proposal will enhance access to care by Union County residents by alleviating the burden of traveling outside of the county to receive services.

#### Conclusion

The Agency reviewed the:

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

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

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

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The applicant proposes to acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services.

In Section Q, Form H, page 12, the applicant provides historical and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

|                         | Historical FTE Staff |  | Projected FTE<br>Staff                           |  |
|-------------------------|----------------------|--|--|--|
| Position                | As of 12/31/2021     | 1 <sup>st</sup> Full<br>Fiscal Year<br>(CY 2024) | 2 <sup>nd</sup> Full<br>Fiscal Year<br>(CY 2025) | 3 <sup>rd</sup> Full<br>Fiscal Year<br>(CY 2026) |
| Radiology Technologists | 3.8                  | 4.3  | 4.5  | 4.5  |
| Registered Nurse        | 1.6                  | 1.6  | 1.6  | 1.8  |
| Administrative Director | 0.5                  | 0.5  | 0.5  | 0.5  |
| Chief RTT/Asst Director | 1.0                  | 1.0  | 1.0  | 1.0  |
| Clinical Coordinator    | 2.0                  | 2.3  | 2.3  | 2.3  |
| Physicist               | 1.0                  | 1.0  | 1.0  | 1.0  |
| Dosimetrist             | 1.0                  | 1.0  | 1.0  | 1.0  |
| Total                   | 10.9                 | 11.7   | 11.9   | 12.1   |

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 67-69, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- CMHA has two schools of nursing within its system to recruit nursing staff.
- CMHA recruits non-nursing staff through traditional means such as the hospital website, advertising in professional journals, job posting websites, career fairs, and implementing strategies to attract and recruit staff.
- Continuing education is required in addition to maintaining performance standards and competency levels specific to the position.

# Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

 $\mathbf{C}$ 

The applicant proposes to acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services.

# **Ancillary and Support Services**

In Section I, page 70, the applicant identifies the necessary ancillary and support services for the proposed services. The applicant also explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based Atrium Health Union's status as a full-service acute care hospital with all necessary ancillary and support services in place.

### **Coordination**

In Section I, page 71, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based the facility's established relationships with area healthcare and social service providers.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

The applicant proposes to acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services.

In Section K, page 74, the applicant states that the project involves renovating 640 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

On pages 74-75, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant is proposing to develop a CT simulator in an existing space which is more cost-effective than constructing a new space.
- The proposed equipment will improve quality and access to simulation services.

On page 75, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The construction costs are necessary to develop the project to allow the provision of essential CT simulation services.
- CMHA sets aside excess revenues to develop projects without increasing the costs or charges to pay for projects.

On pages 75-76, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

#### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

 $\mathbf{C}$ 

In Section L, page 79, the applicant provides the historical payor mix during CY 2021 for the proposed services, as shown in the table below.

| Atrium Health Union<br>Historical Payor Mix<br>01/01/2021-12/31/2021 |          |  |  |
|--|----------|--|--|
| Payor  | Percent  |  |  |
| Category   | of Total |  |  |
| Self-Pay   | 8.1%     |  |  |
| Charity Care <sup>^</sup>  |          |  |  |
| Medicare*  | 41.7%    |  |  |
| Medicaid*  | 14.9%    |  |  |
| Insurance*   | 33.0%    |  |  |
| Workers Compensation^^   |          |  |  |
| TRICARE^^  |          |  |  |
| Other  | 2.3%     |  |  |
| Total  | 100.0%   |  |  |

<sup>\*</sup>Including any managed care plans.

In Section L, page 80, the applicant provides the following comparison.

<sup>^</sup>CMHA internal data does not include charity care as a payor source. Patients in any category can receive charity care.

<sup>^^</sup>Included in Other payor category.

| Atrium Health Union        | Percentage of Total Patients Served by the Facility or Campus during the Last Full FY | Percentage of the<br>Population of the<br>Service Area |
|----------------------------|---|--|
| Female                     | 56.7%   | 50.4%  |
| Male                       | 43.2%   | 49.6%  |
| Unknown                    | 0.1%  | 0.0%   |
| 64 and Younger             | 64.7%   | 86.8%  |
| 65 and Older               | 35.3%   | 13.2%  |
| American Indian            | 0.6%  | 0.7%   |
| Asian                      | 1.5%  | 4.2%   |
| Black or African-American  | 22.8%   | 12.6%  |
| Native Hawaiian or Pacific |   |  |
| Islander                   | 0.1%  | 0.1%   |
| White or Caucasian         | 69.9%   | 80.2%  |
| Other Race                 | 1.0%  | 2.2%   |
| Declined / Unavailable     | 4.1%  | 0.0%   |

<sup>\*</sup>The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <a href="https://www.census.gov/quickfacts/fact/table/US/PST045218">https://www.census.gov/quickfacts/fact/table/US/PST045218</a>. Just enter in the name of the county.

# The Agency reviewed the:

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

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

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

 $\mathbf{C}$ 

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 81, the applicant states:

"Atrium Health Union has 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, Atrium Health Union 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 82, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

 $\mathbf{C}$ 

In Section L, page 83, 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.

| Atrium Health Union (CT Simulator)<br>Projected Payor Mix<br>3 <sup>rd</sup> Full FY, CY 2026 |          |  |
|---|----------|--|
| Payor   | Percent  |  |
| Category  | of Total |  |
| Self-Pay  | 1.1%     |  |
| Charity Care^   |          |  |
| Medicare*   | 53.0%    |  |
| Medicaid*   | 6.9%     |  |
| Insurance*  | 33.8%    |  |
| Workers   |          |  |
| Compensation^^  |          |  |
| TRICARE^^   |          |  |
| Other   | 5.2%     |  |
| Total   | 100.0%   |  |

<sup>\*</sup>Including any managed care plans.

<sup>^</sup>CMHA internal data does not include charity care as a payor source. Patients in any category can receive charity care.

<sup>^^</sup>Included in Other payor category.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.1% of total services will be provided to self-pay patients, 53.0% to Medicare patients and 6.9% to Medicaid patients.

On page 82, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the historical payor mix of the existing facility. The applicant does not anticipate any changes that would impact the payor mix.

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.

 $\mathbf{C}$ 

In Section L, page 84, 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

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

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

C

The applicant proposes to acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services.

In Section M, page 86, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting

documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on CMHA's existing relationships with health professional training programs in the service area, and their contractual agreement with the Charlotte Area Health Education Center (AHEC) to produce education programs across several counties.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire one dedicated CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services.

N.C.G.S. §131E-176(24a) states: "Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility." The 2022 SMFP does not define a service area for simulators, nor are there any applicable rules adopted by the Department that define the service area for simulators. In Section C, pages 29-31 the applicant defines the primary service area as Union County and the secondary service area as Anson County and the State of South Carolina. Providers may serve residents of counties not included in their service area. According to the 2022 SMFP, there are no other providers of radiation therapy in the primary service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 88, the applicant states:

"The proposed project is expected to enhance competition in the service area and beyond by promoting cost effectiveness, quality, and access to CT simulation services."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 88, the applicant states:

"The proposed project to acquire a CT simulator at Atrium Health Union will eliminate the need for patients to be referred to Atrium Health Pineville and will allow patients to remain in Union County for their care. CMHA believes the proposed project is the most cost-effective way to better serve the radiation therapy patients who choose Atrium Health Union."

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

Regarding the impact of the proposal on quality, in Section N, page 89, the applicant states:

"The proposed project will serve to improve the quality of radiation therapy and simulation provided in Union County. At present, Atrium Health Union provides exceptional services, by specialized CT simulation equipment will increase the effectiveness, quality, and experience of patient care."

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 89, the applicant states:

"CMHA 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, handicap, or ability to pay...

...

By ensuring access for CMHA's patients, the proposed project will foster competition for radiation therapy and CT simulation services in Union County and the surrounding region, propelling other providers to maximize the level of access to their services, regardless of the patient's payor source."

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

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

1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in

- an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

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

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

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

C

In Section Q, Form O, page 14, 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 11 of this type of facility located in North Carolina.

In Section O, page 93, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents resulting in immediate jeopardy had not 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, two facilities were surveyed and cited for incidences related to Emergency Medical Treatment and Labor Act (EMTALA). Final outcome of both citations is pending as of the date of this review. 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 11 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.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and

may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to acquire one CT simulator and renovate an existing space to house the CT simulator at Atrium Health Union. The applicant is proposing to use the simulator to support radiation therapy services. There are no administrative rules that are applicable to this proposal. Therefore, this Criterion is not applicable.