

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 28, 2020

Findings Date: September 28, 2020

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: F-11902-20

Facility: Levine Cancer Institute-Union West

FID #: 200465

County: Union

Applicant: The Charlotte-Mecklenburg Hospital Authority

Project: Develop a new location of Levine Cancer Institute-Union West, including a hematology/ oncology clinic and outpatient infusion therapy services, in a MOB currently under development on the campus of Atrium Health Union West

### 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 applicant, The Charlotte-Mecklenburg Hospital Authority (CMHA) doing business as (d/b/a) Atrium Health d/b/a Atrium Health Union proposes to develop a new location of Levine Cancer Institute (LCI), to be known as Levine Cancer Institute-Union West (LCI-Union West), in a medical office building (MOB) currently under development on the campus of Atrium Health Union West, which is also currently under development. LCI is a network of unlicensed, provider-based cancer care centers that include a hematology/oncology clinic and outpatient infusion therapy services. LCI has multiple locations throughout North Carolina and LCI-Union West, if approved, would be in addition to the existing locations.

## **Need Determination**

The applicant does not propose to develop any beds or services for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP). Further, the applicant does not propose to acquire any medical equipment for which there is a need determination in the 2020 SMFP.

## **Policies**

There is one policy in the 2020 SMFP applicable to this review.

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 22-23, and Section K.3, pages 71-72, 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 because the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 in that it 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 develop a new, additional location of Levine Cancer Institute-Union West, in a MOB currently under development on the campus of Atrium Health Union-West.

#### **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 2020 SMFP does not define a service area for an unlicensed, provider-based cancer care center that includes a hematology/oncology clinic and outpatient infusion therapy services, nor are there any applicable rules adopted by the Department that define the service area for an unlicensed, provider-based, cancer care center. Thus, the service area in this review is as defined by the applicant.

In Section C, page 29, the applicant defines the service area by the following ZIP codes: 28079, 28104, 28110 and 28173, all of which are in western Union County and by ZIP codes 28227 and 28105 which are in eastern Mecklenburg County. Facilities may also serve residents not included in their service area.

The following tables illustrate projected patient origin.

**Clinic Visits: Projected Patient Origin**

County	1st Full FY of Operation following Project Completion (CY2022)		2nd Full FY of Operation following Project Completion (CY2023)		3rd Full FY of Operation following Project Completion (CY2024)	
	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients	% of Total
Union	1,887	64.5%	2,991	64.5%	4,580	64.5%
Mecklenburg	1,038	35.5%	1,646	35.5%	2,521	35.5%
Total	2,925	100.0%	4,638	100.0%	7,100	100.0%

Source: Section C.3, page 29.

**Infusion Therapy Bay Visits: Projected Patient Origin**

County	1st Full FY of Operation following Project Completion (CY2022)		2nd Full FY of Operation following Project Completion (CY2023)		3rd Full FY of Operation following Project Completion (CY2024)	
	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients	% of Total
Union	1,226	64.5%	1,943	64.5%	2,975	64.5%
Mecklenburg	675	35.5%	1,070	35.5%	1,637	35.5%
Total	1,900	100.0%	3,013	100.0%	4,612	100.0%

Source: Section C.3, page 29.

In Section C, page 29-30, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on historical patient origin of existing LCI patients from western Union County and eastern Mecklenburg County receiving hematology/oncology clinic and outpatient infusion therapy services.

**Analysis of Need**

In Section C.4, pages 30-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- the need for geographic accessibility of LCI cancer services, including hematology/oncology clinic services and infusion therapy services, in western Union County and surrounding counties (pages 32-34).
- The high rate of projected population growth in Union County as a whole and in the western Union County and eastern Mecklenburg County service area ZIP codes specifically (pages 34-37).
- The growth of the over 65 years of age population in Union County as a whole (page 36).

- Projected increases in cancer incidence in Union County which will drive the demand for cancer services (pages 37-38).
- Atrium Health is currently developing a new hospital campus, Atrium Health Union West and the proposed LCI- Union West would be in a medical office building (MOB) currently being developed on the campus of Atrium Health Union West (pages 31 and 37).
- The proposed hospital-based infusion therapy services and hematology/oncology clinic services are needed in the western part of Union County and surrounding communities are part of Atrium Health’s overall focus of bringing cancer care closer to where patients live and work (pages 30-31).

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

- The applicant uses clearly cited and reasonable historical and demographic data to identify the population to be served, its projected growth and aging, and the need the identified population has for the proposed services;
- The applicant demonstrated the need for hematology/oncology clinic services and infusion therapy services for residents of western Union County and eastern Mecklenburg County.
- The applicant factored in the development of Atrium Health Union West and the location of other Levine Cancer Institute facilities.

*Projected Utilization*

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

<b>LCI-Union West- Projected Utilization</b>			
	<b>OY1*</b> <b>CY2022</b>	<b>OY2</b> <b>CY2023</b>	<b>OY3</b> <b>CY2024</b>
<b>Infusion Therapy Services</b>			
# of Bays	22	22	22
Blood Transfusion Visits	74	117	179
Infusion Therapy Visits	1,382	2,190	3,353
Injection Visits	445	705	1,080
<b>Clinic Visits</b>			
# of Exam Rooms	26	26	26
Clinic Visits	2,925	4,638	7,100
<b>Ancillary Services</b>			
Pharmacy Cases	3,958	6,276	9,608
Lab Procedures	3,735	5,922	9,066
<b>Total</b>	<b>12,519</b>	<b>19,848</b>	<b>30,386</b>

Source: Section Q, Form C

\*Operating Year (OY)

In Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

*Step 1: Project Number of Providers at LCI-Union West*

**LCI-Union West Projected Providers**

	<b>OY1 CY2022</b>	<b>OY2 CY2023</b>	<b>OY3 CY2024</b>
# of Physicians	2.0	2.5	3.5
# of ACPs*	0.0	1.0	1.0
<b>Total Providers</b>	<b>2.0</b>	<b>3.5</b>	<b>4.5</b>

\*Advanced Care Practitioner (ACP)

The applicant projects to add 4.5 newly recruited providers based on its historical success in recruiting providers to LCI facilities. Further, Atrium Health states that if its planned recruitment falls short it is committed to identifying existing providers to shift and/or rotate to LCI-Union West to assure that the clinic fully staffed until such time as five new providers have been successfully recruited.

*Step 2: Project Clinic Visits*

**Projected Clinic Visits: LCI-Union West**

	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>
# of Physicians*	2.0	2.5	3.5
Clinic Visits Per Physician	2,250	2,250	2,250
<b>Total Physician Clinic Visits</b>	<b>4,500</b>	<b>5,625</b>	<b>7,875</b>
# of ACPs*	0.0	1.0	1.0
Clinic Visits per ACP	1,000	1,000	1,000
<b>Total ACP Clinic Visits</b>	<b>0</b>	<b>1,000</b>	<b>1,000</b>
<b>Total Projected # of Clinic Visits</b>	<b>4,500</b>	<b>6,625</b>	<b>8,875</b>
Ramp Up %	65.0%	70.0%	80.0%
<b>Total Projected # of Clinic Visits</b>	<b>2,925</b>	<b>4,638</b>	<b>7,100</b>

\*From Step #1.

- The applicant based its projections on the number of clinic visits per physician and the number of clinic visits per ACP on its historical experience at other LCI facilities in community-based settings, including LCI-Union.
- To be conservative, the applicant incorporated a “ramp up” which only reached 80% in the third project year.
- The applicant states that in CY2019 existing LCI facilities provided approximately 14,132 clinic visits to patients residing in western Union County and eastern Mecklenburg County.

*Step 3: Project Infusion Therapy Visits*

Based on historical utilization from CY2019 at LCI-Union, the applicant calculated the ratio of infusion therapy visits to clinic visits as illustrated in the table below.

**Historical Utilization: LCI-Union**

	<b>CY2019</b>
Clinic Visits	9,028
Infusion Therapy Visits	4,264
Ratio: Infusion Therapy Visits per Clinic Visit	0.47

The applicant then applied the ratio of infusion therapy visit per clinic visit to the projected number of clinic visits at LCI-Union for OY1 to OY3 as shown in the following table.

	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>
# of Clinic Visits	2,925	4,638	7,100
Ratio: Infusion Therapy Visits to Clinic Visits	0.47	0.47	0.47
Total Infusion Therapy Visits	1,382	2,190	3,353

*Step 4: Project Blood Transfusion Service Visits*

	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>
# of Clinic Visits	2,925	4,638	7,100
Ratio: Blood Transfusion Visits to Clinic Visits	0.025	0.025	0.025
Total Blood Transfusion Visits	74	117	179

The applicant utilized historical data from Atrium Health Union to calculate the ratio of blood transfusion visits to LCI-Union clinic visits. Outpatient blood transfusions performed at Atrium Health Union were used as LCI-Union does not provide blood transfusion services, instead LCI-Union oncology patients receive outpatient transfusion services at Atrium Health Union. The applicant then applied the ratio to the projected number of clinic visits determined in Step 2 to project blood transfusion visits for OY1 to OY3.

*Step 5: Project Injection Visits*

	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>
# of Clinic Visits	2,925	4,638	7,100
Ratio: Injection Visits to Clinic Visits	0.15	0.15	0.15
Total Injection Visits	445	705	1,080

Utilizing historical data from LCI-Union, the applicant calculated the ratio of injection visits to clinic visits and applied the ratio to the projected number of clinic visits determined in Step 2 to project injection visits for OY1 to OY3.

*Step 6: Project Ancillary Pharmacy Cases*

	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>
# of Clinic Visits	2,925	4,638	7,100
Ratio: Pharmacy Cases per Clinic Visit	1.35	1.35	1.35
Total Pharmacy Cases	3,958	6,276	9,608

Utilizing historical data from LCI-Union, the applicant calculated the ratio of pharmacy cases to clinic visits and applied the ratio to the projected number of clinic visits determined in Step 2 to project pharmacy cases for OY1 to OY3.

*Step 7: Project Ancillary Lab Procedures*

	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>
# of Clinic Visits	2,925	4,638	7,100
Ratio: Lab Procedures per Clinic Visit	1.28	1.28	1.28
Total Lab Procedures	3,735	5,922	9,066

Utilizing historical data from LCI-Union, the applicant calculated the ratio of lab procedures to clinic visits and applied the ratio to the projected number of clinic visits determined in Step 2 to project lab procedures for OY1 to OY3.

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

- The applicant uses historical data and experience to project providers, clinical visits, and ratios to project the number of clinic visits, infusion therapy services, injection visits, blood transfusion visits, pharmacy cases and lab procedures.
- The applicant conservatively projects clinic visits at 65%, 70% and 80% for OY1-OY3, respectively.
- The applicant identified the number of patients (approximately 14,132) who reside in western Union County and eastern Mecklenburg County already utilizing LCI facilities.
- The applicant factored in capacity of the 22 proposed infusion therapy bays.
- The applicant committed to shifting existing providers to the proposed LCI-Union West facility if recruitment of new physicians and/or ACPs did not meet projections.

**Access**

In Section C, page 43, the applicant states, “As a provider-based, unlicensed facility of Atrium Health Union, LCI-Union West will provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment.”

The applicant provides the estimated percentage for each medically underserved group for the third full fiscal year (CY2024), as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients Served- Infusion Bay Visits</b>	<b>Percentage of Total Patients Served- Clinic Visits</b>
-------------------------------------	---	---



Racial and ethnic minorities	29.7%	29.7%
Women	61.3%	61.3%
The elderly	46.6%	46.6%
Medicare beneficiaries	52.2%	43.2%
Medicaid recipients	6.5%	3.7%

Source: Section C.11, page 44

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

### **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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services 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 to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to develop a new, additional location of Levine Cancer Institute-Union West, in a MOB currently under development on the campus of Atrium Health Union-West.

In Section E, pages 53-54, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo- The applicant states that this alternative would not address the need for comprehensive cancer care closer to where patients reside. Thus, this alternative is not the most effective alternative.
- Develop the Project the Existing LCI-Union facility-The applicant states that developing the project at its existing LCI-Union location would not improve access to residents of western Union County or surrounding counties, the LCI-Union facility was not large enough to house additional infusion bays, and the LCI-Union footprint could not meet growing demand for increased infusion therapy capacity, hematology/oncology clinic space and supportive oncology services such as nutrition, social work, palliative medicine, rehabilitation and survivorship. Thus, this alternative is not the most effective alternative.

On pages 53-54, the applicant states that its proposal is the most effective alternative because it will offer a more accessible location for standardized, high quality hematology/oncology clinic and outpatient infusion therapy services as well as supportive oncology services for patients residing in western Union County and surrounding counties which existing LCI locations cannot provide.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- 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 (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

- 2. The certificate holder shall develop a new location of Levine Cancer Institute-Union West, including a hematology/ oncology clinic and outpatient infusion therapy services, in a MOB currently under development on the campus of Atrium Health Union West.**
- 3. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 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. Progress reports shall be due on the first day of every third month. The first progress report shall be due on January 1, 2021. The second progress report shall be due on April 1, 2021 and so forth.**
- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. 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 certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
  - a. Payor mix for the services authorized in this certificate of need.**
  - b. Utilization of the services authorized in this certificate of need.**
  - c. Revenues and operating costs for the services authorized in this certificate of need.**
  - d. Average gross revenue per unit of service.**
  - e. Average net revenue per unit of service.**
  - f. Average operating cost per unit of service.**

**7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new, additional location of Levine Cancer Institute-Union West, in a MOB currently under development on the campus of Atrium Health Union-West.

**Capital and Working Capital Costs**

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

Site Costs	\$0.00
Construction Costs	\$9,418,318
Miscellaneous Costs	\$5,704,717
<b>Total</b>	<b>\$15,123,035</b>

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

In Section F, page 57, the applicant projects there will be no start-up or initial operating expenses for the project because Atrium Health Union, which is an existing licensed acute care hospital, operates a similar service in Monroe, LCI-Union.

**Availability of Funds**

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

Type	CMHA	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$15,123,035	\$15,123,035
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$15,123,035</b>	<b>\$15,123,035</b>

\* OE = Owner's Equity

In Section F, pages 55-56, the applicant states that the capital costs for the project will be funded by accumulated reserves of CMHA d/b/a Atrium Health. In Section F, page 56, the applicant states that the Chief Financial Officer (CFO) of Atrium Health has documented the

availability of funds for this project. Exhibit F.2-1 contains a letter dated June 15, 2020 from the CFO documenting that the funds will be made available for the capital costs of the project. Exhibit F.2-2 also contains the audited financial statements for Atrium Health which indicated the health system had \$370,103,000 million in cash and cash equivalents, \$12.2 billion in assets, and \$7.2 billion in net assets, as of December 31, 2019.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed 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.2, the applicant projects that revenues will exceed operating expenses in the second and third operating years of the project, as shown in the table below.

	<b>1<sup>st</sup> Full Fiscal Year (CY2022)</b>	<b>2<sup>nd</sup> Full Fiscal Year (CY2023)</b>	<b>3<sup>rd</sup> Full Fiscal Year (CY2024)</b>
Total Procedures	12,519	19,848	30,386
Total Gross Revenues (Charges)	\$21,263,829	\$34,724,560	\$54,758,105
Total Net Revenue	\$5,725,444	\$9,349,846	\$14,744,026
Average Net Revenue per Procedure	\$457	\$471	\$485
Total Operating Expenses (Costs)	\$6,425,658	\$8,947,588	12,687,135
Average Operating Expense per Procedure	\$513	\$451	\$418
<b>Net Income</b>	<b>(\$700,214)</b>	<b>\$402,258</b>	<b>\$2,056,891</b>

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

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

### C

The applicant proposes to develop a new, additional location of Levine Cancer Institute-Union West, in a MOB currently under development on the campus of Atrium Health Union-West.

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 2020 SMFP does not define a service area for an unlicensed, provider-based cancer care center that includes a hematology/oncology clinic and outpatient infusion therapy services, nor are there any applicable rules adopted by the Department that define the service area for an unlicensed, provider-based, cancer care center. Thus, the service area in this review is as defined by the applicant.

In Section C, page 29, the applicant defines the service area by the following ZIP codes: 28079, 28104, 28110 and 28173, all of which are in western Union County and by ZIP codes 28227 and 28105 which are in eastern Mecklenburg County. Facilities may also serve residents not included in their service area.

In the defined service areas, the applicant states in Section G, on page 62 of the application, that it is only aware of one other existing or approved facility, Novant Health Matthews Medical Center, as providing infusion therapy within the defined service area. The applicant further states that utilization data for hematology/oncology clinic and outpatient infusion therapy is not publicly available.

In Section G, page 62, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved hematology/oncology clinic and outpatient infusion therapy services in the defined service area. The applicant states: “*the need for the project is driven by the unmet need for cancer services, including hematology/oncology clinic and outpatient infusion therapy services, in western Union County and surrounding areas. LCI patients residing in western Union County must travel to either Monroe or Mecklenburg County, often along heavily congested roads to access cancer care.*”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed cancer care center including hematology/oncology clinic and outpatient infusion therapy services is needed. The discussion regarding need 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 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

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

Position	Projected FTE Staff- Therapy Bays		
	1 <sup>st</sup> Full Fiscal Year (1/1/22-12/31/22)	2 <sup>nd</sup> Full Fiscal Year (1/1/23-12/31/23)	3 <sup>rd</sup> Full Fiscal Year (1/1/24 to 12/31/24)
Registered Nurses	1.7	2.7	4.1
Lab Techs	0.2	0.3	0.4
Pharmacists	0.7	1.1	1.7
Pharmacy Techs	0.5	0.8	1.2
Other (Supervisory)	0.3	0.5	0.8
<b>TOTAL</b>	<b>3.4</b>	<b>5.4</b>	<b>8.2</b>

Position	Projected FTE Staff- Clinic		
	1 <sup>st</sup> Full Fiscal Year (1/1/22-12/31/22)	2 <sup>nd</sup> Full Fiscal Year (1/1/23-12/31/23)	3 <sup>rd</sup> Full Fiscal Year (1/1/24 to 12/31/24)
Registered Nurses	1.3	2.1	3.1
Licensed Practical Nurses	1.0	1.6	2.4
Clerical Staff	1.0	1.6	2.5
Administrator	0.2	0.3	0.5
Other (Supervisory)	0.0	0.1	0.1
<b>TOTAL</b>	<b>3.5</b>	<b>5.7</b>	<b>8.6</b>

The assumptions and methodology used to project staffing are provided in Section Q, Form H. 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.2 and H.3, pages 64-65, the applicant describes the methods to be used to recruit or fill new positions and proposed training and continuing education programs. In Section I, page 67, the applicant identifies the proposed medical director. In Exhibit I.3-1, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Exhibit I.2 and I.3-2, the applicant provides supporting documentation.

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 66, the applicant states that the following ancillary and support services are necessary for the proposed services, but not limited to:

- Medical supplies
- Administration
- Medical records
- Radiology
- Business office/registration
- Maintenance
- Pharmacy
- Pathology
- Housekeeping
- Laboratory
- Laundry
- Emergency response team

On page 66, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Section I, pages 66-67, 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.

## **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 70, the applicant states that the project involves up fitting 23,817 square feet of the Atrium Health Union West MOB which is currently under development. Line drawings are provided in Exhibit C-1.

On page 70, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 71, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibit F.2-2.

In Section B, pages 22-23, and in Section K, pages 71-72, 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.

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

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

C

The proposed facility, LCI-Union West, is not an existing facility, therefore there no prior fiscal year payor source information is available.

However, in Section L, page 77, the applicant provides the historical payor mix during the last full fiscal year (1/1/2019 to 12/31/2019) for Atrium Health Union, as shown in the table below.

Payor Category	Percent of Total Patients
Self-Pay	14.4%
Medicare*	34.9%
Medicaid*	17.9%
Insurance*	29.7%
Other (Gov't, Worker's Comp)	3.1%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 77 of the application based on Atrium Health Union internal data.

\*Including any managed care plans.

In Section L, page 76, the applicant provides the following comparison for Atrium Health Union.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of Union County	Percentage of the Population of Mecklenburg County
Female	57.3%	50.8%	51.9%
Male	42.7%	49.2%	48.1%
Unknown	0.0%	0.0%	0.0%
64 and Younger	71.2%	87.3%	88.8%
65 and Older	28.8%	12.7%	11.2%
American Indian	0.6%	0.6%	0.8%
Asian	0.4%	3.4%	6.4%
Black or African-American	26.4%	12.3%	32.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%	0.1%
White or Caucasian	62.6%	81.6%	57.5%
Other Race	0.5%	2.0%	2.4%
Declined / Unavailable	9.4%	0.0%	0.0%

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 77, the applicant states that Atrium Health Union has no obligations to provide uncompensated care, community service, access by minorities or access by handicapped persons.

In Section L, page 77, the applicant states that during the last five years no patient civil rights equal access complaints have been filed against Atrium Health or any related entity of Atrium Health.

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 78, 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>Payor Category</b>	<b>LCI-Union West Infusion Bay Visits as Percent of Total**</b>	<b>LCI-Union West Clinic Visits as Percent of Total</b>
Self-Pay	1.5%	3.6%
Medicare*	52.2%	43.2%
Medicaid*	6.5%	3.7%
Insurance*	38.7%	48.3%

Other (Gov't, Worker's Comp)	1.1%	1.2%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 78 of the application.

\*Including any managed care plans.

\*\*Includes infusion therapy, blood transfusion, and injection patient visits.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.5% and 3.6% of total services respectively for infusion bay visits and clinic visits will be provided to self-pay patients, 52.2% and 43.2% will be provided respectively for infusion bay visits and clinic visits to Medicare patients, and 6.5% and 3.7% will be provided respectively to Medicaid patients.

On page 78, 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 based on historical LCI patient origin.

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.5, page 79, 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

In Section M, pages 80-81, the applicant describes the extent to which health professional training programs in the area will 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 develop a new, additional location of Levine Cancer Institute-Union West, in a MOB currently under development on the campus of Atrium Health Union-West.

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 2020 SMFP does not define a service area for an unlicensed, provider-based cancer care center that includes a hematology/oncology clinic and outpatient infusion therapy services, nor are there any applicable rules adopted by the Department that define the service area for an unlicensed, provider-based, cancer care center. Thus, the service area in this review is as defined by the applicant.

In Section C, page 29, the applicant defines the service area by the following ZIP codes: 28079, 28104, 28110 and 28173, all of which are in western Union County and by ZIP codes 28227 and 28105 which are in eastern Mecklenburg County. Facilities may also serve residents not included in their service area.

In the defined service areas, the applicant states in Section G, on page 62 of the application, that it is only aware of one other existing or approved facility, Novant Health Matthews Medical Center, as providing infusion therapy within the defined service area. The applicant further states that utilization data for hematology/oncology clinic and outpatient infusion therapy is not publicly available.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 83, the applicant states:

*“The proposed project will foster competition by promoting value, safety and quality, and access to services in the proposed service area...”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 83, the applicant states:

*“...Atrium Health believes the proposed project is being developed in such a way that will involve minimal cost while also expanding access to important patient services ... Further, as a member of Atrium Health, Atrium Health Union and LCI benefit from significant cost saving measures through the consolidation of multiple services and large economies of scale. ... The proposed project will enable Atrium Health to provide its patients with the best care possible, while also being responsive in a healthcare environment that emphasizes cost containment and efficient utilization of existing resources.”*

Regarding the impact of the proposal on quality, in Section N, pages 84-85, the applicant states:

*“Atrium Health believes that the proposed project will promote safety and quality in the delivery of healthcare services. Atrium Health is known for providing high quality services and expects the proposed project to provide patients significant benefits in terms of safety/quality...Atrium Health is dedicated to providing the highest quality care and is continuously recognized locally and nationally for its commitment to delivering efficient, quality care. ... As demonstrated above and in its Performance Improvement, Utilization, and Risk Management Plans ... Atrium Health has made a long-term commitment to providing quality care to its patients.”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 85-86, the applicant states:

*“The proposed project will improve access to cancer services, particularly hematology/oncology clinic and infusion therapy services in western Union County and the surrounding communities, by providing patients with local access to world-class cancer care and also will reduce personal expenses related to traveling. ... Further, Atrium Health has made the recruitment and retention of bilingual staff members a priority at the medical center.”*

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 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.

- (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 facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of over fifteen of this type of facility located in North Carolina.

In Section O, page 89, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none 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, incidents related to quality of care occurred in none of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of the facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to



demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to develop an unlicensed, provider-based cancer care center that includes a hematology/oncology clinic and outpatient infusion therapy services. There are no administrative rules that are applicable to the proposed project.