

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 7, 2016

Findings Date: September 7, 2016

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: F-11181-16

Facility: Levine Cancer Institute-University

FID #: 160211

County: Mecklenburg

Applicants: The Charlotte-Mecklenburg Hospital Authority

Project: Consolidate the operations of Levine Cancer Institute-University and Levine Cancer Institute-Mallard Creek and relocate the facility to new leased space on the campus of Carolinas HealthCare System University

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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.

CA

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (CMC) proposes to consolidate and relocate the Levine Cancer Institute-University (LCI-University) and Levine Cancer Institute-Mallard Creek (LCI-Mallard Creek) to new leased space within a medical office building on the campus of The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System University (CHS University).

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2016 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES, on pages 39-40 of the 2016 SMFP, is applicable to this review. Policy GEN-4 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, the Certificate of Need Section 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 are required to submit a plan of 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.”

In Section III.2, page 50, the applicant states:

“CHS is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves.”

The applicant proposes to consolidate the operations of LCI-University and LCI-Mallard Creek in 1,239 square feet of space on the 4th floor and 18,890 of leased space on the 5th floor of a medical office building on the campus of CHS University for a total of 20,129 square feet. The total projected capital costs for the proposed project is \$8,341,000.

On pages 50-51, the applicant describes CHS’s Energy Efficiency and Sustainability Plan, as summarized below:

- Improve and reduce environmental impact.
- Integrate sustainable operational and facility best practice.
- Encourage partners to engage in environmentally responsible practices.
- Promote environmental sustainability.
- Deliver improved performance to provide a long term return on investment.

On page 51, the applicant states:

“CMC will work with experience architects and engineers to develop the project to ensure energy efficient systems are an inherent part of the proposed project to the degree appropriate with the proposed renovations. ... the team seeks to deliver the following:

- *Meet or exceed the requirements of the NC Building Code ...*
- *Use United States Green Building Council (USGBC) LEED guidelines and GGHC as appropriate to identify opportunities to improve efficiency and performance.*
- *Use EPA Energy Star for Hospitals rating system to compare performance across CHS, North Carolina, and the United States for benchmarking performance following 12 months of operation.*
- *Upgrade any impacted plumbing fixtures to maximize efficiency and life cycle benefits.”*

The applicant adequately demonstrates that the proposal includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4, subject to Condition #3 in Criterion (4).

Conclusion

In summary, the applicant adequately demonstrates that its proposal is consistent with Policy GEN-4 and conforming to this criterion, subject to Condition #3 in Criterion (4).

- (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 consolidate the operations of LCI-University and LCI-Mallard Creek and relocate the facility to new leased space on the campus CHS University.

The medical office building is currently a three-story building owned by HR Carolinas, LLC, a third party developer. The developer plans to expand the building by two floors and to lease a portion of the space to CMC. The proposed new facility would consist of 18 infusion bays (10

bays from LCI University facility and eight bays from LCI-Mallard Creek). The new LCI-University will be located on the 4th and 5th floors of Building 5000. The 5th floor will consist of 18,890 square feet that will house the infusion chairs, physician offices, exam rooms, pharmacy, lab, blood draw area, patient waiting and registration, dedicated art therapy and administrative space. The 4th floor will consist of 1,239 square feet to accommodate additional support services to include genetic counseling, palliative medicine, survivorship classes, support groups and exercise classes.

Population to be Served

The 2016 SMFP does not define a service area for cancer infusion clinics. The applicant defines its service area in Section III.5(a), page 56, as primarily Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section III.4(a), page 54, the applicant states that historically 56.5% of all acute care patients served at CMC in CY 2015 were from Mecklenburg County. On pages 55-56, the applicant provides the individual historical patient origin, by percent for patients served at LCI-University, LCI-Mallard Creek and the combined patient origin for CY 2015 for those two facilities, as illustrated in the table below.

LCI-University CY 2015		LCI-Mallard Creek CY 2015		LCI-University & LCI-Mallard Creek Combined CY 2015	
County	% of Total	County	% of Total	County	% of Total
Mecklenburg	75.2%	Mecklenburg	78.9%	Mecklenburg	77.5%
Iredell	5.5%	Cabarrus	7.9%	Cabarrus	7.0%
Cabarrus	5.4%	Gaston	3.3%	Gaston	3.7%
Gaston	4.5%	Cleveland	2.0%	Iredell	2.9%
Union	2.5%	Iredell	1.4%	Cleveland	1.3%
Other*	7.0%	Other**	6.5%	Rowan	1.2%
Total	100.0%	Total	100.0%	Union	1.0%
				Other*	5.3%
				Total	100.0%

*Other: Durham, Jackson, Lincoln, Rowan, Stanly and Wilkes, Brunswick, Catawba, Davidson, Guildford, Harnett, Lincoln, Montgomery, Orange, Rowan, Rutherford and Stanly counties and other states

In Section III.5(c), page 58, the applicant provides the projected patient origin, by county for LCI-University during the first two operating years following project completion, as shown in the table below.

County	Project Year 1 # of Patients	% of Total Patients	Project Year 2 # of Patients	% of Total Project Year 2
Mecklenburg	4,777	77.5%	5,216	77.5%
Cabarrus	429	7.0%	469	7.0%
Gaston	229	3.7%	250	3.7%
Iredell	180	2.9%	197	2.9%
Cleveland	80	1.3%	88	1.3%
Rowan	72	1.2%	79	1.2%
Union	64	1.0%	70	1.0%
Other*	329	5.3%	359	5.3%
TOTAL	6,161	100.0%	6,727	100.0%

*Other: Anderson, Brunswick, Catawba, Chester, Davidson, Durham, Fairfield, Guilford, Harnett, Jackson, Lincoln, Marion, Montgomery, Orange, Rutherford, Stanly, Wilkes and York counties and other states.

On page 58, the applicant states that its assumptions regarding projected patient origin is based on existing historical patient origin percentages for LCI-University and LCI-Mallard Creek.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section III, pages 33-47, and referenced exhibits, the applicant states the following factors support the need to consolidate the services of LCI-University and LCI-Mallard Creek and to relocate those services, as discussed below:

- Consolidation of existing resources and expand access to patient support services;
- Mecklenburg County population growth including the growth in the 65+ population; and
- The high cancer incidence rates in Mecklenburg County

Consolidation of existing resources and expand access to patient support services

On pages 34-38, the applicant discusses the benefits of consolidating LCI-University and LCI-Mallard Creek and relocating the newly formed LCI-University to leased space on the CHS-University campus. LCI-University is currently located in Building 1000 on the CHS University campus which is located at 1010 East W.T. Harris Boulevard in Charlotte. LCI-Mallard Creek is located at 10826 Mallard Creek Road in Charlotte. The proposed consolidation and relocation of the two infusion clinics would move LCI-University from building 1000 to building 5000, both of which are on the campus of CHS University. The LCI-Mallard Creek facility would move less than five miles from its current location to the new medical office building.

The applicant states on page 35, that the consolidation of LCI-University and LCI-Mallard Creek will allow for enhanced operational efficiencies including overhead expenses, the reduction of duplicative staff and increase physician collaboration. LCI-University is located on the same campus as LCI-University Radiation Therapy Center. This allows for medical and radiation

oncologists to easily provide consultation and coordination of care services to their patients. On page 36, the applicant states, LCI-University currently consists of one medical oncologist and LCI-Mallard Creek currently operates with 1.5 medical oncologist. The consolidation of LCI-University and LCI-Mallard Creek will allow for a greater number of physicians to share the responsibility for providing coverage. LCI-University has recruited for an additional medical oncologist and LCI-Mallard Creek will have an additional 0.5 full time equivalent staff joining the practice in 2016. Upon completion of the proposed project, LCI-University plans to recruit for one additional physician. Additionally, 1.0 advanced care practitioners will also be hired in late 2016 at LCI-University. Thus, the proposed consolidated LCI-University is projected to have 5.0 medical oncologist and one advanced care practitioner.

On page 36, the applicant further states, LCI-University currently mixes all its chemotherapy drugs on-site at its pharmacy. However, LCI-Mallard Creek ceased preparing its chemotherapy drugs on-site in 2015 due to new regulations by the Board of Pharmacy. The upfit required for the LCI-Mallard Creek pharmacy would be approximately \$700,000 and would have required a reduction in the clinical space as the facility currently has no room to expand. LCI-University currently mixes chemotherapy drugs for LCI-Mallard Creek. Thus, the consolidation of the two facilities would further increase operational processes and eliminate the cost and time associated with having to use a courier service.

Furthermore, the applicant states on pages 37-38, that the consolidation of LCI-University and LCI-Mallard Creek will allow the facility to offer patient support services that are not currently offered such as genetic counseling, palliative medicine, survivorship classes, support groups and exercise classes which will include yoga and Tai Chi. Nutritional counseling, art, music and pet therapies will also be offered. Typically, patients have needed to travel to LCI-Morehead (CMC) or LCI-Concord to access these enhanced patient services.

Mecklenburg County population growth including the growth in the 65+ population

On page 38, the applicant states that historically Mecklenburg County residents have comprised nearly 80 percent of the patient population of LCI-University and LCI-Mallard Creek. According to data the applicant provided from the North Carolina Office of State Budget and Management (NC OSBM), Mecklenburg County is the fastest growing county in North Carolina. On page 39, the applicant provides a map which indicates Mecklenburg County is projected to experience population growth of 24.2% between 2010-2020. Furthermore, the applicant states that by 2020 the 65+ population will comprise nearly 12% of Mecklenburg County's population, roughly 136,000 people. The 65+ population of Mecklenburg County is projected to grow by 42.6% from 2010-2020.

The high cancer incidence rates in Mecklenburg County

The applicant provides a table on page 40 which illustrates Mecklenburg County's cancer incident rates as compared to that of North Carolina, as shown below.

2009-2013 Cancer Incidence Rates per 100,000 Population

	<i>Colon/ Rectum</i>	<i>Lung/ Bronchus</i>	<i>Female Breast</i>	<i>Prostate</i>	<i>All Cancers</i>
<i>Mecklenburg County</i>	<i>35.0</i>	<i>59.3</i>	<i>169.4</i>	<i>144.9</i>	<i>472.7</i>
<i>North Carolina</i>	<i>38.5</i>	<i>70.9</i>	<i>157.9</i>	<i>130.6</i>	<i>483.4</i>

The applicant states on page 41, Mecklenburg County is projected to have 4,881 new cancer cases in 2016.

The applicant adequately demonstrates the need to consolidate and relocate LCI-University and LCI-Mallard Creek based on improved operational efficiencies, projected growth in the Mecklenburg County population, especially growth in the 65+ population and the projected growth in cancer incidence rates within the county.

Projected Utilization

In Section IV, page 65, the applicant provides the projected utilization for the consolidated infusion clinics for the first three years of operation following completion of the proposed project, as illustrated below:

LCI-University			
	OY 1 CY 2019	OY 2 CY 2020	OY 3 CY 2021
# of Infusion Patients	4,241	4,679	5,162
# of Injections	1,920	2,048	2,185
# of Infusion Chairs	18	18	18

In Section III.1(b), pages 41-47, the applicant provides the assumptions used to project utilization, which are summarized below.

- LCI-University and LCI-Mallard Creek both currently provide infusion therapy services. From CY2013-CY2015 LCI-Mallard Creek experienced a Compound Annual Growth Rate (CAGR) of 37.5% on its eight infusion chairs. During the same timeframe, LCI-University experienced a 14.4% CAGR with its ten infusion chairs. For a combined CAGR of 20.6% for the 18 infusion chairs. (See pages 41-42).
- Projected utilization is based on one half the 2013-2015 combined CAGR for infusion therapy services for both facilities which is 10.3% [20.6/2= 10.3], as stated on page 43.
- On page 44, the applicant provides the projected growth for infusion patients for both existing facilities and the projected growth for the consolidated LCI-University, as illustrated below:

INFUSION THERAPY PATIENTS								
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CAGR
LCI-Mallard Creek	934	1,030	1,137	1,254	1,384	1,526	1,684	10.3%
LCI-University	1,929	2,128	2,348	2,590	2,858	3,152	3,478	10.3%
Consolidated Clinic	2,863	3,158	3,485	3,844	4,242	4,678	5,162	10.3%

- The applicant projects to have a combined total of 5,162 infusion patients in CY 2021.
- The applicant projects 1.6 infusion patients per chair, per day, (Monday - Friday). (See page 45).
- On page 45, the applicant projects the consolidated LCI-University infusion therapy chairs will operate at 72% capacity. The applicant assumes 1.6 patients per chair, per day for 250 operational days per year (excludes weekends and holidays). This is based on 1.6 (patients per chair, per day) x 250 (days) = 400 x 18 (infusion chairs) = 7,200.
- The applicant proposes to provide injections to patients in the infusion chairs rather than a dedicated injection room. The applicant states on page 46, that it should be noted that injection patients do not typically receive injections the same day as their infusions and vice versa. (See page 45).
- LCI-University and LCI-Mallard Creek both currently provide injection treatments. On page 46, the applicant states the CAGR from CY 2013-2015 for injection patients at LCI-Mallard Creek was -0.1% while LCI-University's CAGR for the same timeframe was 42.0%. The combined CAGR for both facilities during this timeframe was 13.4%.
- The applicant projects injection services forward using one half of 2013-2015 CAGR, 6.7% [$13.4/2 = 6.7$]. (See page 46).
- The applicant provides the projected growth for injection patients for both existing facilities and the projected growth for the consolidated LCI-University facility on page 47, as illustrated below:

INJECTION THERAPY PATIENTS								
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CAGR
LCI-Mallard Creek	825	880	939	1,002	1,069	1,140	1,216	6.7%
LCI-University	657	701	748	798	851	908	969	6.7%
Consolidated Clinic	1,482	1,581	1,687	1,800	1,920	2,048	2,185	6.7%

As illustrated above, the applicant projects to have a combined total of 2,185 injection patients by CY2021.

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth in the patient population.

Access

In Section VI.2, page 76, the applicant states:

“LCI-University 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 VI.12, page 84, the applicant provides the payor mix for CMC, LCI-University and LCI-Mallard Creek for CY 2015. The applicant reports that 51% of all patients who received services at LCI-University and LCI-Mallard Creek had some or all of their services paid by Medicare and/or Medicaid. Additionally, on page 86, the applicant provides the projected payor mix for the consolidated LCI-University in CY 2020. The applicant does not project a change in its payor mix from its historical payor mix.

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

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed services and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (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.

C

The applicant proposes to consolidate the operations of LCI-University and LCI-Mallard Creek and relocate the facility to new leased space within a medical office building on the campus of CHS University. LCI-University is currently located on the CHS University campus and would simply move from Building 1000 to Building 5000. LCI-Mallard Creek would relocate less than five miles to the proposed new LCI-University facility. On page 23, the applicant states the proposed LCI-University facility will continue to provide services to the combined University and Mallard Creek patient population. The applicant adequately demonstrates that the needs of the population presently served will be adequately met by the proposed relocation and there will be no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed healthcare. Therefore, the application is conforming to this criterion.

- (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

In Section III.3, pages 51-53, the applicant discusses the three alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would not be operationally efficient or in the best interest of patient care as it would require patients who wanted access to support services to continue to commute to LCI-Morehead or LCI-Concord for those services. Additionally, LCI-Mallard Creek does not have on-site pharmacy services and currently relies on LCI-University's pharmacy.
2. Renovate Space in Existing Location - the applicant states LCI-Mallard Creek does not have the space to accommodate the consolidation of both facilities. The applicant further states to accommodate the consolidation of both facilities at LCI-University's current location would be disruptive to patients and limit patient support services.
3. Develop the Project as Proposed - the applicant states the development of the project, as proposed, is its most reasonable and cost effective alternative as it allows for greater operational efficiencies, provides on-site pharmacy services for Mallard Creek patients, and additional support services.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall materially comply with all representations made in the certificate of need application.**
- 2. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the applicant and which would otherwise require a certificate of need.**
- 3. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center 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. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center 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 consolidate the operations of LCI-University and LCI-Mallard Creek and relocate the facility to new leased space within a medical office building on the campus of CHS University.

Capital and Working Capital Costs

In Section VIII, pages 97-98, the applicant states the total capital cost is projected to be as follows:

Item	Cost
Construction Contract	\$4,050,000
Fixed Equipment Purchase/Lease	\$83,000
Movable Equipment Purchase/Lease	\$1,150,000
Furniture	\$679,000
Architect & Engineering	\$852,000
CON Fees	\$45,000
IS/Security Equipment, Cabling & Contingency	\$1,482,000
Total	\$8,341,000

In Section IX, page 102, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Availability of Funds

In Section VIII.3, page 98, the applicant states the entire capital cost of the project will be funded with accumulated reserves from Carolinas HealthCare System. Exhibit 26, contains a letter dated May 16, 2016 from the Executive Vice President and Chief Financial Officer of Carolinas HealthCare System documenting the availability of sufficient funds for the capital costs of the proposed project.

Exhibit 27 contains the audited financial statements for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System. As of December 31, 2014, Carolinas HealthCare System had \$96,101,000 in cash and cash equivalents, \$7,213,587,000 in total assets and \$4,029,263,000 in total net assets. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant projects revenues and expenses on page 117 and provides its assumptions on page 118, Form B for CMC, as summarized below:

CMC		
Revenue and Expenses		
	OPERATING YEAR 1 FFY 2019	OPERATING YEAR 2 FFY 2020
Gross Patient Revenue	\$ 7,813,639	\$ 8,504,534
Deductions from Gross Patient Revenue	\$5,898,885	\$6,534,441
Net Patient Revenue	\$ 1,914,754	\$ 1,970,093
Operating Expenses	\$ 1,678,012	\$ 1,741,437
Net Profit	\$ 236,742	\$ 228,656

The applicant projects that revenues will exceed operating expenses in each of the first two Operating Years following completion of the proposed project.

Additionally, in Form C, page 119, the applicant provides the projected revenues and expenses and on page 120 its assumptions, for LCI-University, as illustrated in the table below:

LCI-University		
Revenue and Expenses		
	OPERATING YEAR 1 FFY 2019	OPERATING YEAR 2 FFY 2020
Gross Patient Revenue	\$ 56,919,627	\$ 64,014,670
Deductions from Gross Patient Revenue	\$36,244,503	\$40,762,387
Net Patient Revenue	\$ 20,675,124	\$ 23,252,282
Operating Expenses	\$ 17,238,817	\$ 19,073,374
Net Profit	\$ 3,436,307	\$ 4,178,908

As illustrated, LCI-University’s revenues will also exceed operating expenses in each of the first two Operating Years following completion of the proposed project.

The assumptions used by the applicant in preparation of the pro formas, including projected utilization, costs and charges are reasonable and adequately supported. See page 120 for the assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projects of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial

feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (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 consolidate the operations of LCI-University and LCI-Mallard Creek and relocate the facility to leased space within a medical office building on the campus of CHS University. Both existing facilities currently provide infusion services to cancer patients in Mecklenburg County and surrounding counties.

The 2016 SMFP does not define a service area for cancer infusion services. The applicant defines its service area in Section III.5(a), page 56, as primarily Mecklenburg County. Facilities may also serve residents of counties not included in their service area. The total number of outpatient oncology infusion clinics in the service area will not increase, but rather decrease by one clinic, as a result of this proposal.

In Section III.6, page 59, the applicant provides a list of existing LCI facilities that operate outpatient oncology infusion clinics in Mecklenburg County and the number of infusions and injections performed in CY 2015, as illustrated below:

LCI LOCATIONS IN MECKLENBURG COUNTY			
Facility	Location	Number of Infusion Patients	Number of Injection Patients
LCI-Morehead (CMC)	1021 Morehead Medical Dr. Charlotte	18,067	7,376
LCI-Ballantyne	15830 Ballantyne Medical Pl #200, Charlotte	2,680	1,313
LCI-Cornelius (Closed)	9606 Caldwell Commons Cir, Cornelius	65	59
LCI-Matthews	1401 Matthews Township Pkwy #208, Matthews	748	822
LCI-Pineville	Pineville Medical Plaza, 10650 Park Rd #420, Charlotte	2,379	1,080
LCI-South Tryon	1100 S Tryon St #400, Charlotte	3,142	1,335
LCI-SouthPark	4525 Cameron Valley Pkwy #4100-A, Charlotte	2,017	675

Additionally, on page 59, the applicant provides a list of other facilities in Mecklenburg County that also provide oncology infusion therapy services, as illustrated below.

Provider	Location
Novant Health Huntersville Medical Center	10030 Gilead Rd, Huntersville
Novant Health Matthews Medical Center	1500 Matthews Township Pkwy, Matthews
Novant Health Presbyterian Medical Center	200 Hawthorne Lane, Charlotte
Novant Health Cancer Specialist - Charlotte	1718 E. 4 th street #105, Charlotte
Lake Norman Oncology - Huntersville	10030 Gilead Rd, Suite 250, Huntersville,
The Neurological Institute -Main	2219 E 7 th Street, Charlotte
Neurological Institute - South Charlotte	7000 Shannon Willow Road, Charlotte

On page 59, the applicant states infusion therapy data is not publicly available. As a result of the proposed project, Mecklenburg County would lose one LCI infusion clinic site, but would maintain its current number of infusion therapy chairs with the consolidation of LCI-University and LCI-Mallard Creek. The applicant adequately demonstrates that projected utilization is based on population growth, an aging population and an increase in cancer incident rates with an aging population.

The applicant adequately demonstrates the need to consolidate LCI-University and LCI-Mallard Creek into one infusion clinic and to relocate those services to new leased space on the campus of CHS University. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Mecklenburg County. Consequently, the application is conforming to this criterion.

- (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

LCI-University and LCI-Mallard Creek are existing providers of oncology infusion services in Mecklenburg County. In Section II.4, page 25, the applicant states that the current hours of operations for both facilities is Monday-Friday, 8:00 am to 5:00 pm. The applicant proposes to maintain the same schedule of operations following completion of the proposed project. The VII.1, pages 87-88, the applicant states the 10-chair infusion clinic at LCI-University currently operates with 18.5 full time equivalent (FTE) staff and the 8-infusion chairs at LCI-Mallard Creek operates with 12.1 FTEs. Upon project completion and consolidation of LCI-University and LCI-Mallard Creek, the applicant proposes to operate the new facility with a total of 33.2 FTEs in the second full federal fiscal year (2020), as illustrated below:

POSITION	CURRENT # FTES
LCI-University	
Practice Manager	1.0
Clinical Supervisor	1.0
RN	4.7
LPN	1.0
CMA	1.8
Registrar	3.0
Med Secretary	2.0
Clinical Pharmacist	1.0
Pharmacy Tech III	1.0
Lead Tech	1.0
MLT (lab assistant)	1.0
Financial Counselor	
Total	18.5
LCI-Mallard Creek	
Practice Manager	0.5
Clinical Supervisor	1.0
RN	4.0
Med Secretary	2.0
Registrar	2.0
Financial Counselor	1.0
MLT (lab assistant)	1.0
Clinical Pharmacist Coordinator	0.3
Pharmacy Tech III	0.3
Total	12.1

POSITION	PROJECTED CONSOLIDATED # FTES
NEW LCI-UNIVERSITY	
Practice Manager	1.0
Clinical Supervisor	1.0
RN	10.2
LPN	1.0
CMA	3.0
Registrar	4.0
Med Secretary	4.0
Clinical Pharmacist	1.5
Pharmacy Tech III	1.5
Lead Tech	1.0
MLT (lab assistant)	4.0
Financial Counselor	1.0
Total	33.2

As illustrated above, the consolidation of LCI-University and LCI-Mallard Creek will allow enhanced operational efficiencies and the elimination of duplicative administrative positions. The applicant projects an increase of 2.6 FTE positions which includes an increase of 1.5 RNs and 1.1 CMA FTEs in its second year of operations.

In Section VII.4, page 93, the applicant states Dr. Seung Jean Chai currently services as the Medical Director for LCI-University and LCI-Mallard Creek. Exhibit 21, contains a letter dated May 16, 2016 from Dr. Chai expressing his willingness to serve as the Medical Director for the proposed new LCI-University facility.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed services. Therefore, the application is conforming to this criterion.

- (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

LCI-University and LCI-Mallard Creek are existing providers of the proposed services. In Section II.2, pages 24-25, the applicant describes the ancillary and support services that are currently available and that will continue to be available following completion of the proposed project. Exhibit 8 contains a letter dated May 16, 2016 from the President of CMC documenting the availability of all necessary ancillary and support services. Exhibit 20 contains a copy of a sample transfer agreement and a list of facilities with which CMC has transfer agreements. See Exhibit 30 for copies of letters of support from physicians.

The applicant adequately demonstrates that it will provide or make arrangements for the necessary ancillary and support services and that the proposed services will be coordinated with the existing health care system. Therefore, 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

- (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

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

C

The applicant proposes to consolidate the operations of LCI-University and LCI-Mallard Creek in 1,239 square feet of space on the 4th floor and 18,890 of leased space on the 5th floor of a medical office building on the campus of CHS University for a total of 20,129 square feet.

The medical office building is currently a three-story building owned by HR Carolinas, LLC. The developer plans to expand the building by two floors and to lease a portion of the space to CMC. The proposed new LCI-University facility will be located on the 4th and 5th floors of Building 5000. The 5th floor will consist of 18,890 square feet that will house the infusion chairs, physician offices, exam rooms, pharmacy, lab, blood draw area, patient waiting and registration, dedicated art therapy and administrative space. The 4th floor will consist of 1,239 square feet to accommodate additional support services to include genetic counseling, palliative medicine, survivorship classes, support groups and exercise classes.

In Section III.2, page 50, the applicant states:

“CHS is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves.”

On pages 50-51, the applicant describes CHS’s Energy Efficiency and Sustainability Plan, as summarized below:

- Improve and reduce environmental impact.
- Integrate sustainable operational and facility best practice.
- Encourage partners to engage in environmentally responsible practices.
- Promote environmental sustainability.

- Deliver improved performance to provide a long term return on investment.

On page 51, the applicant states:

“CMC will work with experience architects and engineers to develop the project to ensure energy efficient systems are an inherent part of the proposed project to the degree appropriate with the proposed renovations. ... the team seeks to deliver the following:

- *Meet or exceed the requirements of the NC Building Code ...*
- *Use United States Green Building Council (USGBC) LEED guidelines and GGHC as appropriate to identify opportunities to improve efficiency and performance.*
- *Use EPA Energy Star for Hospitals rating system to compare performance across CHS, North Carolina, and the United States for benchmarking performance following 12 months of operation.*
- *Upgrade any impacted plumbing fixtures to maximize efficiency and life cycle benefits.”*

The total projected capital costs for the proposed project is \$8,341,000. Exhibit 24 contains a letter from an architect that estimates construction costs of \$4,050,000, which corresponds to the project capital cost projections provided by the applicant in Section VIII.1, page 97, of the application. In Section XI.7, pages 111-112, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, 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

In Section VI.12, page 84, the applicant provides the payor mix for CMC, LCI-University and LCI-Mallard Creek for CY 2015, as illustrated in the following tables.

CMC Historical Payor Mix As % of Total Utilization (CY2015)	
Medicare/Medicare Managed Care	33.8%
Medicaid	21.6%
Managed Care/Commercial	34.5%
Self Pay / Other*	10.0%
Total	100.0%

*Other: Worker's compensation and other unspecified payors

LCI-University and LCI-Mallard Creek Historical Payor Mix As % of Total Utilization (CY2015)	
Medicare/Medicare Managed Care	45.0%
Medicaid	6.0%
Managed Care/Commercial	48.1%
Other*	0.3%
Self Pay	0.6%
Total	100.0%

*Other: Worker's compensation and other unspecified payors

As illustrated above, 51% of all patients who received services at LCI-University and LCI-Mallard Creek had some or all of their services paid by Medicare and/or Medicaid. On pages 76-77, the applicant provides a breakdown of the patients who received services at LCI-University and LCI-Mallard Creek in 2015 by sex, age (65+), and Medicaid payor source.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Mecklenburg	10%	52%	51%	15%	6%	19%
Cabarrus	13%	51%	31%	12%	7%	16%
Gaston	15%	52%	25%	17%	13%	18%
Iredell	15%	51%	23%	13%	9%	18%
Cleveland	17%	52%	27%	21%	12%	17%
Rowan	16%	51%	27%	18%	12%	19%
Union	11%	51%	27%	11%	6%	16%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable... The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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

In Section VI.11, page 83, the applicant states that it has no obligation to provide uncompensated care or community service under federal regulations. In Section VI.10, page 83, the applicant states there have been no civil rights access complaints filed within the last five years against CHS. Therefore, 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 VI.14 and VI.15, pages 85-86, the applicant provides the projected payor mix for CMC and the consolidated LCI-University in CY 2020, as illustrated below:

CMC	
Projected Payor Mix As % of Total Utilization (CY2020)	
Medicare/Medicare Managed Care	33.8%
Medicaid	21.6%
Managed Care/Commercial	34.5%
Self Pay / Other*	10.0%
Total	100.0%

*Other: Worker’s compensation and other unspecified payors

LCI-University	
Projected Payor Mix As % of Total Utilization (CY2020)	
Medicare/Medicare Managed Care	45.0%
Medicaid	6.0%
Managed Care/Commercial	48.1%
Other*	0.3%
Self Pay	0.6%
Total	100.0%

As illustrated above, the applicant project that 51% of all patients who receive services at LCI-University will have some or all of those services paid by Medicare and/or Medicaid. The applicant states on pages 85-86 that it does not project a change in its payor mix from its historical payor mix. In Section VI.2, page 76, the applicant states:

“LCI-University 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.”

The applicant adequately demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.9, page 82, the applicant describes the range of means by which patients will have access to LCI-University’s services. The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services. Therefore, 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 V.1, page 66, the applicant states the following about how the facility will accommodate the clinical needs of area health professional training programs:

“As part of CMC, LCI-University has access to established clinical affiliation relationships and training programs supported by all CHS facilities. ... LCI-University is committed to accommodating the clinical training needs of area professional training programs and will provide access to programs requiring clinical training through its infusion therapy program.”

Exhibit 19 contains a list of those health professional training programs which CMC has clinical training agreements. The information provided in Section V and referenced exhibits is reasonable and supports a finding of conformity 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 consolidate the operations of LCI-University and LCI-Mallard Creek and relocate the facility to new leased space within a medical office building on the campus of CHS University.

The 2016 SMFP does not define a service area for cancer infusion services. The applicant defines its service area in Section III.5(a), page 56, as primarily Mecklenburg County. Facilities may also serve residents of counties not included in their service area. The total number of outpatient oncology infusion clinics in the service area will not increase, but rather decrease by one clinic, as a result of this proposal.

In Section III.6, page 59, the applicant provides a list of existing LCI facilities that operate outpatient oncology infusion clinics in Mecklenburg County and the number of infusions and injections performed in CY 2015, as illustrated below:

LCI LOCATIONS IN MECKLENBURG COUNTY			
Facility	Location	Number of Infusion Patients	Number of Injection Patients
LCI-Morehead (CMC)	1021 Morehead Medical Dr. Charlotte	18,067	7,376
LCI-Ballantyne	15830 Ballantyne Medical Pl #200, Charlotte	2,680	1,313
LCI-Cornelius (Closed)	9606 Caldwell Commons Cir, Cornelius	65	59
LCI-Matthews	1401 Matthews Township Pkwy #208, Matthews	748	822
LCI-Pineville	Pineville Medical Plaza, 10650 Park Rd #420, Charlotte	2,379	1,080
LCI-South Tryon	1100 S Tryon St #400, Charlotte	3,142	1,335
LCI-SouthPark	4525 Cameron Valley Pkwy #4100-A, Charlotte	2,017	675

Additionally, on page 59, the applicant provides a list of other facilities in Mecklenburg County that also provide oncology infusion therapy services, as illustrated below.

Provider	Location
Novant Health Huntersville Medical Center	10030 Gilead Rd, Huntersville
Novant Health Matthews Medical Center	1500 Matthews Township Pkwy, Matthews
Novant Health Presbyterian Medical Center	200 Hawthorne Lane, Charlotte
Novant Health Cancer Specialist - Charlotte	1718 E. 4 th street #105, Charlotte
Lake Norman Oncology - Huntersville	10030 Gilead Rd, Suite 250, Huntersville,
The Neurological Institute -Main	2219 E 7 th Street, Charlotte
Neurological Institute - South Charlotte	7000 Shannon Willow Road, Charlotte

On page 59, the applicant states infusion therapy data is not publicly available. As a result of the proposed project, Mecklenburg County would lose one LCI infusion clinic site, but would maintain its current number of infusion therapy chairs with the consolidation of LCI-University and LCI-Mallard Creek. The applicant adequately demonstrates that projected utilization is based on population growth, an aging population and an increase in cancer incident rates with an aging population.

In Section V.7, pages 72-74, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

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

The proposed project will serve to improve quality and efficiency of infusion therapy services provided within the System and more specifically within LCI ... given the proximate location of LCI-University and LCI-Mallard Creek, CMC believes that the operation of these facilities will be more efficient if they were to be consolidated The proposed project will allow LCI-University to operate more efficiently and effectively, which will in turn allow the facility to better meet patient needs and expectations.”

See also Sections II, III, V, VI, and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that LCI-University will continue to provide quality outpatient infusion services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.

- The applicant adequately demonstrates that LCI-University will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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 II, pages 22-23, and Exhibit 11, the applicant describes the methods used by CMC to ensure and maintain quality care. In Exhibit 4, the applicant provides a list of facilities that it currently owns, leases, or manages by type of facility in North Carolina. For the purposes of this review, only those facilities that provide acute care services were considered. The applicant owns, leases, or manages 24 facilities that provide acute patient care. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision no facilities were found to be out of compliance with one or more Medicare conditions of participation. 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 24 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