ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: December 4, 2015
Findings Date: December 4, 2015

Project Analyst: Tanya S. Rupp
Assistant Chief: Martha Frisone

Project ID #: F-11105-15
Facility: Levine Cancer Institute - Concord
FID #: 150434
County: Cabarrus
Applicant: The Charlotte – Mecklenburg Hospital Authority
Project: Expand and renovate the Levine Cancer Institute outpatient infusion clinic and develop a Phase I clinical trials unit

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.

C

The applicant, The Charlotte-Mecklenburg Hospital Authority ("CMHA") is a North Carolina hospital authority which operates several hospitals and other health care facilities in North Carolina and does business as Carolinas HealthCare System. CMHA operates Levine Cancer Institute ("LCI"), which provides community-based cancer care, including treatment, clinical trials and support services in 13 locations. LCI's research and administrative headquarters are located on the campus of Carolinas Medical Center (CMC) in Charlotte. In this application, CMHA proposes to expand the Cabarrus County location, Levine Cancer Institute-Concord ("LCI-Concord"), which is operated as a provider-based unlicensed location of Carolinas Medical Center ("CMC"). The applicant proposes to increase the number of outpatient infusion clinic bays from 25 to 35 and develop a Phase I clinical trials unit by renovating 15,411 existing square feet in the Oncology Building. In Section III.1, page 23, the applicant states the expansion

and development of a Phase I clinical trials unit will expand the current scope of clinical trials offered at LCI-Concord and will also improve geographic accessibility for cancer patients.

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 2015 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to the review of this application.

Policies

There is one policy in the 2015 SMFP that is applicable to this review: Policy GEN-4: Energy Efficiency and Sustainability for health Service Facilities 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 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, from Section VIII.1, page 90, is $4,973,780. In Section III.2, page 44, the applicant states the project will be designed to be in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption. The applicant states the existing Oncology Building was constructed in 2010 to ensure energy efficiency and cost effective utility utilization. In Section III.2, page 45, the applicant states it will work with experienced architects and engineers to ensure that energy efficient systems are an inherent part of the project design.

The applicant adequately demonstrates the proposal includes a 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 the proposal to renovate existing space, increase infusion therapy chairs to 35, and develop a Phase I clinical trials unit is consistent with Policy GEN-4 in the 2015 SMFP. Therefore, the application is conforming to this criterion as conditioned.

(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 expand LCI-Concord's outpatient infusion clinic from 25 to 35 bays, and to develop a Phase I clinical trials unit by renovating 15,411 existing square feet in the Oncology Building.

Population to be Served

The 2015 SMFP does not define a service area for an oncology facility such as LCI – Concord. The applicant defines its service area in Section III.5, page 49, as Cabarrus, Rowan and Stanly counties. Facilities may also serve residents of counties not included in their service area.

In Section III.4, pages 48 - 49, the applicant provides historical patient origin for LCI – Concord's infusion therapy and clinical trial services, as shown in the table below:

LCI – Concord Infusion Therapy Patient Origin
CY 2014

Cabarrus	67.04%
Rowan	18.71%
Stanly	5.47%
Mecklenburg	5.41%
Iredell	1.16%
Davidson	0.46%
Gaston	0.40%
Union	0.36%
Montgomery	0.17%
South Carolina	0.29%
Other (defined on page 48)	0.52%
Total	100.0%

LCI – Concord Clinical Trial Patient Origin
CY 2014

COUNTY	% OF TOTAL
Cabarrus	57.5%
Stanly	22.5%
Rowan	7.5%
Mecklenburg	5.0%
Montgomery	5.0%
Union	2.5%
Total	100.0%

In Section III.5, pages 51 – 52, the applicant projects patient origin for LCI – Concord's infusion therapy and clinical trials services, which is similar to the historical patient origin. The applicant states on page 52 that it does not project a significant change in patient origin as a result of the proposed project.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section III.1, pages 23 – 43, the applicant states the need for the project involves both qualitative and quantitative factors, as follows:

- LCI-Concord's existing infusion therapy services are operating above practical capacity and industry benchmarks;
- The continued systematic growth of LCI clinical trials;
- Recruitment of additional hematology/oncology physicians at LCI-Concord;
- Projected growth of the service area population presumes continued increases in demand for healthcare, including the need for infusion therapy services; and
- Cancer incidence rates for service area residents are disproportionately high compared to statewide statistics.

Each point is discussed below.

LCI-Concord Infusion Therapy

In Section III.1, pages 24 – 28, the applicant states chemotherapy administration for cancer patients has shifted from an inpatient setting to outpatient infusion centers, thereby improving quality of life for both the patient and the family. However, according to the applicant, excessive appointment delays and lack of adequate infusion chairs have resulted in a need to address timeliness and efficiency when considering the quality of treatment offered to patients. On pages 24 – 25, the applicant cites a 2012 survey from the *Journal of Oncology Practice,* which surveyed oncology practices nationwide. The study results reported the benchmark for infusion therapy services was 1.6 patients per treatment chair per workday, as shown in the following tables from page 25:

Infusion Patients Per Chair

METRIC	PATIENTS / TREATMENT CHAIR / WORKDAY
75th Percentile	1.6
Mean	1.3
25th Percentile	0.6

The same study determined that the median number of patients per chair per day for all types of facilities (academic medical centers, teaching hospitals, community-based providers, and freestanding outpatient centers) was 1.7.

On pages 26 – 27, the applicant states its practical capacity is 1.7 patient treatments per chair per day, which includes actual infusion time and time spent on tests, pre-medications, and other accompanying services. The following table shows LCI-Concord's utilization since CY 2012:

YEAR	TOTAL PT. TREATMENTS	# CHAIRS	# DAYS / YEAR	# TREATMENTS / CHAIR / DAY	TOTAL CAPACITY	% CAPACITY
CY 2012	12,053	25	250	1.93	10,625	113.4%
CY 2013	12,011	25	250	1.92	10,625	113.0%
CY 2014	10,934	25	250	1.75	10,625	102.9%
CY 2015	11,185	25	250	1.79	10,625	105.3%

The applicant states CY 2015 information is annualized based on 7 months of data, and capacity is calculated using the benchmark of 1.7 treatments per chair per day [1.7 x 25 chairs x 250 days = 10,625].

The applicant explains the utilization decrease from 2013 – 2014, as follows:

> *"… LCI-Concord experienced negative growth in infusion volume during 2013 and 2014; however, there were specific factors that contributed to the decrease. Specifically, the facility transitioned from the CHS NorthEast physician model to LCI faculty model in 2013-14, which meant the clinic changed to a provider-based facility of CMC. This temporarily affected clinic schedules. Also during that time, two physicians left the clinic for family reasons. LCI has since recruited two new physicians who began practicing at LCI-Concord in 2015. These efforts have resulted in an annualized 2.3 percent increase during CY2015 compared to CY2014."*

Even with the decrease from CY 2013 – CY 2014, LCI-Concord's infusion therapy services have operated above its own practical capacity and industry benchmarks for the last four years.

On page 27, the applicant describes how the proposed expansion will also allow LCI-Concord to offer integrative cancer therapy closer to home. Currently, cancer patients travel to Charlotte for therapeutic massage, education, and other forms of treatment and therapy. With the proposed expansion, LCI-Concord will offer comprehensive cancer treatment for the patient and family members in one place.

LCI Clinical Trials

In Section III.1, pages 28 -31, the applicant states clinical trials have been offered at LCI-Concord for many years; the vast majority of which have been Phase III trials offered by the

National Cancer Institute. With the offering of Phase I clinical trials, the applicant states it can provide more centralized and longer term care for its clinical trial patients. On page 31, the applicant states:

> *"The main purpose of the Phase I program is to provide clinical and translational research opportunities to patients across the Carolinas. The Charlotte Phase I unit currently treats patients with a wide variety of cancers including pancreatic, breast, urothelial, bladder and lung who are participating in clinical trials."*

The applicant states it will be able to treat more patients, for a longer term, and closer to home with the development of its proposed Phase I trials unit.

Physician Recruitment and Support

In Section III, pages 31 – 32, the applicant states it is actively recruiting physicians to LCI-Concord. In addition, in Exhibit 16, the applicant provides 23 letters signed by area physicians who offer support for the proposal. Each of these letters states there is a need in the service area for both increased infusion therapy services and a Phase I clinical trials unit.

Service Area Population and Aging

In Section III, pages 32 – 34, the applicant discusses the projected population growth of primarily Cabarrus County, the county from which it treats the most patients. Citing the North Carolina Office of State Budget and Management information, the applicant states Cabarrus County grew by 35% from 2000 to 2010, while the State as a whole grew by 18.5%. Similarly, the applicant states on page 33 that Cabarrus County is projected to remain in the top 20 fastest growing counties in North Carolina during the next four years.

In addition, the applicant states the incidence of cancer increases with age; likewise, the population in Cabarrus County of those people age 65 and older is projected to grow by a Compound Annual Growth Rate (CAGR) of 4.0% from 2015 to 2019. The applicant states the growth in the older segment of the population, combined with the historical volume of treatment at LCI-Concord, indicates the need for increased efficiency in the delivery of infusion therapy services in Cabarrus County.

Cancer Incidence Rates

In Section III, pages 34 – 36, citing research from the Centers for Disease Control and Prevention, the applicant states that in 2013, cancer was the second leading cause of death nationally, and the primary cause of death in North Carolina. The applicant states those rates are projected to increase, particularly in North Carolina and in the service area, as the age 65 and older population cohorts in Cabarrus County and other counties in the service area continues to increase.

Projected Utilization

In Section III, pages 36 – 43, the applicant provides its methodology for projecting utilization for both the infusion therapy services and the clinical trials proposed in this application. LCI-Concord has historically been operating above its practical capacity, even with the decrease in utilization from the unexpected loss of two physicians in CY 2013 – CY 2014. In addition, the population of those persons age 65 and older is expected to grow faster than other population cohorts in the service area, and the incidence of cancer in Cabarrus County is projected to increase at a faster rate than in other counties.

To project utilization for infusion therapy, the applicant uses a three-step methodology, summarized below.

Infusion Therapy

Step 1: Identify Historical Infusion Therapy Utilization

In Section III, pages 36 – 37, the applicant reiterates that LCI-Concord has operated above industry benchmarks for infusion therapy services since CY 2012; additionally, the existing 25 infusion therapy chairs have been operating at over 100% of LCI-Concord's practical capacity.

Step 2: Project Future Infusion Therapy Utilization

On page 37, the applicant projects the project will be operational by January 2017. Despite the continued increase in utilization, the applicant projects utilization in the "interim" year of CY 2016 to be consistent with CY 2015.

Utilizing historical infusion therapy data from CY 2012 to CY 2015, the applicant first calculates the percentage of infusion therapy treatments performed by county in the service area, as shown in the following table:

LCI-Concord Infusion Therapy Treatments by Service Area County

COUNTY	# PATIENT TREATMENTS	% OF TOTAL SERVICE AREA
Cabarrus	7,330	73.5%
Rowan	2,046	20.5%
Stanly	599	6.0%
Total	9,974	100.0%

The applicant determined that its Cabarrus County patients comprise 73.5% of its total population, Rowan County patients comprise 20.5% of its patient population, and Stanly County patients comprise 6.0% of its total population.

Using North Carolina Office of State Budget and Management population growth projections for those persons age 65 and older from in those three counties, the applicant calculated a four year CAGR from 2015 to 2019, as shown in the following table:

Population of Persons Age 65 and Older

COUNTY	2015	2019	4-YEAR CAGR
Cabarrus	24,731	28,987	4.05%
Rowan	22,432	24,373	2.10%
Stanly	10,871	12,029	2.56%

The applicant then calculated a weighted average growth rate for all three counties, based on the percentage of persons served in each county and the CAGR for each county, as shown in the following table:

COUNTY	% OF TOTAL POPULATION	4-YEAR CAGR	WEIGHTED AVERAGE
Cabarrus	73.5%	4.05%	.735 x .0405 = 2.98%
Rowan	20.5%	2.10%	.205 x .021 = 0.43%
Stanly	6.0%	2.56%	.060 x .0256 = 0.15%
Weighted Average Growth Rate Based on CY 2014 Patient Origin			3.56%

In Section III, page 37, the applicant projects future utilization using 2.35%, which is two-thirds of the weighted average growth rate calculated above [2/3 x 3.56% = 2.35%], as shown in the following table:

Year	Total Treatments	# Chairs	# Days / Year	Total Capacity	% Capacity
CY 2016	11,185	25	250	10,625	105.3%
CY 2017	11,448	35	250	14,875	77.0%
CY 2018	11,717	35	250	14,875	78.8%
CY 2019	11,992	35	250	14,875	80.6%

Capacity is based on 1.7 treatments per chair per workday

On pages 39 - 40, the applicant states:

> *"The projected utilization for LCI-Concord's infusion therapy is both reasonable and conservative. LCI-Concord is a busy infusion therapy center and has operated above practical capacity and well beyond industry benchmarks for several years. The projected growth rate of 2.35 percent approximates the CY2015 annualized growth rate of 2.30 percent and is further supported by the following:*
>
> - *LCI-Concord's existing infusion therapy services are operating above practical capacity; therefore, there is pent-up demand for services. The proposed project will relieve capacity constraints and enable LCI-Concord to treat more patients in a timelier manner.*
> - *LCI has a primary focus to increase its trial participation rate over time, which will increase the number of LCI-Concord cancer patients participating in clinical trials.*
> - *Incremental growth of LCI-Concord hematology/ oncology physicians will contribute to projected utilization increase for infusion therapy services.*

- *The projected growth of the service area population presumes continued increases in demand for healthcare, including the need for infusion therapy services.*
- *Cancer incidence rates for service area residents are disproportionately high compared to statewide statistics."*

Step 3: Patient Injections

In Section III, pages 40 – 41, the applicant explains that chemotherapy injections at LCI-Concord are administered in a dedicated injection room rather than an infusion chair, and thus are excluded from the infusion therapy methodology. The applicant states that injection volumes vary depending on the type of chemotherapy treatment administered and the accompanying side effects. The applicant projects the same static volume for interim year CY 2016, and then applies the same growth rate used for infusion therapy services, as shown in the following table:

	HISTORICAL				PROJECTED			
	CY 2012	**CY 2013**	**CY 2014**	**CY 2015**	**CY 2016**	**CY 2017**	**CY 2018**	**CY 2019**
Injections	3,262	3,591	3,516	3,219	3,219	3,295	3,372	3,452

The applicant states the project does not call for expansion of the injection room.

Phase I Clinical Trial Methodology

In Section III, pages 41 – 43, the applicant projects utilization for its Phase I clinical trial patients. The applicant states:

> *"LCI-Concord intends to develop a Phase I clinical trials unit. The Concord Phase I unit will be a half-size replica of the Charlotte unit. As proposed, the Unit is comprised of six treatment bays (two infusion bays, four infusion chairs) and an appropriately sized Phase I sample processing / storage lab appropriate to support biospecimen management.*
>
> *The main purpose of LCI's Phase I program is to provide clinical and translational research opportunities to patients across the Carolinas. As such, the need for the proposed Phase I unit is primarily qualitative in nature. In addition, LCI has a primary focus to increase its trial participation rate over time, which will increase the number of LCI-Concord cancer patients participating in clinical trials, including Phase I trials.*
>
> *As described previously, Phase I clinical trials typically require more of a time commitment from participants - for example, more frequent trips to LCI, longer hospital stays, lengthier visits or complex dosing requirements. Patients may also need to undergo a more demanding testing schedule, including blood tests, biopsies and scans.*
>
> *While each Phase I trial is unique, the average Phase I patient may actively participate for approximately nine months, then the patient is typically followed for*

life. Most trials have either a PFS (Progression Free Survival) or OS (Overall Survival) endpoint. This means each trial will typically have a follow-up visit scheduled every six months post treatment for a year or two, then annual follow up thereafter."

On page 42, the applicant states that, based on seven months of data annualized for CY 2015, it projects a total of 55 Phase I clinical trial patients will be served at LCI Concord. See the following table, which summarizes Phase I patients served at LCI-Charlotte since CY 2012:

Levine Cancer Institute Charlotte Utilization

Year	Phase I Patients
CY 2011	7
CY 2012	21
CY 2013	39
CY 2014	43
CY 2015	45

The applicant states it bases its projections on its experience with Phase I patients in Charlotte. Since LCI-Concord's Phase I unit is one-half the size of that at Charlotte, the applicant states:

"Given the proposed Phase I unit will be a half-size replica of the Charlotte unit, LCI-Concord projects utilization to gradually ramp up to a level commensurate to LCI's Phase I utilization to date. Specifically, during Project Year 3 (CY2019) LCI-Concord projects it will encounter approximately one-half of the CY2015 (annualized) Charlotte Phase I clinical trial patients (45 + 2 = 22.5, rounded up to 23). To be conservative, Project Year 1Phase I patients will approximate 1/3 of projected CY2019 utilization (1/3 x 23 = 7); and Project Year 2 Phase I patients will approximate 2/3of projected CY2019 utilization (2/3 x 23 = 15).

On page 43, the applicant projects LCI-Concord will serve the following Phase I patients in its proposed unit:

YEAR	PHASE I PATIENTS
CY 2017	7
CY 2018	15
CY 2019	23

The applicant states:

"Based on LCI-Concord's research, there are no performance standards or industry benchmarks specific to Phase I clinical trial utilization. Given the variable and complex nature of Phase I clinical trials, it is virtually impossible and unrealistic to impose a capacity estimate for the proposed Phase I unit. LCI-Concord has planned the Phase I unit based on the extensive experience of LCI's existing services. Patient utilization of the proposed LCI-Concord Phase I unit in

Project Year 3 (CY2019) is consistent with LCI's expectations for an efficient and well-utilized unit of its size."

The applicant states a key component of the project and LCI's philosophy is to decentralize cancer care, thus making treatment access easier for patients and their families. The project as proposed will accommodate that and ultimately benefit LCI's patients.

In Section III.6, page 53, the applicant states the need for this project as proposed is unique to the needs of its patients and the services it provides to those patients. In addition, there are no Regulatory Review Criteria that are applicable to this project; therefore, there are no performance standards for utilization that must be met. The applicant's projections of the infusion therapy and clinical trials patients to be served at LCI-Concord are based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to renovate existing space and increase its infusion therapy chairs, and develop a Phase I clinical trials unit.

Access

In Section VI.2, pages 67 - 68, the applicant states it will continue to provide services to all patients regardless of their income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or other factor that would classify a patient as underserved. 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 by the proposed project, demonstrates the need the population has for the services proposed, and demonstrates 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.

NA

(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 45 – 46, the applicant discusses the alternatives considered prior to the submission of this application, which includes doing nothing or the proposed project. The applicant states that maintaining the status quo results in excessive wait times and lack of

infusion chairs, which ignores patients' needs. In addition, the development of a Phase I clinical trials unit will benefit LCI-Concord's patients by being located closer to their homes.

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

In summary, the applicant adequately demonstrates that its 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 application and that would otherwise require a certificate of need.**

3. **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 Certificate of Need Section, 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 renovate existing space to expand the chemotherapy infusion treatment area from 25 to 35 chairs and develop a Phase I clinical trials unit.

Capital and Working Capital Costs

In Section VIII.1, page 90, the applicant states the capital cost of the project will be as follows:

DESCRIPTION	COST
Construction/Renovation Costs	$2,622,624
Equipment, Fixed and Moveable	$1,359,968
Miscellaneous Costs, Including Professional Fees	$ 991,188
Total	$4,973,780

In Section IX, page 97, the applicant states there will be no working capital costs (start-up costs or initial operating costs) associated with this project, since the facility is operational and the project proposes renovation.

Availability of Funds

In Section VIII.3, page 92, the applicant states that the capital costs of the project will be financed with the accumulated reserves of CMHA d/b/a Carolinas HealthCare System. In Exhibit 15, the applicant provides a September 15, 2015 letter signed by the Executive Vice President and Chief Financial Officer of Carolinas HealthCare System, which confirms the availability of sufficient funds to pay for the capital costs associated with this project, and commits the use of those funds to the project. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provided financial pro forma financial statements for the first three operating years of the project in Section XIII of the application. The applicant projects revenues will exceed expenses in each of the first three operating years, as illustrated in the table below:

	CY 2017	CY 2018	CY 2019
Net Revenue	$32,764,850	$34,315,608	$35,932,745
Operating Expenses	$25,982,761	$27,073,286	$28,212,879
Income (loss)	$ 6,782,089	$ 7,242,323	$ 7,719,866

The applicant also projects a positive net income for the entire facility in each of the first thee operating years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section XIII 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 projections 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 upon 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 expand LCI-Concord's outpatient infusion clinic from 25 to 35 bays and to develop a Phase I clinical trials unit by renovating 15,411 existing square feet in the Oncology Building.

The 2015 SMFP does not define a service area for an oncology facility such as LCI – Concord. The applicant defines its service area in Section III.5, page 49, as Cabarrus, Rowan and Stanly counties. Facilities may also serve residents of counties not included in their service area.

In Section III.6, page 53, the applicant lists three other providers in the proposed service area who provide infusion therapy services to cancer patients, as follows:

- Carolina Oncology Associates in Salisbury, NC (Rowan County)
- Rowan Regional Medical Center in Salisbury, NC (Rowan County)
- LCI – Albermarle (Stanly County)

The applicant states on page 53 that chemotherapy utilization data is not publicly available. Furthermore, the applicant states it is not aware of any other sites that offer Phase I clinical trials for oncology treatment in the service area. However, the applicant provided historical utilization for LCI-Albermarle for the previous full fiscal year, as shown in the following table:

LCI-Albermarle Utilization – CY 2014

# INFUSION TREATMENTS	# INJECTIONS	# CHAIRS
3,343	1,282	9

In Section III. 6(b), page 53, the applicant states the need for the expansion of the infusion therapy areas and development of a Phase I clinical trials unit at LCI-Concord is internal to the applicant because of its own capacity constraints and patient needs. Therefore, it is not a need that could be met by another provider.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing and approved infusion therapy and chemotherapy treatment providers in the service area. Therefore, 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

In Section VII.1, pages 79 – 82, the applicant provides the current and projected staffing for LCI-Concord, as shown in the table below:

POSITION	NUMBER OF FULL-TIME EQUIVALENT (FTE) POSITIONS	
	CURRENT	PROJECT YEAR 2
Nurse Manager	1.0	1.0
Clinical Supervisor	1.0	1.0
Charge Nurse	--	1.0
Pharmacy Manager	1.0	1.0
Pharmacy Clinical Specialist	--	1.0
Registered Nurse	10.25	12.75
Pharmacist	3.6	4.1
Pharmacy Technician	2.0	3.0
Certified Nurse Assistant	--	1.0
Chemo Scheduler	--	1.0
Registered Medical Assistant	1.0	1.0
Medical Lab Technician	1.0	2.0
Clinical Research RN	--	100
Clinical Research Associate	--	1.0
Receptionist/Patient Registration	2.0	2.0
Total	22.85	33.85

In Section VII.6(a), page 84, the applicant describes its experience and process for recruiting and retaining staff. In Section VII.8, page 86, the applicant states Dr. Thomas A. Steffans is and will be the Medical Director for the infusion therapy services, and Dr. Steven A. Limentani is and will be the Medical Director for the clinical trials services. In Exhibit 6 the applicant provides a copy of a letter from each physician, each expressing a desire to continue to serve in the capacity of Medical Director for LCI-Concord's proposed services. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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

In Section II.2, page 17, the applicant describes the necessary ancillary and support services and explains how they will be provided. CMC is an existing acute care hospital and provides all of the necessary support services for LCI-Concord. In Section III, pages 31 – 32, the applicant states it is actively recruiting physicians to LCI-Concord. In addition, in Exhibit 16, the applicant provides 23 letters signed by area physicians who offer support for the proposal. Each of these letters states there is a need in the service area for both increased infusion therapy services and a Phase I clinical trials unit. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed project 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.

NA

(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.13, pages 74 - 75, the applicant provides the payor mix during CY 2014 for the Infusion Therapy services and clinical trials, as shown in the table below.

PAYOR CATEGORY	INFUSION THERAPY	PHASE I CLINICAL TRIALS
Self Pay	2.6%	5.1%
Medicare	57.7%	45.3%
Medicaid	6.4%	2.4%
Managed Care	31.3%	44.9%
Commercial Insurance	1.2%	2.4%
Workers Compensation	0.2%	--
Other	0.7%	--
Total	**100.0%**	**100.0%**

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available. The following counties comprise the proposed service area.

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Cabarrus	14%	4.9%	18.5%
Rowan	19%	7.6%	18.9%
Stanly	17%	7.6%	18.3%
Statewide	**17%**	**6.7%**	**19.7%**

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the chemotherapy infusion and clinical trial services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer 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 medically underserved populations currently have adequate access to the applicant's existing services and 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 72, the applicant states:

> *"LCI-Concord is not obligated under federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. However, as previously stated, LCI-Concord does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. LCI-Concord will continue to provide services to the community as previously described…."*

In Section VI.10, page 73, the applicant states there have been no civil rights complaints filed against CMHA in the last five years. 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.15, pages 76 - 78, the applicant provides the projected payor mix for the second full fiscal year following completion of the proposed project (CY 2018) for the infusion therapy and clinical trial oncology visits to LCI-Concord, as shown in the table below.

PAYOR CATEGORY	INFUSION THERAPY	CLINICAL TRIALS
Self Pay	2.6%	5.1%
Medicare	57.7%	45.3%
Medicaid	6.4%	2.4%
Managed Care	31.3%	44.9%
Commercial Insurance	1.2%	2.4%
Workers' Compensation	0.2%	--
Other	0.7%	--
Total	**100.0%**	**100.0%**

In Section VI.15, pages 76 - 78, the applicant describes the assumptions used to project payor mix.

The applicant 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(a), page 72, the applicant states access to both infusion therapy and Phase I clinical trial services at LCI-Concord will continue to be by referral from physicians who have admitting privileges at CMC, and referrals from *clinicaltrials.gov*. The information provided is reasonable and credible and supports a finding of conformity 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, pages 61 - 62, the applicant discusses the existing health professional training programs with which the Carolinas HealthCare System, of which LCI-Concord is a part, has established relationships. The information provided in Section V.1 is reasonable and credible 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

LCI-Concord proposes to renovate 15,411 square feet of existing clinic space in the Medical Oncology building, increase its infusion therapy bays from 25 to 35 chairs, and develop a Phase I clinical trials unit.

The 2015 SMFP does not define a service area for an oncology facility such as LCI – Concord. The applicant defines its service area in Section III.5, page 49, as Cabarrus, Rowan and Stanly counties. Facilities may also serve residents of counties not included in their service area.

In Section V.7, pages 65 - 66, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

> *"With this expansion in the infusion center, LCI-Concord will be able to treat more patients without delay, provide treatment closer to home, thus increasing patient satisfaction."*

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 those sections 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 proposal, and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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 Exhibit 2, the applicant provides a table that lists all of the facilities that it currently owns, leases, or manages in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by Carolinas HealthCare System (CHS) in North Carolina. 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 CHS 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