

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 11, 2017

Findings Date: August 11, 2017

Project Analyst: Gloria C. Hale

Team Leader: Lisa Pittman

Project ID #: F-11363-17

Facility: Levine Cancer Institute - Huntersville

FID #: 170280

County: Mecklenburg

Applicant: The Charlotte-Mecklenburg Hospital Authority

Project: Develop a new outpatient infusion therapy clinic by renovating existing space on the campus of Carolinas HealthCare System Huntersville

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The Charlotte-Mecklenburg Hospital Authority (CMHA) d/b/a Carolinas Medical Center (CMC) proposes to develop a new outpatient infusion therapy clinic, Levine Cancer Institute – Huntersville (LCIH), by renovating existing space on the campus of Carolinas HealthCare System Huntersville (CHS Huntersville).

#### **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 2017 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 page 33 of the 2017 SMFP, is applicable to this review because the capital cost of the proposed project is \$4,600,000, which is greater than \$2 million.

*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, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 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.”*

In Section B.11, page 29, and Section K.4, pages 73-74, the applicant states it will work with experienced architects, engineers, and others to ensure energy efficient systems are utilized in the renovations of the existing space. The applicant states, on page 29, that its design team will deliver the following:

- Meet or exceed the NC Building Code requirements,
- Utilize United States Green Building Council LEED guidelines and GGHC to identify opportunities to improve efficiency and performance,
- Benchmark performance using the EPA Energy Star for Hospitals rating system for comparing performance across systems, and
- Upgrade plumbing fixtures as appropriate to maximize efficiency and life cycle benefits.

The applicant adequately demonstrates conformance with the requirements of *Policy GEN-4*.

There are no other policies in the 2017 SMFP which are applicable to this review.

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

## C

The applicant, CMHA, proposes to develop a new outpatient infusion therapy clinic, LCIH, by renovating existing space on the campus of CHS Huntersville. LCIH will be developed in unoccupied space on the second floor of a Carolinas HealthCare System (CHS) – owned facility located at 16455 Statesville Road in Huntersville. LCIH will have 12 infusion therapy bays, physician offices and exam rooms, a pharmacy, lab, blood draw area, patient waiting and registration area, and administrative and support spaces. In addition, the proposed project includes renovation of roof space for associated mechanical and equipment needs for the clinic.

### **Patient Origin**

The 2017 SMFP does not define the service area for outpatient infusion therapy clinics. However, the applicant projects, in Section C.3, page 36, that 71.7% of LCIH's patients will be from Mecklenburg County in each of the first three operating years following project completion. Thus, the applicant's service area for the proposed outpatient infusion therapy clinic at LCIH is Mecklenburg County. However, facilities may serve residents of counties not included in their service area.

In Section C.3, page 36, the applicant provides the projected patient origin for LCIH for the first three operating years (OY) following completion of the proposed project, summarized as follows:

**LCIH**  
**Projected Patient Origin**  
**OY1, Calendar Year 2019 (CY2019) through OY3 (CY2021)**

<b>County</b>	<b>OY1 (CY2019) Percent of Total Patients</b>	<b>OY2 (CY2020) Percent of Total Patients</b>	<b>OY3 (CY2021) Percent of Total Patients</b>
Mecklenburg	71.7%	71.7%	71.7%
Iredell	11.6%	11.6%	11.6%
Gaston	9.5%	9.5%	9.5%
Lincoln	7.2%	7.2%	7.2%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

On page 36, the applicant states its projected patient origin is based on historical patient origin for existing LCI outpatient infusion therapy services locations and notes that LCI locations serve a number of patients residing in Huntersville and surrounding areas. The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C.4, pages 37-43, the applicant describes the need for the proposed project, summarized as follows:

- The growth in CHS-wide cancer services of 10.6% annually, from CY2012 through CY2016, and the need for geographic accessibility of LCI cancer services, including infusion therapy, in northern Mecklenburg County (pages 37-40).
- The high rate of historical and projected population growth in Mecklenburg County as a whole and in the Huntersville zip code area specifically as compared to other northern Mecklenburg County zip code areas (pages 40-41).
- The growth of the over 65 years of age population in Mecklenburg County as a whole and in the Huntersville zip code area specifically as compared to other northern Mecklenburg County zip code areas (page 42).
- Projected increases in cancer incidence in Mecklenburg County which will drive the demand for cancer services (page 43).

The information provided by the applicant in the pages referenced above is reasonable and adequately supported.

**Projected Utilization**

In Section Q, pages 1-5, the applicant provides its assumptions and methodology for projecting utilization for outpatient infusion therapy services at LCIH for the first three operating years upon project completion, summarized as follows:

Step 1:

On pages 1-2 of Section Q, the applicant states that it determined it would need two physicians and one advanced care provider (ACP) to meet patients' needs at LCIH. The applicant states that it reviewed the historical productivity of its oncology providers at its LCI community-based settings and determined that, on average, its oncology physicians provided 2,950 patient visits per year and its ACPs provided an average of 1,500 patient visits per year. These patient visits did not include infusion or injection therapy visits. The applicant states, on page 1, that it projects that LCIH will achieve this level of physician and ACP productivity and that patient visits will ramp up gradually over the first three operating years of the proposed project, starting at 75% capacity at the end of OY1, increasing to 90% by the end of OY2, and increasing to 100% by the end of OY3. The projected number of patient visits for the first three operating years, by provider, is illustrated as follows from page 2:

**Projected Total Number of Patient Visits**

	<b>OY1 1/01/19 – 12/31/19</b>	<b>OY2 1/01/20 – 12/31/20</b>	<b>OY3 1/01/21 – 12/31/21</b>
Number of Physicians	2	2	2
Patient Visits per Physician	2,950	2,950	2,950
Total Number Patient Visits for Physicians	5,900	5,900	5,900
Number of ACPs	1	1	1
Patient Visits per ACP	1,500	1,500	1,500
Total Number Patient Visits Physicians and ACPs	7,400	7,400	7,400
Ramp up %	75%	90%	100%
<b>Total Projected Number of Patient Visits</b>	<b>5,550</b>	<b>6,660</b>	<b>7,400</b>

Step 2:

In Section Q, page 2, the applicant averaged the number of infusions per patient visit in other community-based LCI locations, 0.43, and multiplied it by the total projected number

of patient visits for each operating year in Step 1 above to determine the projected number of infusion therapy patients. The results of this calculation are as follows:

**Projected Infusion Therapy Patients**

	<b>OY1</b> 1/01/19 – 12/31/19	<b>OY2</b> 1/01/20 – 12/31/20	<b>OY3</b> 1/01/21 – 12/31/21
Projected Number of Infusion Therapy Patients	2,387	2,864	3,182

The applicant states, on pages 2-3, that the projections in the table above are reasonable given there are 6,631 LCI infusion therapy patients residing in Huntersville and surrounding communities, and that for many of these patients, the LCIH location would be a more convenient location.

Step 3:

The applicant states, on page 5, that injection patients will also be using the infusion therapy chairs and that these patients are also considered in determining the need for the project. Thus, the applicant calculated the ratio of injection patients to infusion therapy patients in its other community-based LCI locations, 0.31, and multiplied it by the projected number of infusion therapy patients. This calculation resulted in the projected number of injection patients for each operating year, summarized as follows:

**Projected Number of Injection Patients**

	<b>OY1</b> 1/01/19 – 12/31/19	<b>OY2</b> 1/01/20 – 12/31/20	<b>OY3</b> 1/01/21 – 12/31/21
Projected Number of Infusion Therapy Patients	2,387	2,864	3,182
Ratio of Injection Patients to Infusion Therapy Patients	0.31	0.31	0.31
Total Projected Number of Injection Patients	746	895	994

Step 4:

On page 5, the applicant provides the projected number of infusion therapy and injection patients at LCIH, for the first three operating years of the project, as follows:

**LCIH**  
**Projected Number of Infusion Therapy and Injection Patients**

	<b>OY1</b> <b>1/01/19 –</b> <b>12/31/19</b>	<b>OY2</b> <b>1/01/20 –</b> <b>12/31/20</b>	<b>OY3</b> <b>1/01/21 –</b> <b>12/31/21</b>
Number of Infusion Therapy Patients	2,387	2,864	3,182
Number of Injection Patients	746	895	994
Total Number of Infusion Therapy and Injection Patients	3,132	3,759	4,176

Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to develop an outpatient infusion therapy clinic in Huntersville.

**Access**

In Section C.10, page 46, the applicant states that LCIH will provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. Exhibit C.10 contains a copy of the applicant's Non-Discrimination policies. In addition, Exhibit L.4 contains CHS' system-wide Hospital Coverage Assistance and Financial Assistance Policy. In Section L.3, page 80, the applicant projects that 54.3% of LCIH's patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

**Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project and adequately demonstrates the extent to which all residents, including underserved groups, will 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 E.2, page 54, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo – The applicant states that this alternative would not address the need for cancer services in a geographically accessible location to Huntersville and the surrounding area. Thus, this alternative is not the most effective alternative.
- Develop the Project at Another Location - The applicant states that the proposed project has many advantages over developing the project at another location. The applicant states that the proposed location on the CHS medical campus is convenient and provides familiar access to patients and physicians. In addition, unlike another location or as a newly built facility, there is cost savings due to shared expenses such as patient access, security, and building and grounds maintenance. Therefore, developing the project at another location is not the most effective alternative.

After considering these alternatives, the applicant states, on page 54, “*No other location in the Huntersville area would provide comparable access and cost-effectiveness.*” Therefore, the proposed project is the most effective alternative to meet the identified need.

Furthermore, the application is conforming or conditionally 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 the 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 shall materially comply with all representations made in the certificate of need application.**
- 2. The Charlotte-Mecklenburg Hospital Authority shall not acquire, as part of this project, any equipment that is not included in the project’s proposed capital expenditure in Section Q of the application and that would otherwise require a certificate of need.**
- 3. The Charlotte-Mecklenburg Hospital Authority shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare**



**Planning and 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, CMHA, proposes to develop a new outpatient infusion therapy clinic, LCIH, by renovating existing space on the campus of CHS Huntersville. LCIH will be developed in unoccupied space on the second floor of a CHS-owned facility located at 16455 Statesville Road in Huntersville.

**Capital and Working Capital Costs**

In Section Q, page 6, the applicant states the total capital cost is projected to be as follows:

**LCIH  
Project Capital Cost**

<b>Capital Cost Category</b>	<b>Total</b>
Construction Costs	\$2,353,925
Architect and Engineering	\$145,000
Equipment, Medical and Non-Medical	\$510,011
Furniture and soft goods, i.e. art, signage	\$193,975
Consultant Fees	\$120,673
Other (information technology, security, internal allocation, and contingency)	\$1,276,416
<b>TOTAL CAPITAL COST</b>	<b>\$4,600,000</b>

In Section F.3, pages 58-59, the applicant states there will be no start up or initial operating expenses for the project since the proposed project is not a new service and that CMC operates many similar, provider-based unlicensed outpatient infusion therapy clinics.

**Availability of Funds**

In Section F.2, page 57, the applicant states that the total project capital costs will be funded by the accumulated reserves or owner's equity of CHS. In Exhibit F.2, the applicant provides a letter dated June 15, 2017, from the Executive Vice President and Chief Financial Officer of CHS, which states that the capital costs of \$4,600,000 will be funded by accumulated reserves of CHS. Exhibit F.2-2 contains a copy of the financial statements for CHS for the years ending December 31, 2015 and December 31, 2014. For the year

ending December 31, 2015, CHS had \$173,812,000 in cash and cash equivalents, \$7,792,619,000 in current assets, and \$3,934,979,000 in total net assets. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

In Section Q, the applicant provided pro forma financial statements for the first three fiscal years of operation following completion of the project. In the pro forma financial statement (Form F.4), the applicant projects that operating expenses will exceed revenues in the first and second operating years of the project, and that revenues will exceed operating costs in the third operating year of the project, as shown in the table below:

**LCIH  
 Projected Revenue and Expenses\***

	<b>OY1 CY2019</b>	<b>OY2 CY2020</b>	<b>OY3 CY2021</b>
Total # of Infusion and Injection Patients	3,132	3,759	4,176
Total Gross Revenue (Charges)	\$32,813,458	\$40,557,434	\$46,415,730
Deductions from Gross Revenues	\$24,681,072	\$30,688,951	\$35,333,017
Total Net Revenue	\$8,132,386	\$9,868,483	\$11,082,712
Average Net Revenue per Patient	\$2,597	\$2,625	\$2,654
Total Operating Expenses (Costs)	\$9,000,389	\$10,253,339	\$9,292,836
Average Operating Expense per Patient	\$2,874	\$2,728	\$2,225
<b>Net Income (Loss)</b>	<b>\$ (868,003)</b>	<b>\$(384,916) [\$(384,856)]</b>	<b>\$1,789,876</b>

\*Correction made by the Project Analyst is in brackets.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**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, CMHA, proposes to develop a new outpatient infusion therapy clinic, LCIH, by renovating existing space on the campus of CHS Huntersville. LCIH will be developed in unoccupied space on the second floor of a CHS-owned facility located at 16455 Statesville Road in Huntersville.

The 2017 SMFP does not define the service area for outpatient infusion therapy clinics. However, the applicant indicates, in Section C.3, page 36, that based on historical utilization at its other LCI outpatient infusion therapy locations, it projects that over 70% of LCIH's outpatient infusion therapy patients will reside in Mecklenburg County for each of the first three operating years of the proposed project. Thus, the applicant's service area for the proposed services is Mecklenburg County. However, facilities may serve residents of counties not included in their service area.

The number and location of outpatient infusion therapy services are not publicly reported. However, in Section G.1, page 64, the applicant states that there are four oncology infusion providers in Huntersville and surrounding communities, as follows:

<b>Provider Name</b>
Lake Norman Oncology-Huntersville
Lake Norman Oncology-Mooresville
Lake Norman Regional Medical Center
Novant Health Huntersville Medical Center

The applicant provides a map of LCI infusion therapy clinics in Mecklenburg County in Section C.4, page 39. According to the map provided there are nine LCI infusion therapy services locations in Mecklenburg County. However, a patient residing near the proposed location in Huntersville would have to drive nearly 17 miles to the LCI Concord infusion therapy services clinic or 14 miles to the LCI Mallard Creek infusion therapy services clinic. The applicant states, on page 38, that there is a significant volume of patients in the Huntersville area and that LCI does not currently have cancer services along the I-77 corridor, therefore patients must travel along heavily congested roads while experiencing the common, unpleasant side effects of chemotherapy.

The applicant adequately demonstrates the need for the proposed outpatient infusion therapy services at LCIH. The discussion regarding need found in Criterion (3) is incorporated herein by reference. Consequently, the applicant adequately demonstrates that the proposed project will not result in unnecessary duplication of existing or approved

health service capabilities or facilities. 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 Q, Form H, the applicant provides the projected staffing for the proposed infusion therapy services at LCIH for the second operating year, as follows:

**LCIH  
Projected Staffing**

<b>Position</b>	<b>Total Projected Number of FTE Positions OY2, CY2020</b>
Practice Manager	1.0
Clinic Registered Nurses (RNs)	4.0
Infusion RNs	4.0
Lab Personnel	1.0
Pharmacist	1.0
Pharmacy Technician	1.0
Patient Service Specialists	2.0
<b>TOTAL</b>	<b>14.0</b>

In Section H.4, page 67, the applicant states that Dr. Seungjean (Jean) Chai will provide medical direction for LCIH. Exhibit H.4-1 contains a copy of a letter from Jean Chai, M.D., dated June 15, 2017, expressing willingness to serve as the Medical Director for LCIH. In Section H.2, pages 66-67, and Section H.4, page 68, the applicant describes its resources and procedures for recruiting and retaining staff. 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 I.1, page 69, the applicant states that CHS has all the necessary ancillary and support services in place for the proposed services. In addition, the applicant states, on page 69, that the ancillary and support services in place on the CHS Huntersville campus will

be made available to LCIH patients. Exhibit I.1 contains a letter from the President of CMC, dated June 15, 2017, documenting that these services are available at CMC and will continue to be provided following completion of the proposed project. In addition, Exhibit I.1-2 contains letters from the Presidents of CHS University and LCI, dated June 15, 2017, documenting that necessary ancillary and support services will be available to patients at LCIH. In Section I.2, page 70, the applicant states that LCI has existing relationships with local healthcare providers such as hospitals, home health and hospice agencies, and many other health-related providers. In addition, the applicant states, on page 70, that CHS is a multi-faceted, vertically integrated healthcare system and that, as such, patients of CMS have access to a broad continuum of health and human services. Exhibit I.2 contains copies of letters from area physicians indicating support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will continue to be available and that the proposed services will be coordinated with the existing healthcare 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, CMHA, proposes to develop a new outpatient infusion therapy clinic, LCIH, by renovating existing space on the campus of CHS Huntersville. LCIH will be developed in unoccupied space on the second floor of a CHS-owned facility located at 16455 Statesville Road in Huntersville. In Section K.2, page 72, the applicant states that the renovated space will be 9,040 square feet. In Section Q, Form F.1a, the applicant states that the capital cost of the project will be \$4,600,000.

Exhibit F.1 contains a letter from an architect that estimates the construction costs will total \$2,353,925, which corresponds to the construction cost projections provided by the applicant in Section Q, Form F.1a. The applicant provides line drawings of the existing space to be renovated in Exhibit C.1. In Section K.4, pages 73-74, the applicant describes the methods that will be used by the facility to maintain efficient energy operations. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates 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;

NA

- (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 L.2, page 79, the applicant states that it has no obligations to provide uncompensated care, community services or access to underserved populations,

however it will continue to provide services to all persons in need of medical care, including the underserved.

In Section L.2, page 80, the applicant states that no civil rights access complaints have been filed against any affiliated entity of CHS in the last five years. The application is conforming to this criterion.

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

C

In Section L.3, page 80, the applicant projects the following payor mix for the proposed outpatient infusion therapy services at LCIH during OY2 (CY2020):

<b>Payor Category</b>	<b>LCIH Patients as Percent of Total*</b>
Self Pay/Indigent/Charity	1.8%
Medicare	47.7%
Medicaid	6.6%
Commercial Insurance/ Managed Care	43.2%
Other**	0.8%
<b>Total</b>	<b>100.0%</b>

\*Total may not foot due to rounding.

\*\*Includes other government.

In Section L.3, pages 80-81, the applicant states that its projected payor mix for the proposed project is based on historical payor mix for LCI patients residing in the Huntersville area during CY2016. 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 L.5, page 81, the applicant states that access to LCIH's outpatient infusion therapy services will be provided through referrals to any LCI physician or via the LCI access center phone line. The applicant adequately demonstrates that the facility 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 M.1, pages 83-84, the applicant states that LCIH, as part of CHS, will have access to health professional training programs supported by CHS and that it will be committed to accommodating clinical training needs of area professional training programs. The applicant states that CHS has established relationships with many clinical education programs, including Cabarrus College of Health Sciences, Carolinas College of Health Sciences, and Presbyterian School of Nursing among others. The application is conforming to this criterion.

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

C

The applicant, CMHA, proposes to develop a new outpatient infusion therapy clinic, LCIH, by renovating existing space on the campus of CHS Huntersville. LCIH will be developed in unoccupied space on the second floor of a CHS-owned facility located at 16455 Statesville Road in Huntersville.

The 2017 SMFP does not define the service area for outpatient infusion therapy clinics. However, the applicant indicates, in Section C.3, page 36, that based on historical utilization at its other LCI outpatient infusion therapy locations, it projects that over 70% of LCIH's outpatient infusion therapy patients will reside in Mecklenburg County for each of the first three operating years of the proposed project. Thus, the applicant's service area for the proposed services is Mecklenburg County. However, facilities may serve residents of counties not included in their service area.

There is no publicly available information on the number or location of outpatient infusion therapy services in Mecklenburg County, however the applicant lists four providers of these services in the Huntersville area and provides a map of existing LCI infusion therapy



clinics throughout Mecklenburg County and the surrounding area on pages 64 and 39, respectively.

In Section N.2, pages 85-87, 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 that the proposed project will be cost-effective because the infusion therapy clinic will be using existing space where there will be shared building costs, will improve local access by reducing personal expense to patients, and will promote quality by improving access to LCI's exceptional cancer services.

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 in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the 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 project 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 it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will 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 O.3, the applicant provides a listing of healthcare facilities owned, managed or leased by CMHA in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHHS, six facilities were found to be out of compliance with one or more Medicare conditions of participation and two of those were found to be out of compliance with Medicare conditions of participation more than once within the 18 months immediately preceding the submission of the application through the date of the decision related to quality of care. As of the date of this decision, the problems

have been corrected. 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 CMHA 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