

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 23, 2018

Findings Date: March 23, 2018

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: F-11424-17

Facility: Carolinas Medical Center

FID #: 943070

County: Mecklenburg

Applicant: The Charlotte-Mecklenburg Hospital Authority

Project: Expand and relocate the existing LCI-Pineville outpatient infusion therapy clinic, including adding 18 additional infusion therapy chairs for a total of 30 infusion therapy chairs, from its existing location to new construction within medical office building space also on the CHS Pineville campus

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, The Charlotte-Mecklenburg Hospital Authority (CMHA) d/b/a Carolinas Medical Center (CMC) proposes to expand and relocate the existing Levine Cancer Institute-Pineville (LCI-Pineville) outpatient infusion therapy clinic), including adding 18 additional infusion therapy chairs for a total of 30 infusion therapy chairs, currently located on the campus of Carolinas Healthcare System Pineville (CHS Pineville) to new construction within medical office space also located on the campus of CHS Pineville.

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 (2017 SMFP). Therefore, there are no new determinations in the 2017 SMFP that are applicable to this review.

Policies

The following policy is applicable to this review:

- Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities

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

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control.”

In Section B, page 29, the applicant provides a written statement describing the proposed project’s plan to assure improved energy efficiency and water conservation including upgrade of any impacted plumbing fixtures, use United States Green Building Council LEED guidelines, Leadership in Energy and Environmental Design guidelines and Hospitals for a Healthy Environment Green Guide for Health Care experience. The applicant adequately demonstrates that the application includes a written statement describing the projects plans to assure improved energy efficiency and water conservation. Therefore, application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 based on the fact that the applicant provides a written statement describing the projects plans to assure improved energy efficiency and water conservation.

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

C

CMC proposes to expand and relocate the existing LCI-Pineville outpatient infusion therapy clinic), including adding 18 additional infusion therapy chairs for a total of 30 infusion therapy chairs, currently located on the campus of CHS Pineville to new construction within medical office space also located on the campus of CHS Pineville.

Patient Origin

The 2017 SMFP does not define a service area for infusion therapy facilities. The applicant identifies the service area for LCI-Pineville as consisting of the following ZIP codes: 29707, 29708, 28277, 28210, 29730, 28226, 29732, 29715, 28278, 28134, 29720, 28273, 29710, 29745, 28112 and 28173 “*which represents 75 percent of its historical and projected patient origin.*” See application Section G, page 65.

In Section C, pages 35-36, the applicant provides historic patient origin for LCI-Pineville Infusion Therapy and Injections as well as historic patient origin for CHS Pineville Outpatient Blood Transfusions, as illustrated in the tables below:

LCI-Pineville: Historic Patient Origin for Infusion Therapy and Injections-CY2016

County	Number of Patients	% of Total
Mecklenburg	1,575	42.0%
York, SC	1,010	26.9%
Lancaster, SC	544	14.5%
Union	332	8.8%
Gaston	75	2.0%
Other*	216	5.8%
Total	3,752	100.0%

*Other includes Brunswick, Burke, Cabarrus, Caldwell, Catawba, Cleveland, Cumberland, Davidson, Durham, Guilford, Iredell, Lincoln, Nash, Stanly, Surry and Wake counties in North Carolina, as well as other states. Source: LCI Pineville internal data.

CHS Pineville: Historic Patient Origin for Outpatient Blood Transfusion-CY2016

County	Number of Patients	% of Total
Mecklenburg	143	57.7%
York, SC	40	16.3%
Lancaster, SC	44	17.9%
Union	9	3.7%
Other*	11	4.5%
Total	247	100.0%

*Other includes Cabarrus, Cleveland, Iredell, Lincoln, and Stanly counties in North Carolina, as well as other states. Source: CHS Pineville internal data.

In Section C, pages 37-38, the applicant provides projected patient origin for LCI-Pineville Infusion Therapy and Injections as well as projected patient origin for Outpatient Blood Transfusions. The proposed project included increasing the number of infusion therapy chairs from 12 chairs to 30 chairs. Blood transfusions can also be performed utilizing the infusion therapy chairs. Based on the increase in the number of infusion therapy chairs, outpatient blood transfusions would be able to be performed at LCI-Pineville instead of CHS Pineville which is reflected in the location of the services, see the tables below:

LCI-Pineville: Projected Patient Origin for Infusion Therapy and Injections- OY –OY3

County	OY1 (CY2020)		OY2 (CY2021)		OY3 (CY2022)	
	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients	% of Total
Mecklenburg	3,372	42.0%	3,758	42.0%	3,841	42.0%
York, SC	2,162	26.9%	2,410	26.9%	2,463	26.9%
Lancaster, SC	1,164	14.5%	1,297	14.5%	1,325	14.5%
Union	710	8.8%	791	8.8%	809	8.8%
Gaston	160	2.0%	179	2.0%	183	2.0%
Other*	463	5.8%	516	5.8%	527	5.8%
Total	8,031	100.0%	8,950	100.0%	9,148	100.0%

*Other includes Brunswick, Burke, Cabarrus, Caldwell, Catawba, Cleveland, Cumberland, Davidson, Durham, Guilford, Iredell, Lincoln, Nash, Stanly, Surry and Wake counties in North Carolina, as well as other states.

LCI-Pineville: Projected Patient Origin for Outpatient Blood Transfusion: OY1 – OY3

County	OY1 (CY2020)		OY2 (CY2021)		OY3 (CY2022)	
	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients	% of Total
Mecklenburg	130	57.7%	132	57.7%	135	57.7%
York, SC	37	16.3%	37	16.3%	38	16.3%
Lancaster, SC	40	17.9%	41	17.9%	42	17.9%
Union	8	3.7%	8	3.7%	9	3.7%
Other*	10	4.5%	10	4.5%	10	4.5%
Total	225	100.0%	229	100.0%	234	100.0%

*Other includes Cabarrus, Cleveland, Iredell, Lincoln, and Stanly counties in North Carolina, as well as other states. Source: CHS Pineville internal data

In Section C, page 38, the applicant states that projected patient origin for infusion therapy and injection and blood transfusion services is based on historical patient origin at LCI-Pineville and CHS Pineville Outpatient Blood Transfusions.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C, pages 38-46, and Section E, pages 56-57, the applicant describes the need for the proposed project, summarized as follows:

- Dynamic population growth in Mecklenburg County and the southern Charlotte region, including growth in the over 65 population. (See application pages 41-45)
- Mecklenburg County resident’s incidence of cancer. (See application pages 45-46)
- The need at LCI-Pineville for additional capacity and improved local access to cancer services. (See application pages 39-41)
- LCI-Pineville has experienced recent and rapid growth in utilization. There is no room to expand in either its existing space or in adjacent space. In addition, the components of LCI-Pineville’s existing services are not currently consolidated, but rather “scattered” throughout two existing buildings with no ability to consolidate at its current location.
- The proposed project location will be in new medical office space, located on the CHS Pineville campus and co-located with LCI-Pineville cancer services. The proposed location will be the most convenient in terms of familiarity, physician and patient convenience, patient access, shared building expenses, security, and ground maintenance. (See application page 57)

The applicant adequately demonstrates the need to relocate and expand the LCI-Pineville infusion therapy services to new construction within medical office space also located on the campus of CHS Pineville.

Projected Utilization

In Section Q, Form C, pages 1-6, the applicant provides projected utilization for the proposed 30 infusion therapy chairs through the first three full years of operation following completion of the project (CY2020 – CY2022), which is summarized below.

	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
Total Infusion Therapy Patients	6,401	7,134	7,291
Blood Transfusion Patients	225	229	234
Total Infusion/Transfusion Patients	6,626	7,363	7,525
# of Chairs	30	30	30
Days/Year	250	250	250
Patients/Chair/Day Capacity	1.6	1.6	1.6
Total Capacity	12,000	12,000	12,000
% Capacity (Infusion/Transfusion)	55.2%	61.4%	62.7%

The applicant describes the assumptions and methodology used to project utilization in Section Q, Form C, as follows:

From CY2014 to CY2017 infusion therapy patients at LCI-Pineville had grown at a CAGR of 10.9%. (See Section Q, Form C, page 1)

Historical: LCI-Pineville Infusion Therapy Patients

	CY2014	CY2015	CY2016	CY2017*	CAGR
# of Chairs	10	10	10	12	na
Infusion Therapy Patients	2,232	2,444	2,826	3,048	10.9%

*Annualized

Infusion therapy patients were grown at a compound annual growth rate (CAGR) of 2.0% starting with a baseline of 3,048 annualized patients from CY2017.

Projected: LCI-Pineville Infusion Therapy Patients

	CY2017	CY2018	CY2019	CY2020	CY2021	CY2022	CAGR
Infusion Therapy Patients	3,048*	3,108	3,169	3,231	3,295	3,360	2.0%

*Annualized

In addition to projecting infusion therapy patients at a CAGR of 2.0%, the applicant projected increased coverage from existing providers and adding three additional providers as summarized in the table below.

	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
# of Infusion Therapy Chairs	30	30	30
Baseline Infusion Therapy Patients	3,231	3,295	3,360
Patients from increased full-time equivalent (FTE) Coverage from Existing Providers	1,161	1,161	1,161
Additional Provider #1 and #2- Patients	1,663	1,847	1,847
Additional Provider #3- Patients	346	831	924
Total Infusion Therapy Patients	6,401	7,134	7,291

Source: Section Q, Form C, pages 2-3. The applicant provides a “ramp-up” calculation for the additional providers.

Infusion therapy services have no standard utilization. Based on studies, the applicant projected 1.6 patients per chair per day, 30 chairs, and 250 days of operation per year for a total patient capacity of 12,000 (30 x 250 x 1.6 = 12,000). See Section Q, Form C, pages 3-4. Based on this calculation, in OY3 the 30 infusion therapy chairs would be operating at 60.76 % of capacity [$7,291 / 12,000 = 0.60758$ or 60.76%].

Outpatient blood transfusions currently being performed at CHS Pineville due to lack of capacity at LCI-Pineville would, upon project completion, be performed at LCI-Pineville. These projected cases were added to the projected utilization. See Section Q, Form C, pages 5-6.

Projected utilization at LCI-Pineville is based on reasonable and adequately supported assumptions.

Access

Exhibit C-10 contains a copy of CHS’s Non-Discrimination policy which states *“No individual shall be subject to discrimination or denied the benefits of the services, programs, or activities of the Carolinas HealthCare System on the basis of race, color, religion, national origin, sex, age, disability or source of payment.”*

In Section L, page 81, the applicant projects the following payor mix during the second full fiscal year (CY2021) of operation following completion of the proposed project, as illustrated in the following table.

Projected Payor Mix in OY2 (CY2021): Current Days as a % of Total Days

Payor Source	LCI-Pineville Infusion/Injection Patients	CHS Pineville Blood Transfusion Patients	CMC Total
Medicaid	1.7%	0.0%	27.6%
Medicare	52.6%	71.4%	24.8%
Self-Pay/ Indigent/ Charity	1.0%	1.2%	13.0%
Commercial/Managed Care	43.5%	25.3%	32.7%
Other*	1.2%	2.1%	1.9%
Total	100.0%	100.0%	100.0%

*Includes other government

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

LCI-Pineville is located on the CHS Pineville campus. CMC proposes to consolidate and relocate LCI-Pineville from existing medical office space on the CHS Pineville campus, including adding 18 additional infusion therapy chairs for a total of 30 infusion therapy chairs, to new medical office space on the same CHS Pineville campus. The applicant does not propose to reduce, eliminate or relocate a facility or service. Therefore, Criterion 3(a) is not applicable to this review.

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

CA

CMC proposes to expand and relocate the existing LCI-Pineville outpatient infusion therapy clinic currently located on the campus of CHS Pineville), including adding 18 additional

infusion therapy chairs for a total of 30 infusion therapy chairs, to new construction within medical office space also located on the campus of CHS Pineville.

In Section E, pages 56-57, the applicant describe the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo- Maintaining the status quo does not reflect and effectively meet the growing patient demand for infusion therapy services at the LCI-Pineville location. Further, the proposed project will offer a more convenient and clinically appropriate location for blood transfusion patients. Therefore, the applicant determined maintaining the status quo is not the most effective alternative.
- Renovate existing space- LCI-Pineville has experienced recent and rapid growth in utilization. There is no room to expand in either its existing space or in adjacent space. In addition, the components of LCI-Pineville's existing services are not currently consolidated, but rather "scattered" throughout two existing buildings with no ability to consolidate at its current location. Therefore, the applicant determined that renovating existing space is not the most effective alternative.
- Develop the project in a different location- The applicant considered and rejected relocating and expanding the infusion therapy services to a different location. Therefore, the applicant determined that a different location than that proposed would be neither the most effective nor the least costly.

On page 57, the applicant states that its proposal is the most effective alternative because the proposed project location will be in new medical office space, located on the CHS Pineville campus and co-located with LCI-Pineville cancer services the proposed location is the most convenient in terms of familiarity, physician and patient convenience, patient access, shared building expenses, security, and ground maintenance.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is 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 expand and relocate the existing LCI-Pineville outpatient infusion therapy clinic from its existing location to new construction within medical office building space also on the CHS Pineville campus**
 - 3. 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 expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 4. 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.**
 - 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
 - 6. 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

CMC proposes to expand and relocate the existing LCI-Pineville outpatient infusion therapy clinic currently located on the campus of CHS Pineville), including adding 18 additional infusion therapy chairs for a total of 30 infusion therapy chairs, to new construction within medical office space also located on the campus of CHS Pineville.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the proposed project will be:

Construction/Renovation:	\$5,100,000
Architect/Engineering Fees:	\$ 200,000
Medical Equipment:	\$1,000,000
Non-Medical Equipment:	\$ 350,000
Furniture:	\$ 450,000
Consultant Fees:	\$ 100,000
Other (IS, Security, Internal Allocation, Contingency):	<u>\$1,300,000</u>
Total:	\$8,500,000

In Section F, pages 60-61, and Exhibit F-2.1, the applicant project there will be no working capital costs (start-up and initial operating expenses) as CMC is an existing acute care hospital that operates LCI-Pineville in addition to other numerous provider-based, unlicensed outpatient infusion therapy clinics.

Availability of Funds

In Section F, page 59, the applicant states that the capital costs will be financed by accumulated reserves of CMHA d/b/a/ CHS.

Exhibit F-2.1, contains a copy of a letter from Greg Gombar, Executive Vice President and Chief Financial Officer of The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System stating that Carolinas HealthCare System will fund the capital cost of the proposed project from existing accumulated reserves identified in the audited financial statements from the line items “Cash and cash equivalents” and “Other assets; designated as funded depreciation”. Exhibit F-2.2 contains a copy of the audited financial statements of The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System showing \$142,725,000 in cash and cash equivalents as of December 31, 2016.

The applicant adequately demonstrated that sufficient funds will be available for the capital needs of the proposed LCI-Pineville project.

Financial Feasibility

The applicant provided pro forma financial statements for LCI-Pineville for the first three full federal fiscal years of operation (CY2020, CY2021, and CY2022) following completion of the project. In the pro forma financial statement (Section Q, Form F.4), the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below.

	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY 2022)
Total Patient Days	8,255	9,180	9,381
Total Revenues (Charges)	\$94,707,532	\$108,614,392	\$114,334,435
Total Net Revenue	\$21,501,276	\$24,208,797	\$24,999,930
Average Net Revenue per patient day	\$2,604.64	\$2,637.12	\$2,664.95
Total Operating Expenses (Costs)	\$17,872,431	\$20,381,912	\$21,406,903
Average Operating Expense per patient day	\$2,165.04	\$2,220.25	\$2,281.94
Net Income	\$3,628,844	\$3,826,885	\$3,593,027

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

CMC proposes to expand and relocate the existing LCI-Pineville outpatient infusion therapy clinic currently located on the campus of CHS Pineville), including adding 18 additional infusion therapy chairs for a total of 30 infusion therapy chairs, to new construction within medical office space also located on the campus of CHS Pineville.

The 2017 SMFP does not define a service area for infusion therapy facilities. The applicant identifies the service area for LCI-Pineville as consisting of the following ZIP codes: 29707, 29708, 28277, 28210, 29730, 28226, 29732, 29715, 28278, 28134, 29720, 28273, 29710, 29745, 28112 and 28173 “which represents 75 percent of its historical and projected patient origin.” See application Section G, page 65. Facilities may also serve residents of counties not included in their service area.

Infusion therapy data is not publically reported. In Section G, page 65, the applicant identifies five outpatient oncology infusion therapy providers in LCI-Pineville’s service area as illustrated in the table below.

Provider Name	ZIP Code	County
LCI-Monroe	28112	Union
LCI-Ballantyne	28277	Mecklenburg
The Neurological Institute-South Charlotte	28226	Mecklenburg
LCI-Carolina Lakes	29707	Lancaster County, SC
LCI-Rock Hill	29732	York County, SC

In Section G, pages 65-66, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved infusion therapy services in the defined service area. The applicant states: *“the need for the proposed project is driven by the need to expand access to infusion therapy services at LCI-Pineville in order to meet the growing demand for these services resulting from population growth and aging, and cancer incidence.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant adequately demonstrates that the proposed additional infusion therapy chairs are needed in addition to the existing or approved infusion therapy chairs.
- The proposal consolidates existing infusion therapy services in new medical office space on the existing CHS-Pineville campus.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

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

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

C

In Section Q, Form H, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

Position	Current	Projected		
	CY 2016- Staff as of 12/31/16	1st Full Fiscal Year (CY2020)	2nd Full Fiscal Year (CY2021)	3rd Full Fiscal Year (CY2022)
Infusion Registered Nurse	4.17	9.18	10.20	10.43
Lab Registered Tech	1.32	2.90	3.23	3.30
Pharmacy Registered Tech	0.99	2.18	2.42	2.48
Pharmacist	1.04	2.29	2.54	2.60
Lab Supervisory	0.90	1.98	2.20	2.25
TOTAL	8.42	18.53	20.60	21.05

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 67-68, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 69, the applicant identifies the current medical director. In Exhibit H.4, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section H, page 69, the applicant describes its physician recruitment plans.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

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

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

C

In Section I, page 70, the applicant states that the following ancillary and support services are necessary for the proposed services: medical records, medical supplies, business office/registration, laboratory, administration, laundry, radiology, pharmacy, maintenance, housekeeping, pathology and emergency response team.

On page 70, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1 and I.1-2.

In Section I, page 70-71, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the

project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

C

In Section K, page 73, the applicant states that the project involves up-fitting 17,504 square feet of leased space. Line drawings are provided in Exhibit C-1.

On page 74, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant also adequately explains why the proposal will not unduly increase costs of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 29 and 74-75, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

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

- (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 L, page 80, the applicant reports that in Calendar Year (CY) 2016, the last Full Fiscal Year (FFY) before submission of the application, 54.3% of LCI-Pineville's patients had some or all of their services paid for by Medicare or Medicaid, as illustrated in the table below.

Historical Payor Mix in CY2016: Current Days as a % of Total Days

Payor Source	LCI-Pineville Infusion/Injection Patients	CHS Pineville Blood Transfusion Patients	CMC Total
Medicaid	1.7%	0.0%	27.6%
Medicare	52.6%	71.4%	24.8%
Self-Pay/ Indigent/ Charity	1.0%	1.2%	13.0%
Commercial/Managed Care	43.5%	25.3%	32.7%
Other*	1.2%	2.1%	1.9%
Total	100.0%	100.0%	100.0%

*Includes other government

In Section L, page 79, the applicant provides the following comparison.

	Percentage Served by CMC during CY 2016	Percentage in the Service Area*
Women	59.5%	51.6%
65 and Older	19.6%	13.7%
Racial Minorities	56.0%	28.6%

*LCI-Pineville's service area is comprised of the following ZIP codes: 29707, 29708, 28277, 28210, 29730, 28226, 29732, 29715, 28278, 28134, 29720, 28273, 29710, 29745, 28112 and 28173 which represents 75 percent of its historical and projected patient origin.

Source: CHS internal data. ESRI population data.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 80, the applicant states *“CMC has had no obligations to provide a specific uncompensated care amount, community service, or access to care by medically underserved, minorities, or handicapped persons during the last three years.”*

In Section L, page 81, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

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

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

C

In Section L, page 81, the applicant provides the projected payor mix for the second full operating year (CY2021) following completion of the proposed project, as illustrated in the table below.

Projected Payor Mix in OY2 (CY2021): Current Days as a % of Total Days

Payor Source	LCI-Pineville Infusion/Injection Patients	CHS Pineville Blood Transfusion Patients	CMC Total
Medicaid	1.7%	0.0%	27.6%
Medicare	52.6%	71.4%	24.8%
Self-Pay/ Indigent/ Charity	1.0%	1.2%	13.0%
Commercial/Managed Care	43.5%	25.3%	32.7%
Other*	1.2%	2.1%	1.9%
Total	100.0%	100.0%	100.0%

*Includes other government

As shown in the table above, applicant projects 52.6% of LCI-Pineville's total services will be provided to Medicare patients, 1.7% to Medicaid patients and 1.0% to self-pay/indigent/charity patients.

In Section L, page 82, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it's based on historical payor mix in CY2016 for LCI-Pineville.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

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

- (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, page 82, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

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

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

C

In Section M, pages 84-85, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.2

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

CMC proposes to expand and relocate the existing LCI-Pineville outpatient infusion therapy clinic currently located on the campus of CHS Pineville), including adding 18 additional infusion therapy chairs for a total of 30 infusion therapy chairs, to new construction within medical office space also located on the campus of CHS Pineville.

The 2017 SMFP does not define a service area for infusion therapy facilities. The applicant identifies the service area for LCI-Pineville as consisting of the following ZIP codes: 29707, 29708, 28277, 28210, 29730, 28226, 29732, 29715, 28278, 28134, 29720, 28273, 29710, 29745, 28112 and 28173 “*which represents 75 percent of its historical and projected patient origin.*” See application Section G, page 65. Facilities may also serve residents of counties not included in their service area.

Infusion therapy data is not publically reported. In Section G, page 65, the applicant identifies five outpatient oncology infusion therapy providers in LCI-Pineville’s service area as illustrated in the table below.

Provider Name	ZIP Code	County
LCI-Monroe	28112	Union
LCI-Ballantyne	28277	Mecklenburg
The Neurological Institute-South Charlotte	28226	Mecklenburg
LCI-Carolina Lakes	29707	Lancaster County, SC
LCI-Rock Hill	29732	York County, SC

In Section N, pages 86-88, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 86, the applicant states “*The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to infusion therapy services.*”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency.

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

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

C

In Section O, page 91, and Exhibit O.3, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 24 of this type of facility located in North Carolina.

In Section O, pages 91-92, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. According to the files in the Acute Care and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in 2 of these facilities. Two facilities, Randolph Hospital and Moses Cone Memorial Hospital, are out of compliance due to potential EMTALA violations and are waiting for decisions from the Centers for Medicare and Medicaid Services. After reviewing and considering information provided by the applicant and by the Acute Care 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

The Department has not adopted any rules which are applicable to infusion therapy services. Therefore, no rules are applicable to this review.