REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date:	April 12, 2021
Findings Date:	April 12, 2021
Project Analyst:	Celia C. Inman
Team Leader:	Fatimah Wilson
Project ID #:	F-12010-20
Facility:	Atrium Health Lake Norman
FID #:	190513
County:	Mecklenburg
Applicant:	The Charlotte-Mecklenburg Hospital Authority
Project:	Develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and 1 undeveloped OR from CMC and 12 undeveloped acute care beds and 1 existing OR from Atrium Health University City which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC)

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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, hereinafter referred to as CMHA or "the applicant", proposes to develop a new separately licensed hospital, Atrium Health Lake Norman (AHLN), by relocating 18 undeveloped acute care beds and one undeveloped operating room (OR) from Carolinas Medical Center (CMC) and 12 undeveloped acute care beds and one existing OR from Atrium Health University City (AHUC) which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F-11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC). Thus, this application is a "Change of Scope" application for Project ID #F-11811-19, Project ID #F-11812-19, and Project ID #F-11815-19.

Need Determination

The project under review proposes to relocate existing and previously approved acute care beds and operating rooms. There are no need determinations in the 2020 State Medical Facilities Plan (SMFP) applicable to the proposed project.

Policies

Policy AC-5: Replacement of Acute Care Bed Capacity and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities in the 2020 SMFP are applicable to this review.

Policy AC-5, pages 19-20 of the 2020 SMFP, states:

> *"Proposals for either partial or total replacement of acute care beds (i.e., construction of new space for existing acute care beds) shall be evaluated against the utilization of the total number of acute care beds in the applicant's hospital in relation to the utilization targets found below. For hospitals **not*** [emphasis in original] *designated by the Centers for Medicare & Medicaid Services as Critical Access Hospitals, in determining utilization of acute care beds, only acute care bed 'days of care' shall be counted. For hospitals designated by the Centers for Medicare & Medicaid Services as Critical Access Hospitals, in determining utilization of acute care beds, only acute care bed "days of care" **and*** [emphasis in original] *swing bed days (i.e., nursing facility days of care) shall be counted in determining utilization of acute care beds. Any hospital proposing replacement of acute care beds must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application. Additionally, if the hospital is a Critical Access Hospital and swing bed days are proposed to be counted in determining utilization of acute care beds, the hospital shall also propose to remain a Critical Access Hospital and must demonstrate the need for maintaining the swing bed capacity proposed within the application. If the Critical Access Hospital does not propose to remain a Critical Access Hospital, only acute care bed "days of care" shall be counted in determining utilization of acute care beds and the hospital must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application.*

Facility Average Daily Census	*Target Occupancy of Licensed Acute Care Beds*
1 – 99	*66.7%*
100 – 200	*71.4%*
Greater than 200	*75.2%"*

In Section B.5, page 18, the applicant states:

> *"As shown in Form C Assumptions and Methodology, the proposed 30 beds are projected to exceed 66.7 percent occupancy in the third project year."*

Form C Utilization - Assumptions and Methodology, page 13, shows the projected acute care bed days of care by the applicant's identified primary service area (PSA), secondary service area

(SSA), and total days of care; total average daily census (ADC); and occupancy rates for the total 30 licensed acute care beds at the proposed AHLN facility, as summarized below.

Projected Atrium Health Lake Norman
Total Acute Care Bed Occupancy

	FY1 CY2024	FY2 CY2025	FY3 CY2026
PSA Days of Care	2,259	3,501	4,823
SSA Days of Care	1,751	2,712	3,735
Total Days of Care	4,010	6,213	8,558
ADC	11	17	23
Licensed Acute Care Beds	30	30	30
Occupancy Rate	**36.6%**	**56.7%**	**78.2%**

The table above shows the applicant projects AHLN will have an ADC between 1-99 and will exceed the target occupancy rate of 66.7% in the third full fiscal year following project completion. Therefore, the application is consistent with Policy AC-5.

Policy GEN-4, on page 31 of the 2020 SMFP, states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure for this project is greater than $5 million. In Section B, pages 23-24, the applicant explains why it believes its application is consistent with Policy GEN-4. On page 23, the applicant provides CMHA's guiding principles related to environmental sustainability and states:

> "*CMHA will work with experienced architects and engineers to develop this proposed project to ensure energy efficient systems are an inherent part of the proposed project.*"

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

The proposed project is a change of scope application for Project ID #F-11811-19 (add no more than 18 acute care beds at CMC), Project ID #F-11812-19 (add no more than 16 acute care beds at AHUC), and Project ID #F-11815-19 (add no more than two ORs at CMC). Though this change of scope application, in and of itself, is not subject to Policy GEN-3, the three projects for which this is a change of scope application were approved pursuant to need determinations in the 2019 SMFP and were subject to the policy. Thus, it may be relevant to the project to discuss Policy GEN-3 in reference to this application.

Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 SMFP, states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."*

The following table compares the capital expense for developing the beds and ORs as approved in the previous projects to the capital expense proposed for the change of scope project to combine portions of the components of the previously approved applications to develop this project.

	Previously Approved Capital Expense	Proposed Change of Scope Capital Expense	Increase in Cost to Develop Change of Scope Project
Project ID #F-12010-20		$153,929,552	
Project ID #F-11811-19	$10,527,737		
Project ID #F-11812-19	$3,766,000		
Project ID #F-11815-19	$7,974,633		
Total	**$22,268,370**	**$153,929,552**	**$131,661,182**

The applicant chose not to provide answers to the questions related to "Change of Scope" in this application; thus, the applicant does not explain why the above increase in capital expense of $131.6 million (500+%) above the approved capital expense of the individual projects is necessary or justified. Therefore, it is difficult to comprehend how the project under review could "*maximize healthcare value for resources expended*" for the acute care beds and ORs

which were approved pursuant to 2019 need determinations. However, as stated above, Policy GEN-3 is not applicable to this review.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 following reasons:

- There are no need determinations in the 2020 State Medical Facilities Plan (SMFP) applicable to the proposed project.
- The applicant adequately demonstrates that the proposal is consistent with Policy AC-5 because the projected occupancy rate in the third full fiscal year following project completion exceeds the minimum required occupancy rate of 66.7 percent at AHLN, as required for a facility with an ADC of 1-99.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

NC

CMHA, the applicant, proposes to develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and one undeveloped OR from CMC and 12 undeveloped acute care beds and one existing OR from AHUC which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC).

In Section C.1, page 26, the applicant states:

> *"Given the inclusion of previously approved, but undeveloped, acute care beds and operating rooms from CMC and Atrium Health University City, the project proposed*

> *in this application represents a change of scope to Project ID #s F-11819-19* [F-11811-19]*, F-11812-19, and F-11815-19 in that the 18 acute care beds approved for CMC, 12 of the 16 acute care beds approved for Atrium Health University City, and one of the two operating rooms approved for CMC in the 2019 Mecklenburg County Acute Care Bed and Operating Room Review will not be developed at CMC and Atrium Health University City as proposed in those applications. Rather, they will be developed at Atrium Health Lake Norman as proposed in this application. While this proposed project does involve a change of scope to these previously approved applications, given the scope of this proposed project – to develop a new acute care hospital – and to ensure that the Agency is provided all information pertinent to the review of this project, CMHA has responded to each question in this application form as it would as a stand-alone project as opposed to a change of scope application, which otherwise may omit information necessary for the complete review of this project."*

On page 30, the applicant states that the project is designed to provide a full-service acute care hospital in the Lake Norman service area in Mecklenburg County. The applicant summarizes the proposed project as follows:

> *"CMHA proposes to develop a new 30-bed acute care hospital in Cornelius that will provide general medical/surgical care, intensive care, outpatient care, obstetrics services, as well as emergency services."*

In Section C, pages 26-30, the applicant states that the proposed hospital project will include the following services at the proposed facility:

- 30 relocated (approved, but undeveloped) acute care beds (18 from CMC and 12 from AHUC)
- Eight non-licensed observation beds
- Two relocated shared ORs (one approved, but undeveloped from CMC and one existing from AHUC)
- One dedicated C-Section OR
- Emergency Department (ED) with eight treatment bays, six general and two trauma, and three triage spaces
- Imaging and ancillary services, including the following:
    - One fixed CT scanner
    - General radiography
    - Fluoroscopy
    - Ultrasound
    - Nuclear medicine
    - Mobile X-ray unit
    - Mobile C-arm
    - Mobile MRI pad/contracted mobile MRI services
    - Diagnostic lab
    - Physical and other therapy

Patient Origin

On page 33, the 2020 SMFP defines the service area for acute care beds as *". . . the service area in which the bed is located. The acute care bed service areas are the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 38, shows Mecklenburg County as its own acute care bed service area. On page 51, the 2020 SMFP defines the service area for ORs as *"…the service area in which the operating room is located. The operating room service areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 57, shows Mecklenburg County as its own OR service area. The proposed facility will be located in Mecklenburg County; thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The proposed project is to develop a new hospital; therefore, it has no historical data. In Section C, pages 31-33, the applicant provides the historical patient origin for CMC adult general medical/surgical beds, CMC operating rooms, AHUC adult general medical/surgical beds, and AHUC operating rooms and states that the data is provided for informational purposes. As would be expected, CMC, a relatively large tertiary medical facility, has a higher percentage of patients from outside Mecklenburg County than AHUC. The applicant does not provide any data or an explanation as to why the historical patient origin at only those two Atrium Health Mecklenburg County facilities in Charlotte is relevant to the patient origin for the proposed facility in Cornelius. Though the applicant proposes to relocate beds and ORs from only those two facilities in Mecklenburg County, it proposes to transfer (shift) patients from CMC, AHUC, Atrium Health Mercy, and Atrium Health Pineville. Thus, the historical patient origin at those two additional Mecklenburg County facilities would also be relevant.

On pages 33-35, the applicant provides the projected patient origin for the proposed acute care beds, ORs, C-Section room, procedure room, emergency department, and the entire facility.

The following tables summarize the projected patient origin of patient days and number of discharges (patients) for acute care beds; the number of patients for the ORs, C-Section room and procedure room; the number of visits (patients) for the ED; and the number of patients for the entire facility during the third full fiscal year following completion of the project.

FY2026
January 1, 2026-December 31, 2026

County	Acute Care Beds		
	# of Days	# of Patients (Discharges)*	% of Total
Mecklenburg	7,337	1,903	85.7%
Iredell	1,221	318	14.3%
Total	**8,558**	**2,221**	**100.0%**

Source: Section C.3, page 33
*Discharges (patients) per Section Q Form C Utilization – Assumptions and Methodology, page 14, total discharges = 2,221, applied to counties of origin by the % of total provided by applicant on page 33.

FY2026
January 1, 2026-December 31, 2026

County	Operating Rooms		C-Section Room		Procedure Room	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	1,402	77.8%	168	85.7%	131	77.8%
Iredell	400	22.2%	28	14.3%	37	22.2%
Total	**1,802**	**100.0%**	**196**	**100.0%**	**168**	**100.0%**

Source: Section C.3, page 34

FY2026
January 1, 2026-December 31, 2026

County	Emergency Department	
	# of Patients (Visits)	% of Total
Mecklenburg	6,307	84.8%
Iredell	1,126	15.2%
Total	**7,433**	**100.0%**

Source: Section C.3, page 34

FY2026
January 1, 2026-December 31, 2026

County	Entire Facility	
	# of Patients	% of Total
Mecklenburg	15,344	84.5%
Iredell	2,812	15.5%
Total	**18,157**	**100.0%**

Source: Section C.3, page 35

In Section C, pages 35-37 and in Section Q Form C Utilization – Assumptions and Methodology, the applicant provides the assumptions and methodology used to project its patient origin. On page 36 of the application, the applicant states:

> *"Projected patient origin for acute care beds is based on the number of patients projected to originate from the assumed geographies as identified in Form C Assumptions, and Methodology. Projected patient origin reflects the historical percentage of Atrium Health Lake Norman appropriate patient days served at Atrium Health Mecklenburg County hospitals by ZIP code and assumed shift of those days in the PSA and SSA, respectively."*

As stated above, the service area for this project is Mecklenburg County. The applicant provides a table on page 37 showing what it calls the primary service area (PSA) ZIP codes in Mecklenburg and Iredell counties and the secondary service area (SSA) ZIP codes in Mecklenburg County, as summarized below.

AHLN Acute Care Bed Patient Origin Projection Detail

	CY2019 AHLN-Appropriate Pt. Days Served by Mecklenburg County Hospitals	Shift Assumption	Shifted Days for Patient Origin Projection	Percent of Shifted Patient Days
PSA				
28031-Mecklenburg	898	80%	718	10.8%
28036-Mecklenburg	411	80%	329	4.9%
28078-Mecklenburg	1,933	80%	1,546	23.2%
28115-Iredell	627	80%	502	7.5%
28117-Iredell	563	80%	450	6.8%
SSA				
28216-Mecklenburg	8,663	20%	1,733	26.0%
28269-Mecklenburg	6,966	20%	1,393	20.9%
Total	20,061		6,671	100.0%
Mecklenburg County as Percentage of Total Patient Origin				**85.7%**
Iredell County as Percentage of Total Patient Origin				**14.3%**

Totals may not sum due to rounding

On page 37, the applicant states that projected patient origin for operating rooms is based on the number of surgical patients projected to originate from the assumed geographies as identified in Form C Utilization-Assumptions and Methodology with patient origin percentages calculated based on an approach consistent with calculations as provided for acute care beds in the table on page 37 and above.

The applicant states that the projected patient origin for obstetrics, ICU, medical/surgical beds, and C-Section room cases is assumed to be consistent with the projected patient origin for acute care beds and the projected patient origin for the procedure room is assumed to be consistent with the projected patient origin for operating rooms. The applicant further states that the projected patient origin for emergency department visits is based on the number of patients projected to originate from the assumed geographies as identified in Form C Utilization-Assumptions and Methodology with patient origin percentages calculated based on an approach consistent with calculations for acute care beds, as in the table on page 37.

On page 37, the applicant states that for simplicity, the projected patient origin for the entire facility is based on the sum of the projected number of patients by county of origin for each identified service above. The applicant further states that the projected patient origin for imaging (which would include CT unless otherwise stated) and other ancillary and support services is assumed to be consistent with the patient origin for the entire facility and is not provided separately.

Per its assumptions as stated above, the number of patients for the entire facility is the sum of the number of patients for the acute care beds, ORs, C-Section room, procedure room and ED. However, the number of patients, as provided by the applicant for the entire facility is not accurate. Instead of using the number of acute care bed patients (discharges, as provided in Section Q), the applicant uses the number of acute care patient days to reach its sum of total patients at the facility, as calculated below for FY2026.

FY2026 January 1, 2026-December 31, 2026
As Provided by the Applicant

County	Entire Facility	
	# of Patients	% of Total
Mecklenburg	7,337 AC Days + 1,402 OR Pts + 168 C-Sec Pts + 131 Proc Rm Pts + 6,307 ED Pts = 15,345	84.5%
Iredell	1,221 AC Days + 400 OR Pts + 28 C-Sec Pts + 37 Proc Rm Pts + 1,126 ED Pts = 2,812	15.5%
Total	**8,558 AC Days + 1,802 OR Pts + 196 C-Sec Pts + 168 Proc Rm Pts +7,433 ED Pts = 18,157**	**100.0%**

Source: Section C.3, pages 33-35, data compiled by Agency

For FY2026, following the applicant's assumptions and methodology, the total number of patients and the patient origin for the entire facility should be as shown below, where the Agency totals the number of patients projected to be served in each of the listed services above.

FY2026 January 1, 2026-December 31, 2026
As Calculated by Agency Based on Applicant's Assumptions

County	Entire Facility	
	# of Patients	% of Total
Mecklenburg	1,903 AC Discharges + 1,402 OR Pts + 168 C-Sec Pts + 131 Proc Rm Pts + 6,307 ED Pts = 9,911	83.8%
Iredell	318 AC Discharges + 400 OR Pts + 28 C-Sec Pts + 37 Proc Rm Pts + 1,126 ED Pts = 1,909	16.2%
Total	**2,221 AC Discharges + 1,802 OR Pts + 196 C-Sec Pts + 168 Proc Rm Pts +7,433 ED Pts = 11,820**	**100.0%**

Source: Agency calculations performed with data from Section C.3, pages 33-35 and Section Q Form C Assumptions and Methodology

As is evident by comparing the two tables above, the applicant overstates the number of patients projected to be served at AHLN in FY2026 by 6,337 patients (18,157-11,820 = 6,337), as summarized in the table below.

Entire Facility Projected Number of Patients
FY2026

County	As Provided by Applicant on Page 35	As Calculated by Agency from Applicant's Assumptions	Difference
	# of Patients	# of Patients	# of Patients
Mecklenburg	15,345	9,911	5,434
Iredell	2,812	1,909	903
Total	**18,157**	**11,820**	**6,337**

As the above table exemplifies, the applicant projects 35% more patients at AHLN in FY2026 than will utilize the facility in FY2026 (6,337/18,157= 0.349).

The applicant also misstates the percent of patients from Mecklenburg and Iredell counties by a small margin. Furthermore, because the applicant bases the projected patient origin for surgical services, obstetrics, ED services, imaging, and other ancillary and support services on the assumption that it is consistent with the patient origin for either acute care services or the entire facility, the projected patient origin for those services is also in question.

In its response to comments, the applicant provides additional information in two tables on page 9 relative to patient origin; however, some of the numbers appear erroneous and the applicant does not adequately explain what the tables represent.

An analysis of the proposed number of FY2026 acute care patients originating from Iredell County (318 acute care discharges) suggests that the projection is not reasonable based on the information provided in the DHSR 2020 Patient Origin and 2020 Facility reports for acute care inpatient services. The patient origin report shows that 2,720 Iredell County residents were acute care inpatients in Mecklenburg County in FY2019. The facility report shows that of the 2,720 Iredell County residents who were hospital patients in Mecklenburg County, 1,091 were patients at Carolinas Medical Center (including AHM) and 599 were patients at Novant Health Presbyterian Medical Center (Presbyterian), for a total of 1,690 patients. Both of these hospitals are large tertiary medical centers. In addition to the Iredell County residents seeking hospital care at CMC and Presbyterian, only 99 Iredell County residents sought care at another Atrium Health hospital in Mecklenburg County: 78 sought care at AHUC and 21 sought care at AH Pineville. The 1,091 patients at CMC represent 91.7% of all FY2019 Iredell County patients seeking care at an Atrium Health Mecklenburg facility. The 78 patients at AHUC represent only 6.6% and the 21 at AHP represent 1.8% of all FY2019 Iredell County patients seeking care at an Atrium Health Mecklenburg facility.

The assumption that 80% of the PSA "Lake Norman Appropriate" Iredell County patients seeking care at an Atrium Health facility in Mecklenburg County will now seek care at the proposed AHLN facility is an unlikely scenario for several reasons. (1) Statistics from FY2019 show that less than 9% of the total number of Iredell County patients seeking care at a Mecklenburg County Atrium Health facility went anywhere other than CMC. (2) It is reasonable to assume that the FY2019 Iredell County patients that circumvented (drove past) AHUC to seek care at CMC instead of AHUC may have been seeking care at a tertiary care facility and would therefore also forgo care at the proposed AHLN facility. (3) There is no reason to assume that the Iredell County patients that circumvented both AHUC and CMC to seek care at AHP would seek care at the proposed AHLN facility.

Thus, the applicant fails to adequately identify the population to be served based on the following:

- The applicant's projection of total number of patients for the entire AHLN facility is overstated by 6,337 patients (34%).
- The inaccurate number of total patients causes the inaccurate identification of the number of patients to be served and the percent by county of origin.
- The assumptions and methodology for the number of Iredell County patients to be served at AHLN is flawed. The applicant does not provide data to adequately support its assumption related to the shift in patients.

Analysis of Need

In Section C, pages 38-61, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 60, the applicant states:

> *". . . There is a need for a new hospital in the Lake Norman service area to enhance the continuum of care for area residents closer to home and/or more conveniently located, shift appropriate patients from CMHA's more congested facilities, and enhance competition within the service area."*

On page 38, the applicant states that the need patients have for a new hospital, including acute care beds and operating rooms, in the Lake Norman service area, as proposed in this application, includes the following factors:

- Growth and development of the Lake Norman service area (pages 38-47)
  - PSA population projected to grow 1.9% annually from 2020 to 2025
  - SSA population projected to grow 1.4% annually from 2020 to 2025
  - PSA and SSA population projected to increase by 30% from 2020 to 2025
- Patients' need for Atrium Health hospital services in the Lake Norman service area (pages 47-58)
  - CHMA's evolving service development in the Lake Norman area includes physician offices, surgery centers, imaging services, and ED services
  - Physician recruitment in the Lake Norman area
  - Extensive network of Atrium Health providers already serving patients in the Lake Norman area
- Need for the project as proposed (pages 58-61)
  - Continuum of care for area residents closer to home
  - Relieve capacity constraints at other Atrium Health Mecklenburg facilities

However, the information provided is not reasonable and adequately supported based on the following:

- The proposed hospital would add a third hospital to provide services in the applicant's identified PSA, including Novant Health Huntersville Medical Center in Mecklenburg County and Lake Norman Regional Medical Center in Iredell County. Per page 44 of the application, the applicant's proposed PSA consists of three Mecklenburg County ZIP codes (28031, 28036, and 28078) and two Iredell County ZIP codes (28115 and 28117) totaling only 208,793 people in 2020. The applicant does not provide information that indicates that either of the two existing hospitals in the specified area are experiencing capacity constraints or are unable to provide adequate hospital services to the population in the proposed PSA.

  In fact, a review of the 2020 License Renewal Application (LRA) for Novant Health Huntersville Medical Center (NHHMC) and Lake Norman Regional Medical Center (LNRMC) reveal the following occupancy rates for acute care beds.

	NHHMC	LNRMC
Number of Licensed Acute Care Beds	139	123
Available Days	50,735	44,895
Acute Care Days of Care Provided	26,800	13,950
Occupancy	52.8%	31.1%

Source: applicable 2020 LRAs containing data on services from October 1, 2018 through September 30, 2019

- The drive times for the PSA and SSA ZIP codes, as provided by the applicant on page 42, are not surprising. As the table clearly shows, AHLN is a shorter drive time to the proposed AHLN facility from the PSA ZIP codes in Iredell County (28115 and 28117) than to the other Atrium Health Mecklenburg County hospitals which are located in central and southern Mecklenburg County. The SSA ZIP codes in Mecklenburg County have a shorter drive time to two out of three of the other Atrium Health Mecklenburg County hospitals shown in the table. Only three Mecklenburg County PSA ZIP codes show a shorter drive time to AHLN than to the other Atrium Health Mecklenburg County hospitals. Thus, two of the five PSA and SSA ZIP codes in Mecklenburg County do not show shorter drive times to AHLN than other Atrium Health Mecklenburg County hospitals. In addition, the applicant does not evaluate the drive time differences for the PSA and SSA ZIP codes between the proposed AHLN and LNRMC in Iredell County or NHHMC in northern Mecklenburg County. (page 42)

- The same major road development plans that will enhance the flow of traffic and provide easier access for patients seeking care at the proposed AHLN facility will also impact commuters traveling to or from the Lake Norman area with *"enhanced access from uptown Charlotte, all the way to the northern Mooresville area."* Thus, the road development will also provide easier access from the Lake Norman area to the existing Atrium Health Mecklenburg County hospitals. (pages 45-47)

- Though the applicant provides data showing that 56 acute care beds at an Atrium Health hospital in Mecklenburg County were occupied every day by patients from the PSA/SSA that would have been appropriate for AHLN based on service and acuity level, there is no evidence that 56 patients, or any other number of patients, would choose AHLN over the other Atrium Health Mecklenburg County hospitals. (pages 54-55)

- During FY2019, 1,091 Iredell County patients chose to drive past AHUC to seek care at CMC, a tertiary care center. There is no evidence or reason to assume that those patients would choose care at AHLN in the future.

- The proposed project would allow Atrium Health Mecklenburg County hospitals, which the applicant states are experiencing significant capacity constraints, to "shift" patients that do not require tertiary/quaternary services to AHLN, freeing up resources to accommodate patients whose acuity and service needs do require care at the more advanced facilities. (page 53) However, the applicant did not adequately demonstrate

the reasonableness of the number of Iredell County patients it proposes to shift to AHLN. Furthermore, the validity of relocating beds and ORs and shifting patients from capacity constrained Atrium Health Mecklenburg County facilities is questionable. If the particular Mecklenburg County facilities from which beds and ORs are being relocated are already experiencing capacity constraints, one must question how the relocation of the beds and ORs away from those facilities would represent a reasonable or effective alternative to meet the need for services in Mecklenburg County.

The applicant demonstrated the need for additional beds and ORs at existing Atrium Health facilities in Mecklenburg County in approved projects: Project ID #F-11811-19, #F-11812-19, and #F-11815-19.

Project ID #F-11811-19 was approved on March 26, 2020 to add 18 acute care beds at CMC with the need for the additional beds being supported in the Findings by the following information provided by the applicant:

- *"CMC's projected deficit of 91 acute care beds is the highest of any hospital in Mecklenburg County.*

- *Because of a lack of capacity, some CMC patients have had to stay in the Post-Anesthesia Care Unit (PACU) after surgery due to the lack of an available bed. Additionally, some patients have had to remain in an OR after a surgery is complete because of the resulting lack of space in the PACU. Further, patients are often housed overnight in the ED due to lack of available beds.*

- *CMC's growth is projected to continue because it is the only provider of quaternary care in Mecklenburg County and the surrounding area."*

Project ID #F-11812-19 was approved on March 26, 2020 to add 16 acute care beds at AHUC with the need for the additional beds being supported in the Findings by the following information provided by the applicant:

- *"AH University City's CY 2016 – CY 2019 annualized CAGR is 7.1 percent, the fastest growth rate for acute care days at any of Atrium's Mecklenburg County hospitals.*

- *AH University City's bed deficit in the Proposed 2020 SMFP is the highest (by percentage) of any hospital in North Carolina in the last decade.*

- *Because of a lack of capacity, patients often must wait many hours or even overnight in the ED for an acute care bed to become available. The applicant states that in 2018, patients waited an average of five and a half hours in the ED before an acute care bed was available, and in some cases, patients waited in the ED for up to 24 hours."*

Project ID #F-11815-19 was approved on March 26, 2020 to add two ORs at CMC with the need for the additional ORs being supported in the Findings by the following information provided by the applicant:

- *"CMC is a Level 1 Trauma Center, offers solid organ transplantation, and is the area's only quaternary academic medical center; as such, it fills a vital role in the region.*
- *CMC's current OR deficit in the 2019 SMF is 12.32 ORs and it provides more hours per OR than any other facility in Mecklenburg County.*
- *Surgical volumes in Mecklenburg County have grown at higher rates than the state average. Outpatient surgical cases in Mecklenburg County are increasing more quickly than inpatient surgical cases. While the number of outpatient cases performed at ASFs have higher growth rates than outpatient cases performed at hospitals, the difference isn't significant, and the increase in the number of outpatient cases performed at hospitals is more than double the increase in the number of outpatient cases performed at ASFs."*

If the basis for the need upon which each of the above projects was approved was valid at the time of the approval of those projects, the need for those services at those facilities would still be valid and contrary to the need to relocate the services from those facilities to develop the proposed project. Furthermore, if these projects reflected the most effective alternatives to provide additional acute care capacity for the service area at that time, it is difficult to see how the proposed project would be a more effective alternative at this time. The applicant addresses these capacity constraints in its Utilization–Assumptions and Methodology. In reference to acute care capacity, on Form C Utilization-Assumptions and Methodology, pages 5-6, the applicant states:

> *"While CMHA is approved to develop additional acute care capacity in Mecklenburg County (and is submitting a separate batch of CON applications to develop additional beds in response to the need identifies in the 2020 SMFP for additional acute care beds in Mecklenburg County), it does not believe such capacity will relieve all of its Mecklenburg County hospitals' existing capacity constraints."*

In reference to operating room capacity, on Form D Utilization-Assumptions and Methodology, page 13, the applicant states:

> *"Additionally, CMC, the largest Atrium Health facility, currently demonstrates a significant deficit of capacity, even with the shifts of cases to other facilities."*

In Form D Assumptions and Methodology, page 1, the applicant states:

> *"Please note that in a separate batch of applications, CMHA is filing applications to develop 119 additional acute care beds and 12 additional*

operating rooms at CMC in response to the needs identified in the 2020 SMFP for additional acute care beds and operating rooms in Mecklenburg County. The utilization projections for CMC shown below incorporate those additions, which are expected to become operational on April 1, 2027."

The applicant submitted two projects (December 1, 2020 review date) to add beds and ORs at CMC pursuant to the 2020 Need Determinations for 126 acute care beds and 12 ORs: Project ID #F-12006-20 (Add no more than 119 acute care beds pursuant to the need determination in the 2020 SMFP for a total of no more than 1,174 acute care beds upon project completion) and Project ID #F-12008-20 (Add no more than 12 ORs pursuant to the need determination in the 2020 SMFP and a change of scope for Project ID #F-11815-19 (approved to add 2 ORs but would only add 1 OR) for a total of no more than 75 ORs upon completion of both projects). The approval of the projects would address the capacity constraints that the applicant states exist at CMC; however, there is no assurance that the projects will be approved, which would leave CMC with existing capacity constraints per the information provided by the applicant.

Section C.4, page 38, requires the applicant to, *"Describe the need the patients projected to use each service component included in the project have for the service component."* The applicant does not provide a separate quantitative discussion of each proposed service component in response to Section C.4, page 38. However, on pages 57-58, the applicant maintains that the service components are needed as part of the proposed hospital and states:

"Further, as discussed in Form C Assumptions and Methodology and incorporated herein by reference, Atrium Health Lake Norman has adequately demonstrated the need for each of these services based on the projected utilization for each service component. Thus, for the specific quantitative need for each service component, including acute care beds by type, emergency services, surgery, imaging and others, please see Form C Assumptions and Methodology in Section Q."

Projected Utilization

In Section Q Form C Utilization, pages 5-8, the applicant provides projected utilization, as illustrated in the following tables.

AHLN Projected Utilization Acute Care Services			
	FY 1 (CY 2024)	**FY 2 (CY 2025)**	**FY 3 (CY 2026)**
Acute Care Beds			
# of Beds	30	30	30
# of Patient Days	4,010	6,213	8,558
Total Patients (Discharges per Section Q, page 14)	1,040	1,612	2,221
Observation Beds			
# of Beds	8	8	8
# of Days	416	645	888
ALOS*	1.49	1.49	1.49
# of Patients (days/ALOS)	279	433	596
Laboratory			
# of Procedures	60,410	93,607	128,930
PT/ST/OT/RT/Other			
# of Procedures	423	655	903
CT Scanner			
# of Units	1	1	1
# of Scans	3,589	5,561	7,659
# of HECT Units	5,857	9,075	12,500
MRI Scanner			
# of Units	Mobile	Mobile	Mobile
# of Scans	71	110	151
# of Weighted Scans	98	152	209
Fixed X-ray (including Fluoroscopy)			
# of Units	2	2	2
# of Procedures	6,902	10,695	14,731
Ultrasound			
# of Units	1	1	1
# of Procedures	1,638	2,538	3,496
Nuclear Medicine			
# of Units	1	1	1
# of Procedures	213	330	455
Emergency Department			
# of Bays (Rooms)	8	8	8
# of Visits	3,800	5,638	7,433

*ALOS = Average Length of Stay

AHLN Projected Operating Room and Procedure Room Services			
	CY 2024	**CY 2025**	**CY 2026**
C-Section ORs			
# of C-Section ORs	1	1	1
# C-Section Surgical Cases	92	142	196
Shared ORs (adjusted planning inventory)			
# of Shared ORs	2	2	2
Surgical Cases			
# of Inpatient Cases (excludes C-Section)	151	234	322
# of Outpatient Cases	693	1,075	1,480
Total # Surgical Cases	844	1,308	1,802
Case Times (Section C, Question 6(c))			
Inpatient	111.6	111.6	111.6
Outpatient	70.9	70.9	70.9
Surgical Hours			
Inpatient	281	435	599
Outpatient	819	1,270	1,749
Total Surgical Hours	1,100	1,705	2,348
# of ORs Needed			
Group Assignment (Section C, Question 9(a))	4	4	4
Standard Hours per OR per Year (Section C, Question 9(a))	1,500	1,500	1,500
Total Surgical Hours / Standard Hours per OR per Year (ORs Needed)	0.73	1.14	1.57
Procedure Rooms			
# of Rooms	1	1	1
# of Procedures	79	122	168

In Section Q Form C Utilization–Methodology and Assumptions, pages 1-38, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Acute Care Services

- The applicant identifies its primary and secondary areas of patient origin (PSA/SSA) and identified a subset of acute care days from patients in the PSA and SSA served at Atrium hospitals in Mecklenburg County in 2020 and which were appropriate to be served at AHLN. (pages 3-8)
- The applicant assumes 80% of the acute care days from the PSA and 20% of the acute care days from the SSA would transfer and be served at AH Lake Norman. The applicant also assumes the number of acute care days would grow at one quarter of the 3-year (2016-2019) CAGR of 3.3% for the projected population growth in the PSA and SSA. The applicant does not provide adequate support for the percentage assumptions, other than being *"agreed upon by Atrium Health clinical leaders and administrative operators*". (pages 8-12)

- The applicant assumes a ramp-up of 50% during CY2024, 75% during CY2025 and 100% of the potential days of care in CY2026, reaching 4,823 days in the PSA and 3,735 days in the SSA for a total of 8,558 days of care in the third year and 78.2% occupancy. (pages 12-14)
- The applicant assumes an ALOS consistent with the CY2019 (to eliminate COVID-19 impact) ALOS for AHLN-appropriate inpatients in the PSA and SSA (served by Atrium Health Mecklenburg County hospitals), 3.69 and 4.09 days, respectively to calculate PSA and SSA discharges of 1,307 and 941, respectively, for a total of 2,221 discharges. (page 14)
- To determine obstetrics days of care, the applicant assumes the percent of obstetrics days to total patient days in Atrium Health Mecklenburg County hospitals for the PSA and SSA of 24.4% and 16.0%, respectively for the AHLN-appropriate days, which results in 1,175 obstetrics days in the PSA and 596 days in the SSA for a total of 1,771 days. (pages 16-17)
- To project the utilization of ICU beds, the applicant assumes ICU days of care will comprise 11.4% and 9.9% of the PSA and SSA non-obstetrics days, respectively, based on Atrium Health Mecklenburg County hospitals CY2019 experience. Thus, in the PSA, 11.4% x (4,823-1,175) = 418 ICU days and in the SSA, 9.9% x (3,735-596) = 310 ICU days for a total of 727 ICU days of care in the third year of operation. (pages 17-18)
- The applicant assumes that the experience of AHUC is reasonable to use to project the utilization of AHLN for a number of ancillary services and observation days. Observation days are projected at 16% of total acute care days or 1,328 days with an ALOS of 1.49 days = 888 observation patients in CY2026. (pages 17-20)

Surgical Services

- To project surgical cases (excluding C-Sections) to be performed at AHLN, the applicant assumes that surgical cases will be 17.8% and 9.8% of total AHLN-appropriate acute care discharges in the PSA and SSA, respectively, based on the percentages provided in Atrium Health Mecklenburg County hospitals in CY2019. The applicant previously projected PSA and SSA acute care discharges of 1,307 and 914, respectively, for a total of 2,221 patients for the third year of operation; thus, at 17.8% and 9.8% respectively, the applicant projects 232 and 90 inpatient surgical cases for the PSA and SSA, respectively for a total of 322 inpatient surgical cases. (pages 20-21)
- Based on the 2019 experience at AHUC, the ratio of outpatient surgical cases to inpatient surgical cases is 4.6 to 1; thus, the applicant projects AHLN's outpatient surgical cases at 4.6 times the projected inpatient surgical cases, or 1,068 for the PSA and 412 for the SSA for a total of 1,480 outpatient surgical cases in CY2026. (pages 21-22)
- Based on its projected surgical utilization, AHLN is assumed to be a new Group 4 facility under the 2020 SMFP Operating Room Methodology, with an inpatient case time of 111.6 minutes and an outpatient case time of 70.9 minutes, resulting in 2,348 surgical hours in CY2026 and the need for 1.57 ORs. (pages 22-23)
- C-Section utilization is based on AHLN-appropriate patients served at Atrium Health Mecklenburg County facilities, with an ALOS of 2.9 days in both the PSA and SSA.

The applicant applies this percentage of the AHLN-appropriate obstetrics discharges that received a C-Section (32%) to its projected obstetrics discharges. CY2026 projected C-Section cases are 1,771 obstetrics days/2.90 ALOS = 611 obstetrics discharges of which 32% or 196 were C-Section surgical cases. (page 25)

- Procedure room projected utilization is based on AHUC's procedure room procedures to OR cases ratio of 0.09; thus, CY2026 procedure room procedures is 168 (1,802 x 0.09). (page 25)

Emergency Department

- The applicant identifies the number of Atrium Health Mecklenburg County facility ED visits by AHLN-appropriate patients from the proposed PSA and SSA. The applicant states the use of CY2016-CY2019 data to eliminate the impact of COVID-19 on projected utilization. (page 26)
- The applicant examines the Atrium Health Huntersville's freestanding ED data for CY2019 and excludes the Level I and Level II visits from the PSA and SSA shift of patients and then assumes AHLN's potential ED visits will be 80% and 20% of the remaining CY2019 Atrium Health Huntersville's ED visits, resulting in 12,117 potential visits in CY2026. (pages 26-28)
- The applicant examines the impact of the development of Atrium Health Mountain Island on the proposed service area, assuming 59.1% (the percent of service area overlap) of the impact will occur in AHLN's service area, resulting in 7,433 adjusted ED visits at AHLN in CY2026. (pages 28-31)

Imaging and Ancillary Services

- The applicant examines imaging and ancillary hospital services based on the AHUC's AHLN-appropriate CY2019 services and determines ratios of inpatient ancillary procedures to discharges and the determined ratios of outpatient procedures to inpatient procedures for each service. (pages 33-35)
- The applicant applies the pre-determined inpatient and outpatient procedure ratios to the proposed AHLN discharges and inpatient procedures, respectively, resulting in the projected inpatient and outpatient service procedures in CY20224-CY2026, as shown on pages 35-36. (pages 35-36)
- The applicant provides the calculations for projected weighted MRI procedures and CT HECT units in the methodology and assumptions. (page 37)
- The applicant sums the total projected inpatient and outpatient imaging and ancillary services to arrive at the projected imaging and ancillary services. (page 38)

However, projected utilization is not reasonable and adequately supported based on the following:

- The applicant assumes 80% of the acute care days from the PSA and 20% from the SSA would transfer and be served at AHLN based on experience and discussion with clinical and administrative leaders. The applicant does not provide adequate support

for the chosen percentages or any information that would support that the patients would choose to transfer their care.

The PSA includes two Iredell County ZIP codes. An analysis of the proposed number of FY2026 acute care patients originating from Iredell County (318 acute care discharges) suggests that the projection is not reasonable based on the information provided in the DHSR 2020 Patient Origin and 2020 Facility reports for acute care inpatient services. The patient origin report shows that 2,720 Iredell County residents were acute care inpatients in Mecklenburg County in FY2019. Of the 2,720 Iredell County residents who were hospital patients in Mecklenburg County, 1,091 were patients at Carolinas Medical Center (including AHM) and 599 were patients at Novant Health Presbyterian Medical Center (Presbyterian), for a total of 1,690 patients. In addition to the Iredell County residents seeking hospital care at CMC and Presbyterian, only 99 Iredell County residents sought care at another Atrium Health hospital in Mecklenburg County: of the 99 patients, 78 sought care at AHUC and 21 sought care at AH Pineville. The 1,091 patients at CMC represent 91.7% of all FY2019 Iredell County patients seeking care at an Atrium Health Mecklenburg facility. The 78 patients at AHUC represent only 6.6% and the 21 at AHP represent 1.8% of all FY2019 Iredell County patients seeking care at an Atrium Health Mecklenburg facility.

- The assumption that 80% of the PSA "Lake Norman Appropriate" Iredell County patients seeking care at an Atrium Health facility in Mecklenburg County will seek care at the proposed AHLN facility is an unlikely scenario for several reasons. (1) Statistics from FY2019 show that less than 9% of the total number of Iredell County patients seeking care at a Mecklenburg County Atrium Health facility went anywhere other than CMC. (2) It is reasonable to assume that the FY2019 Iredell County patients that drove past AHUC for CMC may have been seeking care at a tertiary care facility and would therefore also forgo care at the proposed AHLN facility. (3) There is no reason to assume that the Iredell County patients that drove past AHUC and CMC to seek care at AHP would seek care at the proposed AHLN facility. Thus, the number of acute care patients may be overstated.

- The applicant does not provide adequate evidence that the number of PSA and SSA patients it has projected to seek acute care services at AHLN will seek care there. Thus, the number of acute care patients may be overstated.

- An overstatement of acute care patients also overstates surgical services, obstetrics and ED services which the applicant states is based on acute care services.

- The applicant projects some services and percentage assumptions based on AHLN-appropriate PSA and SSA patients' statistics from all Atrium Health Mecklenburg County hospitals (ALOS for acute care days, obstetrics days of care, and ICU days of care, surgical cases as a percentage of acute care discharges, and C-Section cases) and some services based on AHLN-appropriate PSA and SSA patients' statistics from only AHUC (ancillary services and observation days, ratio of outpatient surgical cases to inpatient surgical cases, and procedure room cases). The applicant does not provide adequate supporting documentation or explanation for using the different basis for the projections for the different services.

Access to Medically Underserved Groups

In Section C, pages 68-69, the applicant states:

> *"CMHA facilities provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment."*

On page 69, the applicant provides the estimated percentage for medically underserved groups, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients					
	Med/Surg/ICU Beds	Obstetrics Beds	Surgical Services	ED	Imaging	Lab/PT/OT/ST/Other
Racial and ethnic minorities	53.0%	35.0%	40.0%	59.4%	44.3%	42.2%
Women	64.5%	99.7%	57.6%	57.9%	65.9%	55.6%
The elderly	33.8%	0.0%	35.6%	11.4%	23.1%	12.4%
Medicare beneficiaries	54.0%	0.3%	43.1%	16.0%	25.7%	17.5%
Medicaid recipients	11.9%	28.5%	3.7%	22.2%	12.6%	26.1%

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

(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, … persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NC

CMHA, the applicant, proposes to develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and one undeveloped OR from CMC and 12 undeveloped acute care beds and one existing OR from AHUC which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC).

In Section D, pages 79-83 and in Section Q Form D Assumptions and Methodology, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 79, the applicant states:

"As discussed previously, with the exception of one operating room proposed to relocate from Atrium Health University City, the acute care beds and remaining operating room proposed to relocate from CMC and Atrium Health University City to Atrium Health Lake Norman are approved but not operational; thus, they are not serving patients today. While the one operating room proposed to relocate from Atrium Health University City to Atrium Health Lake Norman is currently operational and one acute care bed will be operational prior to its relocation, Form D Utilization shows that Atrium Health University City will have the capacity needed to care for its patients after the projected relocation of patients and capacity to Atrium Health Lake Norman. While the acute care beds and operating rooms at CMC are not currently operational, Form D Utilization also demonstrates the projected utilization of CMC's acute care beds and operating rooms, which accounts for two projects proposed in a separate batch of applications being filed in response to the needs identified in the 2020 SMFP for additional acute care beds and operating rooms in Mecklenburg County to develop 119 additional acute care beds and 12 additional operating rooms at CMC."

In Section Q Form D Utilization, the applicant provides projected utilization at Atrium Health University City and CMC, as illustrated in the following tables.

Atrium Health CMC

	CY2020	CY2023	FY 1 (CY 2024)	FY 2 (CY 2025)	FY 3 (CY 2026)
Acute Care Beds					
# of Beds		859	859	859	859
# of Admissions					
# of Patient Days		286,553	283,416	285,016	286,566
Occupancy		91.4%	90.4%	90.9%	91.4%
Operating Rooms					
Adjust Planning Inventory ORs	42	42	42	42	42
Surgical Cases					
# of Inpatient Surgical Cases	15,543	15,701	15,733	16,006	16,283
# of Outpatient Surgical Cases	15,648	15,175	14,997	15,107	15,209
Case Times					
Inpatient	224.0	224.0	224.0	224.0	224.0
Outpatient	147.4	147.4	147.4	147.4	147.4
Surgical Hours					
Inpatient	58,027	58,616	58,736	59,757	60,789
Outpatient	38,442	37,281	36,844	37,113	37,364
Total Surgical Hours	96,470	95,897	95,580	96,869	98,153
# of ORs Needed					
Group Assignment	1	1	1	1	1
Standard Hours per OR per Year	1,950	1,950	1,950	1,950	1,950
Total Surgical Hours/Standard Hours per OR per Year	49.5	49.2	49.0	49.7	50.3
OR Deficit	7.5	7.2	7.0	7.7	8.3

Totals may not sum due to rounding

As the table above shows the applicant projects CMC's acute care bed occupancy rate will be 91.4% in the third full year of operation of the proposed project and CMC will have an OR deficit of 8.3 ORs.

Atrium Health University City

	CY2020	CY2023	FY 1 (CY2024)	FY 2 (CY2025)	FY 3 (CY2026)
Acute Care Beds					
# of Beds	100	105	104	104	104
# of Admissions	7,199	7,756	7,641,	7,686	7,726
# of Patient Days	28,636	30,850	30,392	30,572	30,732
Occupancy		80.5%	80.1%	80.5%	81.0%
Operating Rooms					
Adjust Planning Inventory ORs	7	6	6	6	6
Surgical Cases					
# of Inpatient Surgical Cases	1,080	1,160	1,144	1,151	1,157
# of Outpatient Surgical Cases	3,517	3,507	3,302	3,190	3,071
Case Times					
Inpatient	123.9	123.9	123.9	123.9	123.9
Outpatient	76.7	76.7	76.7	76.7	76.7
Surgical Hours					
Inpatient	2,230	2,395	2,362	2,377	2,389
Outpatient	4,496	4,483	4,221	4,078	3,926
Total Surgical Hours	6,727	6,880	6,583	6,454	6,316
# of ORs Needed					
Group Assignment	4	4	4	4	4
Standard Hours per OR per Year	1,500	1,500	1,500	1,500	1,500
Total Surgical Hours/Standard Hours per OR per Year	4.5	4.6	4.4	4.3	4.2
OR Deficit (Surplus)	(2.5)	(1.4)	(1.6)	(1.7)	(1.8)

Totals may not sum due to rounding

As the table above shows the applicant projects AHUC's acute care bed occupancy rate will be 81.0% in the third full year of operation of the proposed project and AHUC will have an OR surplus of 1.8 ORs.

Exhibit C.10-1 contains supporting data on assumptions and patient shifts. In Section Q Form D Assumptions and Methodology, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Acute Care Beds

- Determine actual historical compound annual growth rate (CAGR) for each facility (pages 1-4)
- Project patient days using an assumed baseline CAGR for each facility and adjust for any periods in which acute care capacity constraints are expected to limit growth (pages 4-5)
- Apply projected shifts to or from other acute care facilities (pages 5-7)
- Determine projected acute care days by facility incorporating any shifts to or from other acute care facilities (pages 8-10)

Operating Rooms

- Determine historical OR utilization for each facility (pages 12-14)
- Project OR volume using an assumed baseline CAGR for each facility supported by specific assumptions (pages 14-16)
- Apply projected shifts to or from other acute care facilities (pages 17-19)
- Determine projected OR volumes by facility incorporating any shifts to or from other acute care facilities (pages 20-25)

On page 25 of Section Q Form D Assumptions and Methodology, the applicant states:

> *"As discussed in Section C.4., the proposed relocation of one operating room from Atrium Health University City and one from CMC represents CMHA's best choice in November 2020 to balance the use of existing and approved assets to address the needs of Lake Norman service area patients. While retaining these relocated assets at CMC and Atrium Health University City would help to address capacity constraints in the near-term, it does not address greater, long-term, system-wide needs that take into account patient demand for Atrium Health hospital services in the Lake Norman service area. Additionally, given the time horizon of the proposed new hospital and the projects proposed in a separate batch of applications being filed in response to the needs identified in the 2020 SMFP for additional acute care beds and operating rooms in Mecklenburg County, as well as the historical and projected growth in utilization of Atrium Health facilities in Mecklenburg County, CMHA reasonably believes that future SMFPs will identify the need for additional acute care beds and operating rooms in the county based on needs generated by Atrium Health facilities (e.g. Atrium Health facilities show a need for 232 additional acute care beds in the Proposed 2021 SMFP) and that its facilities will propose to develop additional capacity. Furthermore, of particular importance, as demonstrated on Form C Assumptions and Methodology, capacity at Atrium Health Lake Norman will be used primarily to care for patients from Cornelius and the Lake Norman service area that historically accessed CMC and Atrium Health University City."*

However, the information is not reasonable and adequately supported based on the following:

- As discussed in Criterion 3, Atrium Health applications to add acute care beds and ORs in Mecklenburg County were approved in March 2020 for CMC and AHUC. The applicant demonstrated the need for additional beds and ORs at existing Atrium Health facilities in Project ID #F-11811-19, #F-11812-19, and #F-11815-19.

  Project ID #F-11811-19 was approved to add 18 acute care beds at CMC with the need for the additional beds being supported in the Findings by the following information provided by the applicant:

  - *"CMC's projected deficit of 91 acute care beds is the highest of any hospital in Mecklenburg County.*

- *Because of a lack of capacity, some CMC patients have had to stay in the Post-Anesthesia Care Unit (PACU) after surgery due to the lack of an available bed. Additionally, some patients have had to remain in an OR after a surgery is complete because of the resulting lack of space in the PACU. Further, patients are often housed overnight in the ED due to lack of available beds.*

- *CMC's growth is projected to continue because it is the only provider of quaternary care in Mecklenburg County and the surrounding area."*

Project ID #F-11812-19 was approved to add 16 acute care beds at AHUC with the need for the additional beds being supported in the Findings by the following information provided by the applicant:

- *"AH University City's CY 2016 – CY 2019 annualized CAGR is 7.1 percent, the fastest growth rate for acute care days at any of Atrium's Mecklenburg County hospitals.*

- *AH University City's bed deficit in the Proposed 2020 SMFP is the highest (by percentage) of any hospital in North Carolina in the last decade.*

- *Because of a lack of capacity, patients often must wait many hours or even overnight in the ED for an acute care bed to become available. The applicant states that in 2018, patients waited an average of five and a half hours in the ED before an acute care bed was available, and in some cases, patients waited in the ED for up to 24 hours."*

Project ID #F-11815-19 was approved to add two ORs at CMC with the need for the additional ORs being supported in the Findings by the following information provided by the applicant:

- *"CMC is a Level 1 Trauma Center, offers solid organ transplantation, and is the area's only quaternary academic medical center; as such, it fills a vital role in the region.*

- *CMC's current OR deficit in the 2019 SMF is 12.32 ORs and it provides more hours per OR than any other facility in Mecklenburg County.*

- *Surgical volumes in Mecklenburg County have grown at higher rates than the state average. Outpatient surgical cases in Mecklenburg County are increasing more quickly than inpatient surgical cases. While the number of outpatient cases performed at ASFs have higher growth rates than outpatient cases performed at hospitals, the difference isn't significant, and the increase in the number of outpatient cases performed at hospitals is more than double the increase in the number of outpatient cases performed at ASFs."*

If the basis for the need upon which each of the above projects was approved was valid at the time of the approval of those projects, the need for those services at those facilities would still be valid and contrary to the need to relocate the services from those facilities to develop the proposed project. Furthermore, if these projects reflected the most effective alternatives to provide additional acute care capacity for the service area at that time, it is difficult to see how the proposed project would be a more effective alternative at this time. The applicant addresses these capacity constraints in its Utilization–Assumptions and Methodology. In reference to acute care capacity, on Form C Utilization-Assumptions and Methodology, pages 5-6, the applicant states:

> *"While AMHA is approved to develop additional acute care capacity in Mecklenburg County (and is submitting a separate batch of CON applications to develop additional beds in response to the need identifies in the 2020 SMFP for additional acute care beds in Mecklenburg County), it does not believe such capacity will relieve all of its Mecklenburg County hospitals' existing capacity constraints."*

In reference to operating room capacity, on Form D Utilization-Assumptions and Methodology, page 13, the applicant states:

> *"Additionally, CMC, the largest Atrium Health facility, currently demonstrates a significant deficit of capacity, even with the shifts of cases to other facilities."*

In Form D Assumptions and Methodology, page 1, the applicant states:

> *"Please note that in a separate batch of applications, CMHA is filing applications to develop 119 additional acute care beds and 12 additional operating rooms at CMC in response to the needs identified in the 2020 SMFP for additional acute care beds and operating rooms in Mecklenburg County. The utilization projections for CMC shown below incorporate those additions, which are expected to become operational on April 1, 2027."*

The applicant submitted two projects (December 1, 2020 review date) to add beds and ORs at CMC pursuant to the 2020 Need Determinations for 126 acute care beds and 12 ORs: Project ID #F-12006-20 (Add no more than 119 acute care beds pursuant to the need determination in the 2020 SMFP for a total of no more than 1,174 acute care beds upon project completion) and Project ID #F-12008-20 (Add no more than 12 ORs pursuant to the need determination in the 2020 SMFP and a change of scope for Project ID #F-11815-19 (approved to add 2 ORs but would only add 1 OR) for a total of no more than 75 ORs upon completion of both projects). The approval of the projects would address the capacity constraints that the applicant states exist at CMC; however, there is no assurance that the projects will be approved, which would leave CMC with existing capacity constraints per the information provided by the applicant.

- In fact, in the footnote on page 26 of the application, the applicant provides evidence of its belief that the project under review is not as effective of an alternative for

development of the proposed hospital as Project ID #F-11810-19, submitted for the November 1, 2019 review, denied by the Agency, and currently in appeal. The footnote states:

> *"CMHA is currently appealing the denial of Project ID # F-11810-19. If that denial is ultimately reversed as CMHA seeks, CMHA will be awarded 30 additional beds pursuant to the 2019 SMFP need determination for additional acute care beds in Mecklenburg County, and the project as proposed in this application will not be developed. In other words, if CMHA prevails in its appeal of Project ID # F-11810-19 and obtains CON approval for the project proposed in this application, CMHA will not develop both projects, which both propose to develop Atrium Health Lake Norman using alternative means. Under those circumstances, CMHA would surrender the CON for the project proposed in this application and retain the assets proposed to be relocated to Atrium Health Lake Norman at CMC and Atrium Health University City."*

Projected utilization is not reasonable and adequately supported based on the following:

- The applicant does not provide adequate data to support its assumptions for the proposed utilization by a shift in Atrium Health acute care patients from Iredell County to be served at AHLN.
- The applicant projects that the acute care beds at CMC following the proposed relocation of acute care beds will be operating at the high level of 91.4% occupancy.
- The applicant projects that following the relocation of the OR from CMC, CMC will have an operating room deficit of 8.3 ORs.

In Section D, pages 81-83, regarding the effect of the proposal on the ability of underserved groups and the elderly to obtain needed health care, the applicant states:

> *"The proposed relocation of acute care beds and operating rooms from CMC and Atrium Health University City will not negatively impact the ability of underserved groups to access care. In fact, CMHA expects the relocation that will result from the proposed project to develop a new acute care hospital in the Lake Norman service area will have a positive impact on the accessibility of healthcare services to patients, including the underserved, by relocating patients it has historically served to a site closer to home and/or more conveniently located.*
>
> *CMHA facilities provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment."*

However, this project results in a change of scope project for three previously approved Atrium Health projects: Project ID #F-11811-19, Project ID #F-11812-19, and Project ID #F-11815-19. A comparison of the estimated access to services for self-pay and Medicaid recipients as provided in this project and the previously approved projects for which this is a change of scope application follows.

Approved Project ID #F-11811-19, from which the applicant proposes to relocate the approved, but undeveloped 18 acute care beds, projected the following percentages of payor sources per the 2019 Mecklenburg Acute Care Bed and OR Review:

Payor Source	F-11811-19 Med/Surg Beds*	F-12010-20 Med/Surg Beds
Self-Pay	7.2%	7.2%
Medicare	47.2%	54.0%
Medicaid	17.0%	11.9%
Insurance	24.9%	23.3%
Other	3.7%	3.6%
Total	**100.0%**	**100.0%**

*Source - 2019 Mecklenburg Acute Care Bed and OR Review Findings

As the table above shows, Project ID #F-11811-19 was approved to provide 7.2% and 17.0% of the care in its Med/Surg Beds to self-pay and Medicaid recipients respectively. The project under review proposes 7.2% self-pay and only 11.9% of care to Medicaid recipients.

Approved Project ID #F-11812-19, from which the applicant proposes to relocate 12 of the 16 approved, but undeveloped acute care beds, projected the following percentages of payor sources per the 2019 Mecklenburg Acute Care Bed and OR Review:

Payor Source	F-11812-19 Med/Surg Beds*	F-12010-20 Med/Surg Beds
Self-Pay	9.4%	7.2%
Medicare	50.0%	54.0%
Medicaid	15.9%	11.9%
Insurance	21.3%	23.3%
Other	3.4%	3.6%
Total	**100.0%**	**100.0%**

*Source - 2019 Mecklenburg Acute Care Bed and OR Review Findings

As the table above shows, Project ID #F-11812-19 was approved to provide 9.4% and 15.9% of the care in its Med/Surg Beds to self-pay and Medicaid recipients, respectively. The project under review proposes only 7.2% and 11.9% of care to self-pay and Medicaid recipients, respectively.

Approved Project ID #F-11815-19, from which the applicant proposes to relocate one of the two approved, but undeveloped operating rooms, projected the following percentages of payor sources per the 2019 Mecklenburg Acute Care Bed and OR Review:

Payor Source	F-11815-19 ORs*	F-12010-20 ORs
Self-Pay	7.0%	4.1%
Medicare	28.2%	43.1%
Medicaid	18.9%	3.7%
Insurance	42.8%	47.2%
Other	3.0%	1.9%
Total	**100.0%**	**100.0%**

*Source - 2019 Mecklenburg Acute Care Bed and OR Review Findings

As the table above shows, Project ID #F-11815-19 was approved to provide 7.0% and 18.9% of the proposed surgical care to self-pay and Medicaid recipients, respectively. The project under review proposes only 4.1% and 3.7% of surgical care to self-pay and Medicaid recipients, respectively.

As the above comparisons show, this change of scope application proposes to provide less access to self-pay and Medicaid recipients than was approved to be provided in the previously approved applications. The applicant chose not to provide answers to the questions related to "Change of Scope" in the application; thus, the applicant does not explain why the above changes in payor source were necessary or even appropriate.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reasons:

- The applicant does not adequately demonstrate that the needs of the population currently using the services to be relocated will be adequately met following project completion for all the reasons described above.
- The applicant does not adequately demonstrate that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

(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.

NC

CMHA, the applicant, proposes to develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and one undeveloped OR from CMC and 12 undeveloped acute care beds and one existing OR from AHUC which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC).

In Section E, pages 84-86, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo,
- Develop the hospital at another location,
- Develop the hospital with a different number of beds, operating rooms or other services, and
- Develop the project as proposed.

On page 86, the applicant states that its proposal is the most effective alternative because the application proposes to relocate 30 acute care beds, two operating rooms, and other ancillary and support services, bridging the gap of CMHA hospital services in the Lake Norman service area, and providing a cost-effective and efficient point of care to patients closer to home and/or more conveniently located.

In fact, in the footnote on page 26 of the application, the applicant provides evidence of its belief that the project under review is not as effective of an alternative for development of the proposed hospital as Project ID #F-11810-19, submitted for the November 1, 2019 review, denied by the Agency, and currently in appeal. The footnote states:

> *"CMHA is currently appealing the denial of Project ID # F-11810-19. If that denial is ultimately reversed as CMHA seeks, CMHA will be awarded 30 additional beds pursuant to the 2019 SMFP need determination for additional acute care beds in Mecklenburg County, and the project as proposed in this application will not be developed. In other words, if CMHA prevails in its appeal of Project ID # F-11810-19 and obtains CON approval for the project proposed in this application, CMHA will not develop both projects, which both propose to develop Atrium Health Lake Norman using alternative means. Under those circumstances, CMHA would surrender the CON for the project proposed in this application and retain the assets proposed to be relocated to Atrium Health Lake Norman at CMC and Atrium Health University City."*

The proposed project is a change of scope application for Project ID #F-11811-19 (add no more than 18 acute care beds at CMC), Project ID #F-11812-19 (add no more than 16 acute care beds at AHUC), and Project ID #F-11815-19 (add no more than two ORs at CMC). The following table compares the capital expense for developing the beds and ORs as approved in the previous projects to the capital expense proposed for the change of scope project to combine the components of the previously approved applications to develop a new hospital.

	Previously Approved Capital Expense	Proposed Change of Scope Capital Expense	Increase in Cost to Develop Change of Scope Project
Project ID #F-12010-20		$153,929,552	
Project ID #F-11811-19	$10,527,737		
Project ID #F-11812-19	$3,766,000		
Project ID #F-11815-19	$7,974,633		
Total	**$22,268,370**	**$153,929,552**	**$131,661,182**

The applicant chose not to provide answers to the questions related to "Change of Scope" in the application; thus, the applicant does not explain why the above increase in capital expense of $131.6 million (500%) above the approved capital expense of the individual projects to develop the beds and ORs is necessary or justified.

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

- The application is not conforming to all statutory and regulatory review criteria.
- The applicant fails to provide credible information to explain why it believes the project as proposed is the most effective alternative in light of the footnote it provides on page 26 of the application.
- The applicant fails to provide credible information to explain why it believes the proposed project is the most effective alternative in light of the convincing arguments CMHA provided in the previously approved applications: Project ID #'s F-11811-19, F-11812-19 and F-11815-19.

<u>Conclusion</u>

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

(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.

NC

CMHA, the applicant, proposes to develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and one undeveloped OR from CMC and 12 undeveloped acute care beds and one existing OR from AHUC which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC).

Capital and Working Capital Costs

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

Project Capital Cost

Land, Closing Costs, Site Costs, Landscaping	$14,023,158
Construction Costs	$77,733,518
Medical Equipment Costs	$20,398,024
Miscellaneous Costs	$ 41,774,853
Total	**$153,929,552**

Totals may not sum due to rounding

In Section Q Form F.1a Assumptions, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides the proposed construction cost, as prepared by the project's licensed North Carolina architect
- The applicant provides vendor quotes for the proposed CT equipment

In Section F, page 90, the applicant projects that start-up costs will be $2,138,267 and initial operating expenses will be $12,829,603 for a total working capital of $14,967,870. On page 90, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- Estimated start-up cost includes expenses based on 30 days of supplies and utilities; cost of hiring and training staff, benefits, insurance; and other indirect expenses
- Estimated initial operating expenses are based on six months of expenses (excluding depreciation); following the initial six months, the highest cumulative negative cash flow occurs in month 14 and is less than the first six months of expenses

Availability of Funds

In Section F, page 88, the applicant states that the capital cost will be funded as shown below in the table.

Sources of Capital Cost Financing

Type	CMHA
Loans	$0
Accumulated reserves or OE *	$153,929,552
Bonds	$0
Other (Specify)	$0
Total Financing	**$153,929,552**

* OE = Owner's Equity.

In Section F, page 91, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

	Sources of Financing for Working Capital	Amount
(a)	Loans	$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or OE	$14,967,870
(c)	Lines of credit	$0
(d)	Bonds	$0
(e)	**Total**	$14,967,870

Exhibit F.2-1 contains a letter from CMHA's Chief Financial Officer documenting the availability of accumulated reserves to be used for the proposed project.

Exhibit F.2-2 contains a copy of the audited financial statements for CMHA which indicate it had cash and cash equivalents in excess of $370 million as of December 31, 2019.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant documents CMHA's intent to fund the proposed capital and working capital costs
- The applicant provides documentation of available funds for CMHA to fund the project

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project for the entire facility and for each of the proposed service categories. In Form F.2, the applicant projects that revenues will exceed operating expenses for the entire facility in the third full fiscal year of operation following completion of the proposed project, as shown in the table below.

Atrium Health Lake Norman
Entire Facility

	1st Full FY CY2024	2nd Full FY CY2025	3rd Full FY CY2026
Total Patient Days	4,010	6,213	8,558
Total Gross Revenues (Charges)	$ 78,639,976	$ 149,796,550	$ 211,396,710
Total Net Revenue	$ 20,805,808	$ 39,639,174	$ 55,950,055
Average Net Revenue per Procedure	$ 5,188	$ 6,380	$ 6,538
Total Operating Expenses (Costs)	$ 32,982,859	$ 41,513,283	$ 49,566,007
Average Operating Expense per Procedure	$ 8,225	$ 6,682	$ 5,792
Net Income	$ (12,177,051)	$ (1,874,109)	$ 6,384,048

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are also questionable.

Furthermore, because the applicant chose not to provide answers to the questions related to "Change of Scope" in the application, the applicant does not explain why the increase in capital expense of $131.6 million (500%) above the approved capital expense of the individual projects is necessary, justified or financially feasible.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate 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.

NC

CMHA, the applicant, proposes to develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and one undeveloped OR from CMC and 12 undeveloped acute care beds and one existing OR from AHUC which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC).

On page 33, the 2020 SMFP defines the service area for acute care beds as *". . . the service area in which the bed is located. The acute care bed service area are the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 38, shows Mecklenburg County as its own acute care bed service area. On page 51, the 2020 SMFP defines the service area for ORs as *"…the service area in which the operating room is located. The operating room service areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 57, shows Mecklenburg County as its own OR service area. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

On page 43, the 2020 SMFP shows there are two health systems, Atrium Health and Novant Health, providing acute care hospital services in Mecklenburg County. Table 5A, page 43, shows there are seven licensed hospitals and one CON approved, but undeveloped hospital, as summarized below.

2020 SMFP Mecklenburg County Acute Care Beds	Licensed Acute Care Beds	Adjustments for CONs/ Need Determinations
Atrium Health Pineville	206	53
Atrium Health University City	100	0
Carolinas Medical Center*	1,010	45
Atrium Health Total	**1,316**	**98**
Novant Health Huntersville Medical Center	91	60
Novant Health Matthews Medical Center	154	0
Novant Health Mint Hill Medical Center	36	14
Novant Health Presbyterian Medical Center**	567	-84
Novant Health Ballantyne Medical Center	0	36
Novant Health Total	**848**	**26**
2019 Acute Care Bed Need Determination	0	76
Total Beds	**2,164**	**200**

*CMC's license includes the Atrium Health-Mercy hospital campus
**Novant Health Presbyterian Medical Center's license includes the Novant Health Charlotte Orthopedic Hospital campus

In addition to the acute care beds listed above, there is a 2020 Need Determination for 126 acute care beds in Mecklenburg County.

In Table 6A, page 64, the 2020 SMFP shows operating rooms located in Mecklenburg County, as summarized in the following table.

Mecklenburg County OR Inventory per 2020 SMFP						
Facility	**IP ORs**	**OP ORs**	**Shared ORs**	**Excluded C-Section and Trauma ORs**	**CON Adjustments**	**CONs for Excluded C-Sec ORs**
AH Huntersville Surgery Center	0	0	0	0	1	0
AH Pineville	3	0	9	-2	1	0
AH University City	1	2	9	-1	-4	0
Carolina Center for Specialty Surgery	0	2	0	0	1	0
Carolinas Medical Center	10	11	41	-5	0	0
Atrium Health System Total	**14**	**15**	**59**	**-8**	**-1**	**0**
Charlotte Surgery Center – Museum	0	7	0	0	-1	0
Charlotte Surgery Center – Wendover	0	0	0	0	6	0
Charlotte Surgery Center System Total	**0**	**7**	**0**	**0**	**5**	**0**
Matthews Surgery Center	0	2	0	0	0	0
NH Ballantyne Medical Center*	0	0	0	0	2	1
NH Ballantyne OPS*	0	2	0	0	-2	0
NH Huntersville Medical Center	1	0	6	-1	1	1
NH Huntersville OPS	0	2	0	0	0	0
NH Mint Hill Medical Center	1	0	3	-1	1	0
NH Matthews Medical Center	2	0	6	-2	0	0
NH Presbyterian Medical Center	6	6	28	-3	-1	0
SouthPark Surgery Center	0	6	0	0	0	0
Novant Health System Total	**10**	**18**	**43**	**-7**	**1**	**2**
Carolinas Ctr for Ambulatory Dentistry**	**0**	**0**	**0**	**0**	**2**	**0**
Mallard Creek Surgery Center**	**0**	**2**	**0**	**0**	**0**	**0**
Metrolina Vascular Access Care	**0**	**0**	**0**	**0**	**1**	**0**
2019 SMFP Need Determination	**0**	**0**	**0**	**0**	**6**	**0**
Total	**24**	**42**	**102**	**-15**	**14**	**2**

Sources: Table 6A, 2020 SMFP
*NH Ballantyne, an approved hospital under development, will have 2 ORs that will be relocated from NH Ballantyne OPS, which will close once the ORs are relocated to NHBMC. One is an excluded C-Section/Trauma OR
**These facilities are part of demonstration projects and the ORs are not included in the SMFP need determination calculations

In addition to the ORs listed above, there is a 2020 Need Determination for 12 operating rooms in Mecklenburg County.

In Section G, pages 97-98, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved hospital services in the Mecklenburg service area. The applicant states that the proposed project will enhance geographic and timely access to hospital services for patients in the Lake Norman area of Mecklenburg County. The applicant further states:

"The proposed project does not seek to develop any of the additional acute care beds or operating rooms identified as needed in the 2020 SMFP. Nonetheless, the 2020 SMFP shows that Mecklenburg County needs 126 additional acute care beds and 12 additional operating rooms, generated by the historical and projected utilization of CMHA facilities. Thus, the proposal to relocate existing capacity to Atrium Health Lake Norman, which capacity the SMFP indicates is needed in the service area and

confirmed by the analyses in this application, coupled with the demonstrated need in this application to develop a new hospital in the Lake Norman region, documents that the proposed project will not result in unnecessary duplication of existing facilities.

All of the services proposed for Atrium Health Lake Norman, which include not only acute care inpatient services, but also emergency services, surgical services, imaging services, as well as ancillary and support services, are part of its application to develop a hospital and are essential to the development and operation of its proposed facility as a hospital. While some of the proposed services, such as surgery, can and will be provided on an outpatient basis, having them anchored to a hospital will provide access to inpatients and emergency patients, as well as outpatients for whom clinical reasons dictate their procedure be performed in a hospital-based setting."

On page 98, the applicant further states that development of the proposed services will not result in the unnecessary duplication of services already existing in the Lake Norman area or elsewhere, as the applicant states that it has demonstrated the need for each of the proposed services based on the projected utilization for each service component.

However, the applicant does not adequately demonstrate 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 does not adequately demonstrate the need the population proposed to be served has for the proposed project. The discussion regarding need found in Criterion (3) is incorporated herein by reference.

- The applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the reasons stated above.

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

C

CMHA, the applicant, proposes to develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and one undeveloped OR from CMC and 12 undeveloped acute care beds and one existing OR from AHUC which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC).

In Section Q Form H Staffing, the applicant provides the current and projected full-time equivalent (FTE) staffing for the proposed services, as shown in the table below.

AHLN Projected Staffing			
Position	**CY 2023 (FY 1)**	**CY 2024 (FY 2)**	**CY 2025 (FY 3)**
Registered Nurses	59.00	72.60	75.70
Surgical Technicians	6.70	7.20	8.70
Aides/Orderlies	10.50	14.70	14.70
Clerical Staff	20.20	23.30	25.20
Laboratory Technicians	8.40	8.40	8.40
Radiology Technologists	6.20	6.70	7.20
Pharmacists	1.00	1.00	1.00
Pharmacy Technicians	1.50	1.50	1.50
Physical Therapists	1.20	1.20	1.20
Speech Therapists	0.50	0.50	0.50
Occupational Therapists	0.25	0.25	0.50
Respiratory Therapists	8.40	8.40	8.40
Dieticians	0.50	0.50	1.00
Cooks	12.00	13.00	15.00
Social Workers	0.50	0.50	1.00
Housekeeping	10.50	12.60	12.60
Materials Management	2.00	2.00	2.00
Maintenance/Engineering	1.25	1.75	2.50
Administrator	7.80	7.80	13.50
Director of Nursing	1.00	1.00	1.00
Business Office	2.00	2.00	2.00
Specialists	1.75	1.75	2.25
Security	6.90	8.40	8.40
Lactation Consultant	0.25	0.25	0.25
Diagnostic Technician	8.40	8.40	8.40
EEG Tech	0.50	0.50	0.50
Total	**179.20**	**206.20**	**223.40**

The assumptions and methodology used to project staffing are provided in Section Q Form H Assumptions. Adequate costs for operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 100-101, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibit C.4-2, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- Types of positions are projected based on AHUC's historical experience with staffing patterns for hospital services
- Number of FTE positions is based on AHUC's historical experience with staffing patterns for hospital services
- Annual salary per FTE position is based on the current salary per FTE position, inflated by 3.0% annually

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

CMHA, the applicant, proposes to develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and one undeveloped OR from CMC and 12 undeveloped acute care beds and one existing OR from AHUC which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC).

Ancillary and Support Services

In Section I, pages 102-03, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service will be made available. The applicant provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides a listing of the necessary ancillary and support services based on CMHA experience providing hospital services

- The applicant provides documentation of CMHA's intent to provide all necessary ancillary and support services

Coordination

In Section I, page 103, 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 based on the following:

- CMHA is an existing provider and has established relationships
- The applicant states that CMHA's established relationships will be extended to AHLN

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

(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.

(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

CMHA, the applicant, proposes to develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and one undeveloped OR from CMC and 12 undeveloped acute care beds and one existing OR from AHUC which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC).

In Section K, page 107, the applicant states that the project involves constructing 160,000 square feet of new space. Line drawings are provided in Exhibit C.1.

On pages 110-111, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibits K.4-1 and K.4-2. The site appears to be suitable for the proposed hospital based on the applicant's representations and supporting documentation.

On page 108, the applicant explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- the applicant states the overall layout of the hospital is based on a configuration that provides the most efficient circulation and throughput for patients and caregivers
- sizes of spaces are based on best practice guidelines
- specific strategies are incorporated into the building plans to ensure energy efficiency

On page 108, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- the applicant states that the proposed project would provide access to essential acute care services for patients at a new hospital
- CMHA has set aside excess revenues from previous years to enable it to pay for projects such as the one proposed in this application, without necessitating an increase in costs or charges to pay for the project

On pages 108-109, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation from CMHA's existing policies and documented commitment for organization-wide energy savings.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

(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 … persons [with disabilities], 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

AHLN is not an existing hospital; therefore, it has no historical payor mix. For informational purposes, on page 115, the applicant provides the payor mix for both CMC and AHUC during CY2019, as summarized below.

Payor Mix Last Full Fiscal Year CY2019						
	Carolinas Medical Center			Atrium Health University City		
Payor Source	**Total Facility**	**M/S Beds**	**ORs**	**Total Facility**	**M/S Beds**	**ORs**
Self-Pay	15.3%	7.6%	7.5%	20.4%	10.8%	10.8%
Medicare*	27.2%	47.2%	29.5%	22.2%	52.6%	40.0%
Medicaid*	23.5%	15.7%	18.8%	20.3%	13.2%	9.5%
Insurance*	32.2%	25.8%	41.2%	33.6%	19.8%	35.8%
Other**	1.9%	3.7%	3.0%	3.6%	3.6%	3.9%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Source: Atrium Health internal data
*Including any managed care plans
** Includes Workers compensation and TRICARE

In Section L, page 114, the applicant provides the following comparison of CMC and AHUC with the percentage of population of the service area.

Last Full Fiscal Year CY2019			
	CMC Percentage of Total Patients Served	**AHUC Percentage of Total Patients Served**	**Percentage of the Population of the Service Area**
Female	59.3%	59.1%	51.9%
Male	40.7%	40.8%	48.1%
Unknown	0.0%	0.0%	0.0%
64 and Younger	77.3%	82.3%	88.5%
65 and Older	22.7%	17.7%	11.5%
American Indian	0.7%	1.4%	0.8%
Asian	1.3%	1.3%	6.3%
Black or African-American	30.5%	47.6%	33.0%
Native Hawaiian or Pacific Islander	0.2%	0.1%	0.1%
White or Caucasian	43.7%	31.4%	57.3%
Other Race	0.2%	0.4%	2.5%
Declined / Unavailable	23.5%	17.8%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and … persons [with disabilities] 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 116, the applicant states:

> *"Neither CMC nor Atrium Health University City, from which acute care beds and operating rooms are proposed to be relocated, has any obligations to provide a specific uncompensated care amount, community service, or access to care by medically underserved, minorities, or handicapped persons. However, as previously stated, CMHA facilities provides and will continue to provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. The same will be true for Atrium Health Lake Norman."*

In Section L, page 116, the applicant states that during the last five years no patient civil rights access complaints have been filed against CMC, AHUC 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
- Written comments
- Responses to comments

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

NC

In Section L, page 117, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

AHLN Projected Payor Mix – Third Full FY (CY 2026)								
Payor Source	**Total Facility**	**M/S Beds**	**ICU Beds**	**OB Beds***	**Surg Svcs**	**ED**	**Imaging**	**Other****
Self-Pay	16.6%	7.2%	7.2%	1.5%	4.1%	21.1%	9.8%	6.4%
Medicare***	24.7%	54.0%	54.0%	0.3%	43.1%	16.0%	25.7%	17.5%
Medicaid***	22.0%	11.9%	11.9%	28.5%	3.7%	22.2%	12.6%	26.1%
Insurance***	33.2%	23.3%	23.3%	69.3%	47.2%	36.8%	50.1%	49.2%
Other****	3.4%	3.6%	3.6%	0.4%	1.9%	4.0%	1.8%	0.4%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

*Obstetrics Beds
**Other includes laboratory services, physical therapy, occupational therapy, speech therapy, and other services.
***Including any managed care plans
****Includes TRICARE and worker's compensation
Totals may not sum due to rounding

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 16.6% of total services will be provided to self-pay patients, 24.7% to Medicare patients and 22.0% to Medicaid patients. The applicant states that its internal data does not report charity care as a payor source and that patients from any payor source can and do receive charity care.

On page 117, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project, stating that it relies on historical CY2019 Atrium Health Mecklenburg facility data for the projections, adjusted with consideration to healthcare reform and Medicaid expansion.

This project results in a change of scope project for three previously approved Atrium Health projects: Project ID #F-11811-19, Project ID #F-11812-19, and Project ID #F-11815-19. A comparison of the estimated access to services for self-pay and Medicaid recipients as provided in this project and the previously approved projects for which this is a change of scope application follows.

Approved Project ID #F-11811-19, from which the applicant proposes to relocate the approved, but undeveloped 18 acute care beds, projected the following percentages of payor sources per the 2019 Mecklenburg Acute Care Bed and OR Review:

Payor Source	**F-11811-19 Med/Surg Beds***	**F-12010-20 Med/Surg Beds**
Self-Pay	7.2%	7.2%
Medicare	47.2%	54.0%
Medicaid	17.0%	11.9%
Insurance	24.9%	23.3%
Other	3.7%	3.6%
Total	**100.0%**	**100.0%**

*Source - 2019 Mecklenburg Acute Care Bed and OR Review Findings

As the table above shows, Project ID #F-11811-19 was approved to provide 7.2% and 17.0% of the care in its Med/Surg Beds to self-pay and Medicaid recipients

respectively. The project under review proposes 7.2% self-pay and only 11.9% of care to Medicaid recipients.

Approved Project ID #F-11812-19, from which the applicant proposes to relocate 12 of the 16 approved, but undeveloped acute care beds, projected the following percentages of payor sources per the 2019 Mecklenburg Acute Care Bed and OR Review:

Payor Source	F-11812-19 Med/Surg Beds*	F-12010-20 Med/Surg Beds
Self-Pay	9.4%	7.2%
Medicare	50.0%	54.0%
Medicaid	15.9%	11.9%
Insurance	21.3%	23.3%
Other	3.4%	3.6%
Total	**100.0%**	**100.0%**

*Source - 2019 Mecklenburg Acute Care Bed and OR Review Findings

As the table above shows, Project ID #F-11812-19 was approved to provide 9.4% and 15.9% of the care in its Med/Surg Beds to self-pay and Medicaid recipients, respectively. The project under review proposes only 7.2% and 11.9% of care to slf-pay and Medicaid recipients, respectively.

Approved Project ID #F-11815-19, from which the applicant proposes to relocate one of the two approved, but undeveloped operating rooms, projected the following percentages of payor sources per the 2019 Mecklenburg Acute Care Bed and OR Review:

Payor Source	F-11815-19 ORs*	F-12010-20 ORs
Self-Pay	7.0%	4.1%
Medicare	28.2%	43.1%
Medicaid	18.9%	3.7%
Insurance	42.8%	47.2%
Other	3.0%	1.9%
Total	**100.0%**	**100.0%**

*Source - 2019 Mecklenburg Acute Care Bed and OR Review Findings

As the table above shows, Project ID #F-11815-19 was approved to provide 7.0% and 18.9% of the proposed surgical care to self-pay and Medicaid recipients, respectively. The project under review proposes only 4.1% and 3.7% of surgical care to self-pay and Medicaid recipients, respectively.

As the above comparisons show, this change of scope application proposes to provide less access to self-pay and Medicaid recipients than was approved to be provided in the previously approved applications. The applicant chose not to provide answers to the questions related to “Change of Scope” in the application; thus, the applicant does not explain why the above changes in payor source were necessary or even appropriate.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the reasons stated above.

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

C

In Section L, page 118, 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
- Written comments
- Responses to comments

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

CMHA, the applicant, proposes to develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and one undeveloped OR from CMC and 12 undeveloped acute care beds and one existing OR from AHUC which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC).

In Section M, page 120, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- CMHA has extensive, existing relationships with health professional training programs
- Each of the programs listed in Exhibit M.1 will have access to clinical training opportunities at AHLN, as appropriate

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

(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.

NC

CMHA, the applicant, proposes to develop a new separately licensed hospital by relocating 18 undeveloped acute care beds and one undeveloped OR from CMC and 12 undeveloped acute care beds and one existing OR from AHUC which is a change of scope for Project ID #F-11811-19 (add 18 beds to CMC), Project ID #F 11812-19 (develop 16 beds at Atrium Health University City), and Project ID #F-11815-19 (add 2 ORs to CMC).

On page 33, the 2020 SMFP defines the service area for acute care beds as *". . . the service area in which the bed is located. The acute care bed service area are the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 38, shows Mecklenburg County as its own acute care bed service area. On page 51, the 2020 SMFP defines the service area for ORs as *"...the service area in which the operating room is located. The operating room service areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1, on page 57, shows Mecklenburg County as its own OR service area. Thus, the service area for

this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

On page 43, the 2020 SMFP shows there are two health systems, Atrium Health and Novant Health, providing acute care hospital services in Mecklenburg County. Table 5A, page 43, shows there are seven licensed hospitals and one CON approved, but undeveloped hospital, as summarized below.

2020 SMFP Mecklenburg County Acute Care Beds	Licensed Acute Care Beds	Adjustments for CONs/ Need Determinations
Atrium Health Pineville	206	53
Atrium Health University City	100	0
Carolinas Medical Center*	1,010	45
Atrium Health Total	**1,316**	**98**
Novant Health Huntersville Medical Center	91	60
Novant Health Matthews Medical Center	154	0
Novant Health Mint Hill Medical Center	36	14
Novant Health Presbyterian Medical Center**	567	-84
Novant Health Ballantyne Medical Center	0	36
Novant Health Total	**848**	**26**
2019 Acute Care Bed Need Determination	0	76
Total Beds	**2,164**	**200**

*CMC's license includes the Atrium Health-Mercy hospital campus
**Novant Health Presbyterian Medical Center's license includes the Novant Health Charlotte Orthopedic Hospital campus

In addition to the acute care beds listed above, there is a 2020 Need Determination for 126 acute care beds in Mecklenburg County.

In Table 6A, page 64, the 2020 SMFP shows operating rooms located in Mecklenburg County, as summarized in the following table:

Mecklenburg County OR Inventory per 2020 SMFP						
Facility	**IP ORs**	**OP ORs**	**Shared ORs**	**Excluded C-Section and Trauma ORs**	**CON Adjustments**	**CONs for Excluded C-Sec ORs**
AH Huntersville Surgery Center	0	0	0	0	1	0
AH Pineville	3	0	9	-2	1	0
AH University City	1	2	9	-1	-4	0
Carolina Center for Specialty Surgery	0	2	0	0	1	0
Carolinas Medical Center	10	11	41	-5	0	0
Atrium Health System Total	**14**	**15**	**59**	**-8**	**-1**	**0**
Charlotte Surgery Center – Museum	0	7	0	0	-1	0
Charlotte Surgery Center – Wendover	0	0	0	0	6	0
Charlotte Surgery Center System Total	**0**	**7**	**0**	**0**	**5**	**0**
Matthews Surgery Center	0	2	0	0	0	0
NH Ballantyne Medical Center*	0	0	0	0	2	1
NH Ballantyne OPS*	0	2	0	0	-2	0
NH Huntersville Medical Center	1	0	6	-1	1	1
NH Huntersville OPS	0	2	0	0	0	0
NH Mint Hill Medical Center	1	0	3	-1	1	0
NH Matthews Medical Center	2	0	6	-2	0	0
NH Presbyterian Medical Center	6	6	28	-3	-1	0
SouthPark Surgery Center	0	6	0	0	0	0
Novant Health System Total	**10**	**18**	**43**	**-7**	**1**	**2**
Carolinas Ctr for Ambulatory Dentistry**	**0**	**0**	**0**	**0**	**2**	**0**
Mallard Creek Surgery Center**	**0**	**2**	**0**	**0**	**0**	**0**
Metrolina Vascular Access Care	**0**	**0**	**0**	**0**	**1**	**0**
2019 SMFP Need Determination	**0**	**0**	**0**	**0**	**6**	**0**
Total	**24**	**42**	**102**	**-15**	**14**	**2**

Sources: Table 6A, 2020 SMFP
*NH Ballantyne, an approved hospital under development, will have 2 ORs that will be relocated from NH Ballantyne OPS, which will close once the ORs are relocated to NHBMC. One is an excluded C-Section/Trauma OR
**These facilities are part of demonstration projects and the ORs are not included in the SMFP need determination calculations

In addition to the ORs listed above, there is a 2020 Need Determination for 12 operating rooms in Mecklenburg County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 122, the applicant states:

"The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to acute care services."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 122, the applicant states:

"The proposed application is indicative of CMHA's commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended, while also

ensuring that it develops the services and capacity to meet the needs of the population it serves."

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 123, the applicant states:

"CMHA believes that the proposed project will promote safety and quality in the delivery of healthcare services. CMHA is known for providing high quality services and expects the proposed project to expand its hospital services while bolstering its high quality reputation."

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 124, the applicant states:

"The proposed project is designed to expand and improve access to all patients, including the medically underserved, particularly geographic and timely access to the hospital services proposed in the application."

See also Sections L and C of the application and any exhibits.

However, the applicant does not adequately demonstrate how any enhanced competition will have a positive impact on the cost-effectiveness of the proposal, based on the following analysis:

- The applicant does not adequately demonstrate the need the population proposed to be served has for the proposed project. The discussion regarding need found in Criterion (3) is incorporated herein by reference.
- The applicant does not adequately demonstrate that the projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- The applicant does not adequately demonstrate that the financial feasibility of the project is based on reasonable and adequately supported assumptions. The discussion regarding financial feasibility in Criterion (5) are incorporated herein by reference.
- The applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Responses to comments

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

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q Form A Facilities, the applicant identifies the healthcare facilities with acute care beds or ORs located in North Carolina which are owned, operated or managed by the applicant or a related entity. The applicant identifies a total of approximately 30 hospitals, ASFs, and EDs located in North Carolina.

In Section O, page 129, the applicant states that, during the 18 months immediately preceding the submittal of the application, none of the identified facilities were found to have any incidents resulting in a finding of immediate jeopardy. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 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.

G.S. 131E-183 (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.

NC

The Criteria and Standards for Acute Care Beds as promulgated in 10A NCAC 14C .3800 and the Criteria and Standards for Surgical Services and Operating Rooms as promulgated in 10A NCAC 14C .2100 are not applicable to this review because the applicant does not propose to develop new acute care beds or new operating rooms.

The Criteria and Standards for computed tomography as promulgated in 10A NCAC 14C .2300 is applicable to this review.

SECTION .2300 – CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT

10A NCAC 14C .2303 PERFORMANCE STANDARDS

An applicant proposing to acquire a CT scanner shall demonstrate each of the following:

(1) each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;

-NC- The applicant proposes to develop AH Lake Norman, a new separately licensed hospital, and proposes to acquire a CT scanner as part of that project. In Section C.12, page 72 and Section Q Utilization Assumptions and Methodology, page 37, the applicant projects to perform 12,500 HECT units in the third year of operation of the proposed equipment. However, the applicant does not adequately demonstrate the need to develop the new hospital or that projected utilization, including for the proposed CT scanner, is reasonable and adequately supported. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. Therefore, the application is not conforming with this Rule.

(2) each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application; and

-NC- The defined service area for the development of the proposed hospital, of which this CT is one of the proposed services, is Mecklenburg County. In Section C, page 72, the applicant identifies its CT service area as the PSA and SSA which it provides for patient origin at the proposed hospital. The applicant states it currently owns and operates one existing fixed CT scanner in its independently identified CT service area, located at Carolinas Imaging Services – Huntersville. On page 73, the applicant states that the CT scanner at Carolinas Imaging Services – Huntersville performed 14,288 HETC units for the twelve-month period from August 2019 through July 2020.

Carving out a separate service area for a service component developed as part of the proposed hospital may not be appropriate and the applicant does not provide the CT

utilization for all its CT scanners operating in Mecklenburg County for evaluation against this performance standard.

However, the applicant does not adequately demonstrate the need to develop the new hospital or that the projected utilization, including for the proposed CT scanner, is reasonable and adequately supported. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. Therefore, the application is not conforming with this Rule.

(3) *each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.*

-NC- In Section C, pages 72-73, the applicant identifies its CT service area as the PSA and SSA which it provides for patient origin at the proposed hospital. The applicant states it currently owns and operates one existing fixed CT scanner in its independently identified CT service area, located at Carolinas Imaging Services – Huntersville, and was approved to relocate a fixed CT scanner to be relocated from CMC as part of developing AH Mountain Island ED (Project I.D. #F-11658-19). On page 74, the applicant provides the projected HECT units to be performed by the Atrium CT scanners in the applicant's stated PSA and SSA ZIP codes in its third full fiscal year, CY2026, and states that the combined average of the three existing, approved, and proposed CT scanners is projected to be more than 5,100 HECT units annually in CY2026, as shown on page 74 and summarized below.

Projected Utilization CY2026 for Applicant's Identified CT PSA/SSA ZIP Code CT Service Area			
	Projected HECT Units	**# of CT Scanners**	**HECT Units / CT Scanner**
AH Lake Norman HECT Units	12,500	1	12,500
AH Mountain Island HECT Units for CY2023, Project I.D. #F-11658-19, held constant through CY2026	3,452	1	3,452
CIS-Huntersville HECT Units from August 2019-July 2020 (ED and Outpatient diagnostic units)	13,008	1	13,008
PSA/SSA ZIP Code Service Area Total	22,031	3	9,653

However, the performance standard clearly states, "*each existing and approved fixed or mobile CT scanner . . . shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.*" The applicant's interpretation that the performance standard suggests it is permissible to average the utilization of CTs in separate facilities is not accurate. As the table above clearly shows, The Atrium Health Mountain Island scanner is not projected to perform at least 5,100 HECT units.

Furthermore, carving out a separate service area for a service component developed as part of the proposed hospital may not be appropriate and the applicant does not provide

the CT utilization for all its CT scanners operating in Mecklenburg County for evaluation against this performance standard.

Moreover, the applicant does not adequately demonstrate the need to develop the new hospital or that the projected utilization, including for the proposed CT scanner, is reasonable and adequately supported. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. Therefore, the application is not conforming with this Rule.