REQUIRED STATE AGENCY FINDINGS

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

Decision Date: September 23, 2022
Findings Date: September 23, 2022

Project Analyst: Julie M. Faenza
Co-signer: Gloria C. Hale

COMPETITIVE REVIEW

Project ID #:	J-12211-22
Facility:	Duke University Hospital
FID #:	943138
County:	Durham
Applicant:	Duke University Health System, Inc.
Project:	Develop no more than 68 additional acute care beds pursuant to the 2022 SMFP need determination for a total of no more than 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds)

Project ID #:	J-12214-22
Facility:	UNC Hospitals-RTP
FID #:	210266
County:	Durham
Applicants:	University of North Carolina Hospitals at Chapel Hill University of North Carolina Health Care System
Project:	Develop no more than 34 additional acute care beds pursuant to the 2022 SMFP need determination which is a change of scope to approved Project ID #J-12065-21 (develop a new acute care hospital) for a total of no more than 74 acute care beds upon project completion

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

Given the complexity of this review and the nuances of the types of care proposed, the Project Analyst created the tables below listing acronyms or abbreviations used in the findings.

Acronyms/Abbreviations Used	
Acronym/Abbreviations Used	**Full Term**
ADC	Average Daily Census (# of acute care days / 365 days in a year)
ALOS	Average Length of Stay (average number of acute care days for patients)
CAGR	Compound Annual Growth Rate
CY	Calendar Year
ED	Emergency Department
FFY	Federal Fiscal Year (October 1 – September 30)
FY	Fiscal Year
HSA	Health Service Area
ICU	Intensive Care Unit
IP	Inpatient
LRA	License Renewal Application
NC OSBM	North Carolina Office of State Budget and Management
SHCC	State Health Coordinating Council
SFY	NC State Fiscal Year (July 1 – June 30)
SMFP	State Medical Facilities Plan

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.

NC – Duke University Hospital
C – UNC Hospitals-RTP

Need Determination – Chapter 5 of the 2022 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional acute care beds in North Carolina by service area. Application of the need methodology in the 2022 SMFP identified a need for 68 additional acute care beds in the Durham/Caswell multicounty service area. Two applications were submitted to the Healthcare Planning and Certificate of Need Section ("CON Section" or "Agency") proposing to develop a total of 102 new acute care beds in Durham County. However, pursuant to the need determination, only 68 acute care beds may be approved in this review for the Durham/Caswell multicounty service area. See the Conclusion following the Comparative Analysis for the decision.

Only qualified applicants can be approved to develop new acute care beds. On page 37, the 2022 SMFP states:

> *"A qualified applicant is a person who proposes to operate the additional acute care beds in a hospital that will provide:*
>
> *(1) a 24-hour emergency services department,*
> *(2) inpatient medical services to both surgical and non-surgical patients, and*
> *(3) if proposing a new licensed hospital, medical and surgical services on a daily basis within at least five of the following major diagnostic categories (MDC) recognized by the Centers for Medicare & Medicaid services (CMS) listed below…* [listed on page 37 of the 2022 SFMP]*."*

Policies – There are two policies in the 2022 SMFP which are applicable to this review.

Policy GEN-3: Basic Principles, on page 30 of the 2022 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."

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on pages 30-31 of the 2022 SMFP, states:

"Any person proposing a capital expenditure greater than $4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

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

Policy GEN-3 applies to both applications. Policy GEN-4 applies to Project ID #**J-11214-22** but does not apply to Project ID #**J-12211-22**.

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

Duke University Health System, Inc. (hereinafter referred to as "Duke" or "the applicant") proposes to add 68 new acute care beds to Duke University Hospital

(DUH), a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

Need Determination. The applicant does not propose to develop more acute care beds than are determined to be needed in the Durham/Caswell multicounty service area. In Section B, page 22, the applicant adequately demonstrates that it meets the requirements of a "qualified applicant" as defined in Chapter 5 of the 2022 SMFP.

***Policy GEN-3*.** In Section B, page 25, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximizing healthcare value for resources expended. The applicant does not adequately demonstrate the need to develop 68 new acute care beds and does not adequately demonstrate that developing 68 new acute care beds would not be an unnecessary duplication of existing and approved services. The discussions regarding analysis of need (including projected utilization) and unnecessary duplication found in Criterion (3) and Criterion (6), respectively, are incorporated herein by reference. An applicant that does not demonstrate the need for the proposed project (including projected utilization that is reasonable and adequately supported) and does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved health care services in the service area cannot demonstrate that it will maximize healthcare value for resources expended in meeting the need identified in the 2022 SMFP. Thus, the application is not consistent with Policy GEN-3.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

- The applicant does not adequately demonstrate the need to develop 68 new acute care beds or that developing 68 new acute care beds would not be an unnecessary duplication of existing and approved health care services.

- Therefore, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum healthcare value for resources expended as required in Policy GEN-3.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

University of North Carolina Hospitals at Chapel Hill and University of North Carolina Health Care System (hereinafter referred to as "UNC" or "the applicant") was approved by the Agency on September 21, 2021, to develop a new hospital with 40 acute care beds and 2 operating rooms (ORs) pursuant to need determinations in the 2021 SMFP. The decision to approve Project ID #J-12065-21 is currently under appeal and no certificate of need (CON) has been issued. In this project, UNC proposes a change of scope to Project ID #J-12065-21, by proposing to add 34 acute care beds and additional hospital-based services. If a CON is issued to UNC for Project ID #J-12065-21, UNC would have a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

Need Determination. The applicant does not propose to develop more acute care beds than are determined to be needed in the Durham/Caswell multicounty service area. In Section B, page 25, the applicant adequately demonstrates that it meets the requirements of a "qualified applicant" as defined in Chapter 5 of the 2022 SMFP.

***Policy GEN-3*.** In Section B, pages 27-31, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

***Policy GEN-4*.** The proposed capital expenditure for this project is greater than $4 million. In Section B, page 32, the applicant describes the project's plan to improve energy efficiency and conserve water.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

- The applicant does not propose to develop more acute care beds than are determined to be needed in the Durham/Caswell multicounty service area.

- The applicant adequately demonstrates it is a "qualified applicant" as defined in Chapter 5 of the 2022 SMFP.

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:

- The applicant adequately documents how the project will promote safety and quality in the delivery of acute care bed services in the Durham/Caswell multicounty service area.

- The applicant adequately documents how the project will promote equitable access to acute care bed services in the Durham/Caswell multicounty service area.
- The applicant adequately documents how the project will maximize healthcare value for the resources expended.

- The applicant adequately demonstrates that 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 – Duke University Hospital
C – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

The applicant was part of a competitive review for acute care beds in the Durham/Caswell multicounty service area based on a need determination in the 2021 SMFP. The Agency issued a decision on that competitive review on September 21, 2021, awarding 40 acute care beds to the other applicant for acute care beds in that competitive review. Duke has appealed that decision. As of the date of these findings, that decision is still under appeal, and no CON has been issued. In Section C, page 27, and in Section Q, the applicant states that if the Agency decision is reversed and the 40 acute care beds are awarded to DUH, the applicant plans to develop those 40 acute care beds in addition to the 68 acute care beds it is proposing to develop as part of the current application. Thus, DUH would potentially have 1,170 acute care beds upon completion of this project and other associated projects.

Patient Origin – On page 33, the 2022 SMFP defines the service area for acute care beds as *"… the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on

page 38, shows Durham and Caswell counties in a multicounty grouping. Thus, the service area for these facilities is the Durham/Caswell multicounty service area. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin. Duke's fiscal year is July 1 – June 30, which is also North Carolina's state fiscal year (SFY).

Historical and Projected Patient Origin – Adult Acute Care Services								
Area	SFY 2021		FY 1 (SFY 2024)		FY 2 (SFY 2025)		FY 3 (SFY 2026)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Alamance	1,389	3.9%	1,578	4.2%	1,602	4.2%	1,626	4.2%
Caswell	172	0.5%	190	0.5%	192	0.5%	195	0.5%
Chatham	230	0.6%	206	0.5%	209	0.5%	212	0.5%
Cumberland	837	2.3%	880	2.4%	893	2.4%	906	2.4%
Durham	10,153	28.2%	10,412	28.0%	10,567	28.0%	10,727	28.0%
Franklin	588	1.6%	488	1.3%	496	1.3%	503	1.3%
Granville	1,361	3.8%	1,479	4.0%	1,502	4.0%	1,524	4.0%
Guilford	586	1.6%	606	1.6%	615	1.6%	624	1.6%
Harnett	328	0.9%	406	1.1%	412	1.1%	418	1.1%
Johnston	471	1.3%	424	1.1%	431	1.1%	437	1.1%
Lee	282	0.8%	321	0.9%	326	0.9%	331	0.9%
Nash	336	0.9%	309	0.8%	314	0.8%	318	0.8%
Orange	1,456	4.0%	1,405	3.8%	1,426	3.8%	1,448	3.8%
Person	1,095	3.0%	1,228	3.3%	1,246	3.3%	1,265	3.3%
Robeson	552	1.5%	509	1.4%	517	1.4%	524	1.4%
Vance	988	2.7%	973	2.6%	987	2.6%	1,002	2.6%
Wake	4,522	12.6%	4,782	12.9%	4,854	12.9%	4,927	12.9%
Warren	338	0.9%	328	0.9%	333	0.9%	338	0.9%
Wilson	248	0.7%	266	0.7%	270	0.7%	274	0.7%
Other NC Counties	5,790	16.1%	6,155	16.5%	6,247	16.5%	6,341	16.5%
Virginia	2,405	6.7%	2,365	6.4%	2,401	6.4%	2,437	6.4%
Other States	1,892	5.3%	1,906	5.1%	1,934	5.1%	1,964	5.1%
International	2	0.0%	6	0.0%	6	0.0%	6	0.0%
Total	**36,021**	**100.0%**	**37,222**	**100.0%**	**37,780**	**100.0%**	**38,347**	**100.0%**

Source: Section C, pages 28 and 30

In Section C, page 30, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant's projected patient origin is based on historical patient origin at the same facility.

- The applicant states it does not project any material change to its historical patient origin as a result of the proposed project because it is expanding the existing services that it is using to project future patient origin.

Analysis of Need – In Section C, pages 32-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states that the need determination in the 2022 SMFP for 68 beds is entirely the result of utilization at DUH, and the other two hospitals in Durham County both have surpluses. The applicant states the actual acute care bed need for DUH is 141 acute care beds, but the total is offset by the surplus of acute care beds at Duke Regional Hospital (DRH) and the 2021 SMFP need determination of 40 acute care beds (which is currently under appeal).

- The applicant states that between SFY 2016 and SFY 2021, inpatient days of care increased by 14%, or at a Compound Annual Growth Rate (CAGR) of 2.6%. The applicant states that growth in discharges was lower than inpatient days of care which reflects longer inpatient stays over time. The applicant states the longer inpatient stays cause capacity constraints and limit Duke's ability to serve more patients.

- The applicant states DUH is the state's *"preeminent academic medical center"* and provides specialized quaternary care across a range of service lines. The applicant states DUH is ranked nationally by US News and World Report and the same report ranks DUH as the best hospital in the state. The applicant states that the need for this specialized level of care is demonstrated by the fact that less than 30% of their patient origin is from Durham County. The applicant states that due to the level of care provided, providers often request to transfer high acuity patients to DUH, and capacity constraints can prevent the ability to transfer patients to DUH.

- The applicant states that, according to information from the North Carolina Office of State Budget and Management (NC OSBM), population growth in the Durham/Caswell multicounty service area is expected to grow by a total of 13.4% between July 2020 and July 2030 (a CAGR of 1.4%). The applicant states that population in nearby counties from which it has historically served patients is projected to increase by varying amounts, and that statewide population is projected to increase by 10.2% between July 2020 and July 2030 (a CAGR of 1.1%). The applicant states that the counties from which DUH draws most heavily are among the fastest growing in the state and will contribute, along with the overall statewide increase in population, to demand for specialized services at DUH.

- The applicant states that Duke's medical staff and referral network have grown by almost 3% during the past year. The applicant states its physicians with admitting privileges rely on access to surgical services at DUH and that the Private Diagnostic Clinic (PDC), the practice for Duke's School of Medicine faculty, is implementing a recruitment plan to grow further.

However, the information is not reasonable or adequately supported for the following reasons:

- In Section C, pages 32-34, Duke states the need for 68 acute care beds in the Durham/Caswell multicounty service area was generated entirely by DUH. However, anyone may apply to meet the need, not just Duke. Duke has the burden of demonstrating the need for the proposed acute care beds in its application as submitted.

  In early 2022, Duke submitted a spring petition to the State Health Coordinating Council (SHCC) proposing to eliminate neonatal intensive care unit (NICU) beds (Levels II-IV) and days of care from the planning inventory and need methodology calculations of acute care beds. The petition was widely supported, including by UNC, who submitted comments in support of the petition. Duke stated that NICU beds are so unlike every other kind of acute care bed that it is impossible to treat them as interchangeable with other acute care bed inventory, because of the specialized equipment and spaces needed to support NICU patients. The Agency evaluated the petition and recommended the removal of the NICU beds and acute care days from the acute care bed planning inventory and need methodology calculations. The Agency's recommendation was accepted by the Acute Care Services Committee at its meeting on April 12, 2022 and accepted by the entire SHCC at its meeting on June 1, 2022.

  In the Agency Report evaluating the impact of removing NICU beds and days of care from the acute care bed planning inventory and need methodology calculations, analysis of the data showed there would be no new need determinations in the 2022 SMFP as a result of the proposed change. The data also showed that while two service areas would have a slight increase in the number of beds in the need determination in the 2022 SMFP, four other service areas would have declines in the number of beds in the need determination in the 2022 SMFP. On page 4 of the Agency Report, it states:

  > *"In sum, in particular service areas, NICU beds accounted for a large portion of the bed need, suggesting that the actual need for new general acute care beds was not as high as the need determination indicated."*

  On page 5 of the Agency Report, a table displays the changes in need determinations in the 2022 SMFP that would have occurred if the proposed elimination of NICU beds and days of care from the acute care bed need methodology had been in effect. The table is reproduced in part below.

Acute Care Bed Need Determinations, 2022 SMFP			
Service Area	**With NICUs**	**Without NICUs**	**Change**
Buncombe/Graham/Madison/Yancey	67	75	8
Cumberland	29	43	14
Durham/Caswell	***68***	***28***	***-40***
Mecklenburg	65	26	-39
Pitt	43	28	-15
Wake	45	44	-1
Total	**317**	**244**	**-73**

As shown in the table above, with the NICU beds and days of care removed from the planning inventory and need methodology calculations, the Durham/Caswell multicounty service area would have had the largest reduction out of all acute care bed need determinations in the state and would have had a need determination of 28 beds – less than half of the current need determination the applicant states demonstrates the need for the proposed project.

The applicant is not proposing to add new NICU beds to their inventory as part of the proposed project. The applicant submitted the petition in late February or early March of 2022, at least a month prior to the submission date of this application which suggests there was overlap in the time developing the petition and this application. The data and methodology Duke used in its application does not take into account its own facts and data as presented in its petition. The application as submitted does not address why the applicant needs 68 non-NICU acute care beds when the applicant's own historical data shows more than half of that need determination is due to NICU utilization.

- In July 2021, Duke submitted a summer petition to the SHCC proposing to eliminate or defer the need determination for acute care beds in the Durham/Caswell multicounty service area and to adjust the Wake County need determination that appeared in the Proposed 2022 SMFP. Duke stated that because there were so many acute care bed need determinations in Durham County over the past five years, and because a significant number of those beds had been brought online in June 2021, it proposed to eliminate or defer the need determination in the Durham/Caswell multicounty service area until the utilization patterns of the newly licensed acute care beds could be determined. Duke stated this was consistent with other approved petitions for adjustments to bed needs submitted in the past.

  On page 4 of the petition, Duke stated:

  > *"…in Durham County, there are already significant number* [sic] *of beds under development or review.* ***Further adding to the inventory may lead to the unnecessary duplication of existing and approved services, at least until the effects of the additional capacity are known.****"* (emphasis added)

While the petition seems at times to tie the reduction of the acute care bed need determination in the Durham/Caswell multicounty service area to the adjusted need determination proposed for Wake County in the same petition, need determinations in separate acute care bed service areas are calculated independently of any other acute care bed service areas. Duke does not state the proposed elimination or deferral of the need determination in Durham County is contingent upon an adjusted need determination for more acute care beds in Wake County; rather, it states the beds are not needed or should be deferred.

On page 6 of the petition, Duke stated:

> *"Given the large number of beds already under development or review in Durham County, eliminating the need in Durham County is consistent with ensuring appropriate utilization of existing and approved assets as well as those under review."*

On pages 3-4 of the Agency Report in response to the Duke petition, the Agency stated that Duke had not shown in its petition how an adjustment of the need determination in Wake County would be the most effective alternative to the actual need determination for Wake County.

With regard to the Durham/Caswell multicounty service area, on page 4 of the Agency Report, the Agency stated:

> *"Historically, the Agency has recommended removal of an acute care bed need determination when the actual conditions in a service area are not adequately reflected in a component of the methodology, thereby causing a need determination. The Petitioner does not present evidence that this has occurred in the Durham/Caswell service area for the 2022 SMFP cycle."*
>
> *…*
>
> *…the Agency emphasizes that the Durham/Caswell service area's need determination is an appropriate projection of bed need because it is based on the service area's total planning inventory and a GRM* [Growth Rate Multiplier] *that accounts for any growth in actual bed utilization. Finally, while the utilization by Duke Health System hospitals created the need in the service area, another entity in the service area is eligible to apply for the beds."*

On September 14, 2021, the Acute Care Services Committee voted to accept the Agency's recommendation and rejected the petition for an adjusted need determination in Wake County and elimination of the need determination in Durham County. The SHCC accepted the Committee's recommendations at its September 29, 2021 meeting.

However, less than a year after Duke submitted the petition to the SHCC, before all of its approved beds were brought online and in use, and despite its stated need to eliminate or defer the 2022 need determination for acute care beds, Duke filed this application to develop 68 new acute care beds. Comments received during the public comment period pointed out Duke's 2021 petition to remove the acute care bed need determination for the Durham/Caswell multicounty service area.

Duke did not explain in its application as submitted what circumstances changed between July 2021, when Duke stated its concern that the need determination of 68 acute care beds in the Durham/Caswell multicounty service area would potentially be an unnecessary duplication, and when Duke submitted the current application. Further, Duke provided no response to comments submitted during the public comment period that pointed out the discrepancy in Duke's positions.

Projected Utilization – On Forms C.1a and C.1b in Section Q, the applicant provides historical and projected utilization, as illustrated in the following table.

DUH Historical & Projected Utilization – Acute Care Beds				
	SFY 2021	**FY 1 (SFY 2024)**	**FY 2 (SFY 2025)**	**FY 3 (SFY 2026)**
# of Beds	960	1,130	1,130	1,130
# of Discharges	40,906	44,254	44,917	45,591
# of Patient Days	311,279	333,559	338,558	343,639
ALOS*	7.61	7.54	7.54	7.54
Occupancy Rate	88.8%	80.9%	82.1%	83.3%

*ALOS = Average Length of Stay

In the Form C.1 Assumptions subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for DUH, which are summarized below.

- The applicant discussed the impact of the COVID-19 pandemic on historical data. Specifically, the applicant discussed the decline in discharges in SFYs 2020 and 2021 compared to prior years. The applicant states this was due to reductions in elective surgeries and other procedures, restrictions in place at DUH, patient reluctance to seek non-emergency healthcare, and decreases in ED admissions due to injuries to children involved in sports and other activities.

- The applicant states that despite the reduction in discharges, there has been a significant increase in days of care during SFYs 2020 and 2021 due to longer average length of stay (ALOS).

- The data for SFY 2022 annualized is based on the first six months of utilization for SFY 2022 (July 2021 through December 2021).

- The applicant projected a 1.5% annual growth rate in adult patient discharges beginning in SFY 2023. The applicant assumed the ALOS would be 7.25 days, which is an average of the ALOS from SFYs 2021 and 2022 annualized.

- The applicant projected a 1.5% annual growth rate in pediatric patient discharges (excluding neonatal) beginning in SFY 2023. The applicant assumed the ALOS would remain consistent at the SFY 2022 annualized level of 6.50 days.

- The applicant projected a 10% increase in NICU discharges between SFY 2022 annualized and SFY 2023. The applicant states it has 14 approved NICU beds that will begin serving patients in SFY 2023 and because of the increased capacity, there will be a temporary large increase in discharges. The applicant projects growth for NICU discharges at 1.5% per year after SFY 2023. The applicant assumed the ALOS would be 30 days, which is an approximate average of the ALOS for SFY 2021 and SFY 2022 annualized.

- The applicant states that its projections are reasonable and conservative because of the need previously discussed, historical growth trends where days of care increased by more than 1.5% each year, and the anticipated increases in volume that DUH will be able to serve with increased capacity.

The applicant's assumptions, methodology, and projected utilization of acute care beds at DUH during the first three full fiscal years following project completion are summarized in the table below.

DUH Projected Utilization						
	SFY 2021	**SFY 2022***	**SFY 2023**	**SFY 2024**	**SFY 2025**	**SFY 2026**
Adult Discharges	36,021	36,130	36,672	37,222	37,780	38,347
Adult ALOS	7.13	7.37	7.25	7.25	7.25	7.25
Adult Days of Care	256,841	266,186	265,872	269,860	273,905	278,016
Pediatric Discharges	5,419	6,082	6,173	6,266	6,360	6,455
Pediatric ALOS	6.32	6.50	6.50	6.50	6.50	6.50
Pediatric Days of Care	34,222	39,526	40,119	40,721	41,331	41,951
Neonatal Discharges	717	686	755	766	777	789
Neonatal ALOS	31.62	29.04	30.00	30.00	30.00	30.00
Neonatal Days of Care	22,675	19,924	22,638	22,978	23,322	23,672
Total Discharges	40,906	42,898	43,600	44,254	44,917	45,591
Total ALOS	7.53	7.59	7.54	7.54	7.54	7.54
Total Days of Care	311,279	325,636	328,629	333,559	338,558	343,639
ADC**	853	892	900	914	928	941
Total Licensed Beds	960	1,048	1,062	1,130	1,130	1,130
Utilization	88.9%	85.1%	84.7%	80.9%	82.1%	83.3%

*SFY 2022 is annualized based on July-December 2021 data.
**Average Daily Census = Number of days of care / 365 days per year

Duke University Health System

The Duke System for acute care beds in the Durham/Caswell multicounty service area consists of DUH and DRH. Pursuant to 10A NCAC 14C .3803(a), an applicant proposing to add new acute care beds to a service area must reasonably project that all acute care beds in the service area under common ownership will have a utilization of at least 75.2 percent when the projected Average Daily Census (ADC) is greater than 200 patients in the third operating year following completion of the proposed project.

However, pursuant to G.S. 131E-183(b):

> *"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."*

In Appendix F on page 423 of the 2022 SMFP, DUH is defined as an academic medical center teaching hospital. Therefore, projected utilization at DRH is not included as part of determining whether DUH meets the performance standard promulgated under 10A NCAC 14C .3803(a).

As shown in the table above, in the third full fiscal year following project completion, the applicant projects the utilization for all acute care beds at DUH will be 83.3%. This meets the performance standard promulgated in 10A NCAC 14C .3803(a), which requires an applicant proposing to add new acute care beds to a service area to reasonably project that all acute care beds in the service area under common ownership will have a utilization of at least 75.2% when the projected ADC is greater than 200 patients.

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

- The applicant projects discharges at DUH based on a projected growth rate that is not reasonable and adequately supported.

  The applicant projects adult and pediatric discharges will increase at a rate of 1.5% each year, and that after an initial increase of 10% in one year, neonatal discharges will increase by 1.5% per year. The applicant states its projections are reasonable because of the historical growth rate of acute care days along with the factors it identified as supporting the need for the proposed project. However, the applicant does not explain in the application as submitted what, if any, correlation exists between an increase in acute care days and an increase in discharges. In Section C, page 34, the applicant states that acute care days between SFY 2016 and SFY 2021 increased by a total of 14% and had a CAGR of 2.6%. However, based on the

applicant's License Renewal Applications (LRAs), discharges between SFY 2016 and SFY 2021 decreased by a total of -0.2% and by a CAGR of -0.03%. The applicant does not provide a reasonable basis in the application as submitted for applying a 1.5% growth rate to any of the categories of discharges when its historical growth rate for discharges was essentially flat.

- Duke uses an ALOS which is not reasonable or adequately supported in its utilization projections.

  In the Form C.1 Assumptions subsection of Section Q, the applicant states:

  > *"…, FY 2021 inpatient days of care reflect a significant increase not only over FY 2020 but also over previous years due to longer average length of stay."*

  In Section C, page 34, Duke provides historical information about days of care, discharges, and ALOS, consistent with the information found on its historical LRAs submitted to the Agency. Information about DUH and historical utilization is shown in the table below.

DUH Historical Utilization – Acute Care Days, Discharges, & ALOS

	SFY 2016	SFY 2017	SFY 2018	SFY 2019	SFY 2020	SFY 2021
Acute Care Days	273,758	284,052	292,286	303,409	296,466	311,279
Discharges	40,975	42,083	42,469	43,055	40,715	40,906
ALOS (in days)	6.68	6.75	6.88	6.98	7.24	7.61

Source: Section C, page 34; Agency records

Between SFY 2016 and SFY 2019, the ALOS for DUH increased by 0.3 days, a total increase of 4.5% and a CAGR of 1.5%. Between SFY 2019 and SFY 2020, the ALOS for DUH increased by 0.26 days, a 3.7% increase in a single year and more than double the CAGR for the previous four SFYs. Between SFY 2020 and SFY 2021, the ALOS for DUH increased by 0.37 days, a 5.1% increase in a single year and more than the entire cumulative increase in ALOS between SFYs 2016 and 2019.

In its utilization projections, Duke assumes that adult inpatient ALOS will remain at an average of the ALOS for SFYs 2021 and 2022 annualized (based on July – December 2021 data) and assumes that pediatric inpatient ALOS will remain at the ALOS for SFY 2022. Duke does not provide any information in the application as submitted as to adequately support the ALOS' it uses. The applicant does not adequately address why the ALOS has increased more in the last two years compared to the historical ALOS or why use of the more recent ALOS (or an average ALOS of two recent years) is reasonable and adequately supported compared with historical utilization.

Comments submitted during the public comment period state that the ALOS used by Duke is artificially inflated due to the effects of COVID-19 and creates an unreasonably high number of acute care days. In its response to those comments, the applicant states:

> *"…, Duke University Hospital has experienced a higher ALOS in recent years, but DUHS did not identify that this increase was solely due to COVID-19. DUHS documented that even pre-COVID, its ALOS had increased significantly…, reflecting ongoing evolution in care, such as the shift of some surgical procedures from requiring short inpatient stays to outpatient encounters."*

However, as quoted above from the Form C.1 Assumptions subsection of Section Q, Duke discusses the impact of COVID-19 on both its discharges and its ALOS for SFY 2020 and SFY 2021. Moreover, the ALOS used by Duke in its utilization projections is far higher than the historical "significant increase" in ALOS prior to COVID-19.

Moreover, while Duke states that it did not identify that COVID-19 was the "sole" reason for the increase in acute care days, statewide data provided to the Agency indicates that hospitals statewide are reporting a much higher ALOS than would be expected normally. The written summary of recommendations of the Acute Care Services Committee to the SHCC published on June 1, 2022, states:

> *"…, the Committee addressed continuing effects of the COVID-19 pandemic on bed need. Initial calculations showed that the state had a need for 1,481 additional beds. This number is about three to four times more than in a typical year. Analysis showed that the large number of needs was partly due to the fact that the overall average length of stay increased by about 20-25% from 2020 to 2021. This increase is unprecedented, but not expected to be permanent. Rather, it is most likely related to the lengthier stays of COVID patients."*

The recommendation of the Acute Care Services Committee was to offset this seemingly artificial increase for the 2023 SMFP by using county growth rate multipliers from the 2021 SMFP, reflecting pre-pandemic years. The SHCC accepted that recommendation at the June 1, 2022 meeting.

While Duke is not required to provide utilization projections that are consistent with historical utilization, Duke does not demonstrate that the utilization projections it provides are reasonable and adequately supported.

Access to Medically Underserved Groups – In Section C, page 43, the applicant describes how it will provide access to medically underserved groups. On page 43, the applicant states:

> *"All individuals including low income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients and other underserved groups, will have access to DUH, as clinically appropriate. DUHS does not discriminate on the basis of race, ethnicity, age, gender, or disability. Policies to provide access to services by low income, medically indigent, uninsured, or underinsured patients are described and provided in Exhibit C.6. As set forth in the pro formas, a significant proportion of DUH's proposed services will be provided to Medicare, Medicaid, and uninsured patients."*

On page 43, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	% of Total Patients
Low-income persons	18%
Racial and ethnic minorities	39%
Women	59%
Persons aged 65 and older	34%
Medicare beneficiaries	38%
Medicaid recipients	12%

In Section C, page 43, the applicant states that "low-income persons" is not defined and estimates the percentage based on projected Medicaid beneficiaries and charity or reduced cost recipients. The applicant also states it does not keep data on persons with disabilities but emphasizes that disabled people have not and will not be denied access to care.

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 based on the following:

- The applicant provides its Notice of Nondiscrimination in Exhibit C.6 and its financial assistance policies in Exhibit L.4.

- The applicant provides a statement clearly stating that all residents of the service area, including underserved groups, are not discriminated against or turned away from the proposed services based on belonging to an underserved group.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

The applicant was part of a competitive review for acute care beds and operating rooms (ORs) in the Durham/Caswell multicounty service area based on need determinations in the 2021 SMFP. The applicant proposed to develop a new hospital with 40 acute care beds and 2 ORs. The Agency issued a decision in that competitive review on September 21, 2021, approving the applicant's proposal to develop a new hospital with 40 acute care beds and 2 ORs. That decision was appealed. As of the date of these findings, that decision is still under appeal, and a CON has not been issued.

The applicant assumes the Agency's decision will be upheld and proposes a change of scope to its previously approved project. The applicant proposes to develop 34 acute care beds pursuant to the need determination in the 2022 SMFP. If the Agency decision is upheld in the appeal of the original application to develop UNC Hospitals-RTP, the facility will have 74 acute care beds upon completion of that project and the project under review.

UNC also proposes to add two additional labor and delivery room (LDR) beds, two additional procedure rooms, ten additional observation beds, eight additional emergency department (ED) bays, one additional CT scanner, and one additional ultrasound unit. The applicant proposes to more than double the original square footage of the facility as part of this proposed project.

Patient Origin – On page 33, the 2022 SMFP defines the service area for acute care beds as *"... the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on page 38, shows Durham and Caswell counties in a multicounty grouping. Thus, the service area for these facilities is the Durham/Caswell multicounty service area. Facilities may also serve residents of counties not included in their service area.

UNC Hospitals-RTP is not an existing facility and thus has no historical patient origin to report. The table below shows the projected patient origin for the entire facility. UNC's fiscal year is July 1 – June 30, which is also the North Carolina SFY.

Projected Patient Origin – UNC Hospitals-RTP – Entire Facility						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	192,416	85.0%	267,223	85.0%	306,385	85.0%
Wake	31,239	13.8%	43,384	13.8%	49,742	13.8%
Chatham	2,037	0.9%	2,829	0.9%	3,244	0.9%
Caswell	679	0.3%	943	0.3%	1,081	0.3%
Total	**226,371**	**100.0%**	**314,379**	**100.0%**	**360,452**	**100.0%**

Source: Section C, page 69

The following tables illustrate projected patient origin for the proposed project's stated service components.

Projected Patient Origin – UNC Hospitals-RTP – Acute Care Discharges						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	2,084	85.0%	2,877	85.0%	3,279	85.0%
Wake	338	13.8%	467	13.8%	532	13.8%
Chatham	22	0.9%	30	0.9%	35	0.9%
Caswell	7	0.3%	10	0.3%	12	0.3%
Total	**2,451**	**100.0%**	**3,384**	**100.0%**	**3,858**	**100.0%**

Source: Section C, page 67

Projected Patient Origin – UNC Hospitals-RTP – Outpatient Surgical Services						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	1,649	85.0%	2,356	85.0%	2,776	85.0%
Wake	268	13.8%	382	13.8%	450	13.8%
Chatham	17	0.9%	25	0.9%	29	0.9%
Caswell	6	0.3%	8	0.3%	10	0.3%
Total	**1,940**	**100.0%**	**2,771**	**100.0%**	**3,265**	**100.0%**

Source: Section C, page 67

Projected Patient Origin – UNC Hospitals-RTP – Emergency Department						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	9,131	85.0%	12,608	85.0%	14,372	85.0%
Wake	1,483	13.8%	2,047	13.8%	2,333	13.8%
Chatham	97	0.9%	133	0.9%	152	0.9%
Caswell	32	0.3%	44	0.3%	51	0.3%
Total	**10,743**	**100.0%**	**14,832**	**100.0%**	**16,908**	**100.0%**

Source: Section C, page 67

Projected Patient Origin – UNC Hospitals-RTP – Imaging						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	22,996	85.0%	31,938	85.0%	36,622	85.0%
Wake	3,733	13.8%	5,185	13.8%	5,946	13.8%
Chatham	243	0.9%	338	0.9%	388	0.9%
Caswell	81	0.3%	113	0.3%	129	0.3%
Total	**27,053**	**100.0%**	**37,574**	**100.0%**	**43,085**	**100.0%**

Source: Section C, page 68

Projected Patient Origin – UNC Hospitals-RTP – Therapy						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	28,086	85.0%	39,008	85.0%	44,729	85.0%
Wake	4,560	13.8%	6,333	13.8%	7,262	13.8%
Chatham	297	0.9%	413	0.9%	474	0.9%
Caswell	99	0.3%	138	0.3%	158	0.3%
Total	**33,042**	**100.0%**	**45,892**	**100.0%**	**52,623**	**100.0%**

Source: Section C, page 68

Projected Patient Origin – UNC Hospitals-RTP – Lab						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	128,471	85.0%	178,436	85.0%	204,607	85.0%
Wake	20,858	13.8%	28,970	13.8%	33,218	13.8%
Chatham	1,360	0.9%	1,889	0.9%	2,166	0.9%
Caswell	453	0.3%	630	0.3%	722	0.3%
Total	**151,142**	**100.0%**	**209,925**	**100.0%**	**240,713**	**100.0%**

Source: Section C, page 68

In Section C, page 69, the applicant provides the assumptions and methodology used to project patient origin. The applicant states projected patient origin assumes 85% of patients will originate from Durham County and 15% of patients will originate from surrounding counties. The applicant provides an explanation of the Durham County service area by ZIP code in the Form C Utilization – Assumptions and Methodology subsection of Section Q. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant states it did not significantly adjust its patient origin from the previously approved application because the types of services it will offer are the same, even if there will be more capacity for those services.

- The applicant's projected patient origin is similar to the patient origin it projected in Project ID #J-12065-21, which was found to be reasonable and adequately supported, and nothing in the current application as submitted would affect that determination.

Analysis of Need – In Section C, pages 52-65, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states many of the same conditions documented by the applicant in Project ID #J-12065-21 are still relevant in this review:
  - the projected population increase in Durham County overall;
  - the projected population increase in southern Durham County, where UNC Hospitals-RTP will be located; and
  - more than half of the population of Durham County is concentrated in southern Durham County.

- The applicant states acute care days in Durham County hospitals grew at a CAGR of 2.7% between CY 2017 and CY 2019. The applicant explains its choice to exclude utilization data from CY 2020 and the first half of CY 2021 and describes the analysis it used in determining to exclude that data.

- The applicant states there is a greater need for "basic community (non-tertiary) services," which it defines as low acuity services needed in high frequencies by a significant portion of the population. The applicant states that, based on its analysis of "basic community (non-tertiary) services" using data from IBM Watson Health, acute care days for "basic community (non-tertiary) services" at Durham County hospitals grew at a CAGR of 3.7% between CY 2017 and CY 2019, compared with growth of higher acuity acute care days at a CAGR of 1.2%. The applicant states that at both DRH and DUH, "basic community (non-tertiary) services" grew at a higher rate than other services.

- The applicant states that, based on its analysis of data from IBM Watson Health, Durham County residents from the southern part of Durham County had higher utilization rates for "basic community (non-tertiary) services" than the central/west and northern parts of Durham County. The applicant further states that when comparing data for all Durham County residents served at any hospital – not just Durham County hospitals – utilization of "basic community (non-tertiary) services" grew at a CAGR of 3.4% between CY 2017 and CY 2019, while utilization of higher acuity services by Durham County residents at any hospital decreased by a CAGR of 1.0% between CY 2017 and CY 2019.

- The applicant states that despite not having an existing hospital in Durham County, its hospitals in Wake and Orange counties served more Durham County residents than any other hospital system except Duke. The applicant states that utilization of "basic community (non-tertiary) services" by Durham County residents at UNC hospitals in Orange and Wake counties increased at a CAGR of 2.9% between CY 2017 and CY 2019, and that in each of those three years, utilization by residents of the southern part of Durham County exceeded utilization by residents of both the central/west and northern areas of Durham County.

- The applicant states that it proposes to add additional services such as ED treatment bays, procedure rooms, imaging equipment, and other ancillary and support services to accommodate the projected increase in patients it will serve with more acute care beds.

The information is reasonable and adequately supported for the following reasons:

- The applicant uses data collected by IBM Watson Health to analyze utilization patterns.

- The applicant provides reasonable explanations and thorough analysis of why it chose to use CY 2017 to CY 2019 for historical utilization patterns.

- The applicant uses assumptions consistent with those it used in Project ID #J-12065-21, which the Agency found to be reasonable and adequately supported, and there are no changes to the specific conditions in the proposed service area or in the application as submitted which would affect that determination.

Projected Utilization – On Forms C.1b-4b in Section Q, the applicant provides projected utilization as illustrated in the following tables.

UNC Hospitals-RTP Projected Utilization Acute Care Services			
	FY 1 – SFY 2030	**FY 2 – SFY 2031**	**FY 3 – SFY 2032**
Acute Care Beds			
# of Beds	74	74	74
# of Patient Days	11,847	16,455	18,869
# of Discharges	2,451	3,384	3,858
ALOS	4.8	4.9	4.9
Occupancy Rate	43.9%	60.9%	69.9%
CT Scanner			
# of Units	2	2	2
# of Scans	7,646	10,620	12,177
# of HECT Units	12,708	17,651	20,240
Fixed X-ray (including fluoroscopy)			
# of Units	3	3	3
# of Procedures	11,903	16,532	18,957
Mammography			
# of Units	1	1	1
# of Procedures	3,006	4,175	4,787
Nuclear Medicine			
# of Units	1	1	1
# of Procedures	360	500	574
Ultrasound			
# of Units	3	3	3
# of Procedures	4,138	5,747	6,590
Emergency Department			
# of Bays (Rooms)	20	20	20
# of Visits	10,743	14,832	16,908
Observation Beds			
# of Beds	20	20	20
Days of Care	1,230	1,709	1,959
Laboratory			
# of Tests	151,142	209,925	240,713
Therapy			
PT Treatments	18,271	25,377	29,099
ST Treatments	1,641	2,279	2,613
OT Treatments	13,130	18,236	20,910

NOTE: Totals may not sum due to rounding.

UNC Hospitals-RTP Projected Operating Room and Procedure Room Services			
	FY 1 – SFY 2030	**FY 2 – SFY 2031**	**FY 3 – SFY 2032**
ORs - # of Rooms by Type			
# of Dedicated C-Section ORs	2	2	2
# of Shared ORs	2	2	2
Total ORs	4	4	4
# of Excluded ORs	2	2	2
Adjusted Planning Inventory	2	2	2
Surgical Cases			
# of Inpatient Cases (excludes C-Section)	867	1,238	1,459
# of Outpatient Cases	1,317	1,034	689
Total # Surgical Cases	2,184	2,273	2,148
Case Times (Section C, Question 5(c))			
Inpatient	113.7	113.7	113.7
Outpatient	72.7	72.7	72.7
Surgical Hours			
Inpatient	1,643	2,347	2,765
Outpatient	1,596	1,253	835
Total Surgical Hours	3,239	3,600	3,600
# of ORs Needed			
Group Assignment	4	4	4
Standard Hours per OR per Year	1,500	1,500	1,500
ORs Needed*	2.2	2.4	2.4
Procedure Rooms			
Rooms	4	4	4
Procedures	623	1,737	2,576

NOTE: Totals may not sum due to rounding
* ORs Needed = Total Surgical Hours / Standard Hours per OR per Year

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

Acute Care Services

- The applicant obtained days of care for Durham County residents from IBM Watson Health for CY 2017 through CY 2019 and calculated a CAGR of 2.1% for medicine, 6.4% for surgery, -3.8% for obstetrics, and 1.9% for total days of care. (page 3)

- The applicant states that certain higher acuity services will not be provided at UNC Hospitals-RTP and reduced the number of acute care days provided to Durham County residents based on the excluded higher acuity services. (page 4)

- The applicant calculated potential days of care for Durham County residents between CY 2017 and CY 2019 after excluding the higher acuity services and

calculated a CAGR of 2.9% for medicine, 7.1% for surgery, -0.9% for obstetrics, and 3.4% for total days of care. (page 4)

- The applicant assumes the identified potential days of care will grow through 2032 at a rate equal to the CY 2017 through CY 2019 CAGR for each service. The table below shows the projected potential days of care for Durham County residents during CYs 2029 through 2032. (pages 4-5)

Durham County Resident Potential Days of Care CYs 2029-2032				
	CY 2029	CY 2030	CY 2031	CY 2032
Medicine	72,920	75,031	77,203	79,438
Surgery	44,144	47,288	50,655	54,263
Obstetrics	10,486	10,387	10,289	10,191
Total Days	**127,550**	**132,706**	**138,147**	**143,892**

- The applicant converted calendar years to the hospital's fiscal year (SFY 2030 = 0.5 * CY 2029 + 0.5 * CY 2030), resulting in the following potential days of care for Durham County residents. (pages 5-6)

Durham County Resident Potential Days of Care SFYs 2030-2032			
	SFY 2030	SFY 2031	SFY 2032
Medicine	73,976	76,117	78,321
Surgery	45,716	48,971	52,459
Obstetrics	10,436	10,338	10,240
Total Days	**130,128**	**135,426**	**141,020**

- The applicant used the same historical market share analysis as in Project ID #J-12065-21. The percentages it calculated represented UNC's average market share of Durham County residents between CY 2017 and CY 2019. The applicant calculated an average of 8.5% of medicine patients, 12.1% of surgery patients, and 15.6% of obstetrics patients. These percentages reflect UNC Health's market share of Durham County residents in facilities outside of Durham County. (pages 6-7)

- The applicant states that because the project will take three years longer to develop than the previously approved project, and have nearly double the amount of beds as the previously approved project, it now projects it will serve 110% of its historical market share. The applicant states that the additional time to develop the proposed project will also give it more time to broaden its patient base and further support its projected market share. (page 7)

- The applicant states it projects utilization will ramp up over the first three full fiscal years of operation, with 75% of historical market share utilization in its first fiscal year, 100% of historical market share utilization its second fiscal year, and 110% of historical market share utilization in its third fiscal year. The applicant states that while it projects a 10% increase from its previous market share, the actual increase

in the overall market share will be minimal. The increase in percentage of market share is shown below. (page 7)

UNC Hospitals-RTP Market Share of Durham County Potential Days of Care				
	SFY 2030 (75%)	SFY 2031 (100%)	SFY 2032 (110%)	CYs 2017-2019 Avg
Medicine	6.3%	8.5%	9.3%	8.5%
Surgery	9.1%	12.1%	13.3%	12.1%
Obstetrics	11.7%	15.6%	17.2%	15.6%

- The applicant applied the percentages above to the projected potential days of care for Durham County residents to calculate projected utilization, as shown in the table below. (pages 7-8)

UNC Hospitals-RTP Projected Acute Care Days – Durham County Residents			
	SFY 2030	SFY 2031	SFY 2032
Medicine	4,697	6,444	7,294
Surgery	4,149	5,926	6,983
Obstetrics	1,224	1,617	1,762
Total Days	**10,070**	**13,987**	**16,038**
ADC	**27.6**	**38.3**	**43.9**

- The applicant then projected in-migration. The applicant states that it examined the in-migration of all 116 North Carolina acute care hospitals (Exhibit C.5-2) to determine a reasonable and appropriate in-migration rate for the proposed facility. The applicant states that while it used an in-migration projection of 10% in Project ID #J-12065-21, based on the additional time it will take to develop and the higher number of beds, it projects in-migration will be 15%. The applicant states that out of all 116 acute care hospitals in North Carolina, only 15 had in-migration rates of 15% or less. The applicant applied an assumed 15% in-migration rate to its previous utilization projections. (pages 9-10)

- The applicant based its projected discharges on its projected days of care, including the in-migration, and the CY 2019 ALOS for Durham County residents at UNC hospitals. (page 10)

The applicant's projected utilization calculations are summarized in the table below.

UNC Hospitals-RTP Projected Utilization – Acute Care Beds			
	SFY 2030	SFY 2031	SFY 2032
Medicine	4,697	6,444	7,294
Surgery	4,149	5,926	6,983
Obstetrics	1,224	1,617	1,762
Total Durham County Days	10,070	13,987	16,038
In-migration (15%)	1,777	2,468	2,830
Total Acute Care Days	11,847	16,455	18,869
ADC	32.5	45.1	51.7
Total Acute Care Beds	74	74	74
Occupancy Rate	43.9%	60.9	69.9%
Total Discharges	2,451	3,384	3,858

UNC does not currently have any acute care beds in the Durham/Caswell multicounty service area. Pursuant to 10A NCAC 14C .3803(a), an applicant proposing to add new acute care beds to a service area must reasonably project that all acute care beds in the service area under common ownership will have a utilization of at least 66.7 percent when the projected Average Daily Census (ADC) is fewer than 100 patients in the third operating year following completion of the proposed project.

As shown in the table above, in the third full fiscal year following project completion, the applicant projects the utilization for all acute care beds at UNC Hospitals-RTP will be 69.9%. This meets the performance standard promulgated in 10A NCAC 14C .3803(a), which requires an applicant proposing to add new acute care beds to a service area to reasonably project that all acute care beds in the service area under common ownership will have a utilization of at least 66.7% when the projected ADC is fewer than 100 patients.

The applicant states that it projects to serve a portion of the projected growth in acute care days for Durham County residents. The applicant states that, based on the historical growth rate of acute care days for the selected services it proposes to offer, there will be 143,892 potential days of care during CY 2032 for Durham County residents receiving the selected services proposed by the applicant – an increase of 55,358 days of care over CY 2019. The applicant states that since it proposes to serve only a portion of the projected growth in days of care for Durham County residents, it does not expect the development of UNC Hospitals-RTP to impact other hospitals that serve residents of Durham County, because those hospitals are expected to serve the same number of patients or more than they currently do. The applicant also notes that UNC Hospitals-RTP does not project to serve higher acuity patients and growth in those days of care are not included in the applicant's analysis of projected utilization. (pages 11-12)

Surgical Services

- The applicant proposes to develop two procedure rooms as part of the proposed project for a total of four approved and proposed procedure rooms but is not

applying to increase the number of ORs at UNC Hospitals-RTP. However, the applicant updated its projected OR utilization based on its updated projections for acute care days and the shift in the first three full fiscal years, and relies on the updated surgical cases to project procedure room utilization. Thus, the applicant's updated OR utilization is included in the discussion of projected utilization for procedure rooms. (pages 20-21)

- Consistent with Project ID #J-12065-21, the applicant used the FFY 2019 experience at UNC Hillsborough and assumed a ratio of 1.5 outpatient surgical cases to inpatient surgical cases and a ratio of 0.29 procedure room procedures to OR surgical cases. (pages 21-22)

- The applicant used the 2022 SMFP Group 4 inpatient and outpatient case times to project surgical hours through the third full fiscal year following project completion. (pages 22-23)

- The applicant assumed it would operate both approved ORs at 90% of capacity, or 1,800 hours per OR per year, that all inpatient surgical cases would be performed in one of the two approved ORs, and that any outpatient surgical cases that could not be performed in one of the ORs operating at 90% of capacity would be performed in a procedure room (which would be built to OR standards). (pages 23-26)

The applicant's OR and procedure room utilization assumptions are summarized below.

UNC Hospitals-RTP Projected Utilization – Surgical Services			
	SFY 2030	**SFY 2031**	**SFY 2032**
Inpatient Surgical Cases	867	1,238	1,459
Inpatient Surgical Hours (113.7 minutes)	1,643	2,347	2,765
Outpatient Surgical Cases (Inpatient * 1.5)	1,317	1,881	2,217
Outpatient Surgical Hours (72.7 minutes)	1,596	2,279	2,686
Total Surgical Cases (Inpatient & Outpatient)	**2,184**	**3,120**	**3,676**
Total Surgical Hours	**3,239**	**4,626**	**5,451**
ORs Needed (Group 4, 1,500 hours)	2.2	3.1	3.6
Available Surgical Hours (at 90% capacity)	3,600	3,600	3,600
Inpatient Surgical Hours	1,643	2,347	2,765
Remaining Surgical Hours for Outpatient Cases	1,957	1,253	835
Outpatient Surgical Cases in ORs (72.7 minutes)	1,317	1,034	689
Remaining Outpatient Surgical Cases in Procedure Rooms	0	847	1,528
Total Surgical Cases (Inpatient & Outpatient)	2,184	3,120	3,676
Procedure Room Procedures (0.29 ratio)	623	890	1,048
Total Outpatient Surgical Cases/Procedures in Procedure Rooms	623	1,737	2,576

The applicant states that it needs four procedure rooms due to the projected utilization of the ORs (and resulting need to perform outpatient cases in procedure rooms) and

because of the efficiencies involved in turning around procedure rooms typically used for shorter cases with faster turnaround times. (pages 26-27)

LDR and C-Section Rooms

The applicant is proposing to develop two unlicensed LDR beds in addition to the four unlicensed LDR beds approved in Project ID #J-12065-21 for a total of six unlicensed LDR beds. The applicant does not propose to develop any additional dedicated C-Section ORs and will have a total of two dedicated C-Section ORs (approved in Project ID #J-12065-21).

Consistent with its projections in Project ID #J-12065-21, the applicant used the same assumptions, based on IBM Watson Health data, that 90% of Durham County resident obstetrics acute care discharges in CY2019 resulted in a delivery and that 23.7% of those deliveries were via C-Section. The applicant's updated projections for obstetrics discharges, deliveries, and C-Sections are shown below. (page 27)

UNC Hospitals-RTP Projected Obstetrics Discharges, Deliveries, & C-Sections			
	SFY 2030	**SFY 2031**	**SFY 2032**
Obstetric Discharges	539	712	776
Deliveries	485	641	698
C-Sections	115	152	165

The applicant states it proposes to add two additional unlicensed LDR beds for a total of six unlicensed LDR beds to support the number of deliveries and discharges during SFY 2032.

Emergency Department

The applicant is proposing to add eight additional ED bays in addition to the 12 ED bays approved in Project ID #J-12065-21 for a total of 20 ED bays. Consistent with its projections in Project ID #J-12065-21, the applicant used the same assumptions, based on IBM Watson Health data, that 61.4% of Durham County resident acute care discharges in CY2019 were admitted through the ED and therefore 61.4% of UNC Hospitals-RTP's projected discharges would be admitted through the ED, and that 14% of ED visits for Durham County residents at all hospitals resulted in an admission and therefore 14% of UNC Hospitals-RTP's ED visits would result in an admission. (pages 12-14)

The applicant's projected ED visits and admissions are summarized in the table below.

UNC Hospitals-RTP Projected ED Utilization			
	FY 1 (SFY 2030)	FY 2 (SFY 2031)	FY 3 (SFY 2032)
Total Discharges	2,451	3,384	3,858
% Admitted from ED	61.4%	61.4%	61.4%
ED Admissions	1,505	2,078	2,369
ED Admissions as % of Visits	14.0%	14.0%	14.0%
ED Visits	10,743	14,832	16,908
Visits per ED Bay (20)	537	742	845

The applicant states its average visits per ED bay is slightly higher in the current application than in Project ID #J-12065-21, which it believes supports the need for the additional ED bays, and also states that the American College of Emergency Physicians guidelines state that a facility with 20,000 annual visits should have between 14-16 ED bays. The applicant states that having 20 ED bays will allow for continued growth before operational issues would require expansion.

The applicant further states that even assuming a slightly negative growth rate in ED visits, it would have a market share of approximately 13.9% of Durham County resident ED visits by its third full fiscal year, and that UNC facilities already served 9.5% of Durham County resident ED visits in CY 2019, without having any facilities in Durham County.

Imaging and Ancillary Services

- The applicant proposes to add one fixed CT scanner and one ultrasound unit in addition to the fixed CT scanner, two ultrasound units, and other imaging equipment approved in Project ID #J-12065-21.

- Consistent with its projections in Project ID #J-12065-21, the applicant assumed the ratio of procedures to acute care days at UNC Hillsborough during FFY 2019 would be the most appropriate assumption to project future imaging and ancillary procedures. Projected ratios and utilization of imaging and ancillary services is shown in the table below. (pages 15-18)

UNC Hospitals-RTP Projected Utilization – Imaging and Ancillary Services				
	Ratio to Days	FY 1 (SFY 2030)	FY 2 (SFY 2031)	FY 3 (SFY 2032)
Projected Acute Care Days		11,847	16,455	18,869
CT Scans	0.60	7,646	10,620	12,177
Ultrasound Procedures	0.30	4,138	5,747	6,590
X-ray Procedures	1.00	11,903	16,532	18,957
Nuclear Procedures	0.03	360	500	574
Mammography Procedures	0.30	3,006	4,175	4,787
Physical Therapy Units	1.50	18,271	25,377	29,099
Occupational Therapy Units	1.10	13,130	18,236	20,910
Speech Therapy Units	0.10	1,641	2,279	2,613
Lab Tests	12.80	151,142	209,925	240,713

- The applicant provides the calculations for CT HECT units using UNC Hillsborough's FFY 2019 ratio of HECT units to CT scans (1.66), as shown below. (page 18)

UNC Hospitals-RTP Projected CT Utilization			
	FY 1 (SFY 2030)	FY 2 (SFY 2031)	FY 3 (SFY 2032)
CT Scans	7,646	10,620	12,177
HECT Units per Scan	1.66	1.66	1.66
HECT Units	12,708	17,651	20,240
CT Scanners	2	2	2
HECT Units per CT Scanner	6,354	8,826	10,120

Observation Beds

The applicant proposes to add 10 unlicensed observation beds in addition to the 10 unlicensed observation beds approved in Project ID #J-12065-21 for a total of 20 unlicensed observation beds.

Consistent with its projections in Project ID #J-12065-21, the applicant assumed the ratio of observation days to acute care days at UNC Hillsborough during FFY 2019 (0.10) would be the most appropriate assumption to project future observation days. The applicant projects observation patient days of 1,230, 1,709, and 1,959 for SFY 2030, SFY 2031, and SFY 2032, respectively. (pages 19-20)

The applicant states that observation beds are also used for patients who need extra recovery time after procedures, for ED patients who need additional observation before determining if an inpatient admission is needed, or for ED patients waiting for test results during times of higher ED utilization. The applicant further states that developing the number of proposed observation beds will allow for future growth beyond the first three full fiscal years before utilization would require expansion.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant bases its projections for all services on historical IBM Watson Health data, historical experience at UNC Hillsborough, a satellite campus of UNC Hospitals in Orange County with 83 acute care beds, or the historical experience of Durham County residents at UNC facilities.

- The applicant provides examples of data from other similarly situated facilities around the state to support the reasonableness of its assumptions.

- The applicant limits the projected utilization to inpatients needing the services and having the appropriate acuity level based on the services it proposes to offer.

- The applicant relies on either a historical 2-year CAGR or CY 2019 data as a base point in projections, which is consistent with Project ID #J-12065-21. The Agency

found Project ID #J-12065-21 and its projected utilization reasonable and adequately supported and there is nothing in the application as submitted or in other public materials that suggests the same type of projections in this specific application would not be reasonable or adequately supported.

- The applicant explains in detail why it chose to rely on CY 2019 data and not more recent data in making its utilization projections.

- The applicant provides analysis to show that projected growth in Durham County acute care bed utilization would exceed its own projected utilization.

Access to Medically Underserved Groups – In Section C, page 70, the applicant states:

> *"Access by medically underserved groups will not be different from what was projected in the previously approved application in terms of the percentage of care provided to underserved groups. UNC Hospitals 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 the UNC Hospitals-RTP upon completion of the proposed change of scope project."*

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 based on the following:

- The applicant provides its policy on Assuring Access at UNC Health Care in Exhibit B.20-5, which states it does not exclude or otherwise discriminate against medically underserved groups.

- The applicant provides copies of its financial policies in Exhibit B.20-6.

- Project ID #J-12065-21 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

NA – Both Applications

Neither of the applicants propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

NC – Duke University Hospital
C – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

In Section E, pages 52-53, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states inpatient utilization increases combined with the current occupancy rate at DUH demonstrate that maintaining the status quo is not an effective option and it would face ongoing pressures to meet demand due to severe capacity constraints; therefore, maintaining the status quo was not an effective alternative.

- Develop Beds at a New Campus or Facility: the applicant states developing a new inpatient hospital would require extensive work, including site identification and preparation, utility and infrastructure construction, and numerous other challenges that would be costly and require lots of time. Additionally, the applicant states the services that are needed are the tertiary and quaternary care services that can't be

provided at another facility; therefore, developing beds at a new campus was not an effective alternative.

- Develop Beds at DRH: the applicant states there is more capacity at DRH than at DUH right now, so the more pressing need to develop new capacity is at DUH. The applicant also states DRH could not necessarily accommodate demand for DUH's tertiary and quaternary care; therefore, developing beds at DRH was not an effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant did not adequately demonstrate the need it has for the proposed project or that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference. A proposal that is not needed by the population proposed to be served cannot be the most effective alternative.

- The applicant did not demonstrate in the application as submitted that it was conforming with the Criteria and Standards for Acute Care Beds promulgated in 10A NCAC 14C .3803(a). The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference. A proposal that cannot meet required performance standards cannot be the most effective alternative.

- Because the applicant did not demonstrate the need to develop the proposed project, the applicant cannot demonstrate that it needs to develop 68 new acute care beds in addition to the existing and approved acute care beds in the Durham/Caswell multicounty service area. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference. A project that is unnecessarily duplicative cannot be the most effective alternative.

- Because the applicant did not demonstrate the need to develop 68 new acute care beds, it cannot demonstrate that any enhanced competition in the service area includes a positive impact on the cost-effectiveness of the proposed services. An applicant that did not demonstrate the need for a proposed project cannot demonstrate the cost-effectiveness of the proposed project. The discussion regarding demonstrating 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, found in Criterion (18a) is incorporated herein by reference. A project that cannot show a positive impact on the cost-effectiveness of the proposed services as the result of any enhanced competition cannot be the most effective alternative.

- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

In Section E, pages 78-79, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states maintaining the status quo would not address any part of the need for 68 additional acute care beds and would prevent UNC from having sufficient capacity to expand access for the growing population particularly in the southern part of Durham County. The applicant also states that adding more beds to the facility while it is under development is more patient-focused and financially prudent than doing the same thing after the facility has opened, and that the types of services driving the need for additional acute care beds are lower acuity services which it can provide at an appropriately-sized community hospital. Therefore, this was not an effective alternative.

- Develop the Hospital at a Different Location: the applicant states development of the hospital at a different location may end up being a better alternative than the selected site, but at this time the most effective location is the approved site in southern Durham County; therefore, this was not an effective alternative.

- Develop a Different Number of Beds: the applicant states that developing fewer acute care beds would be less effective at meeting the needs of physicians and patients, and developing more acute care beds, while likely feasible, would prevent the development of additional acute care bed capacity at tertiary and quaternary hospitals in the service area; therefore, this was not an effective alternative.

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

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

- The application is conforming to all other statutory and regulatory review criteria.

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 all 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 – Duke University Hospital
C – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

Capital and Working Capital Costs – On Form F.1a in Section Q, the applicant projects a total capital cost of $4,828,000, consisting entirely of medical equipment.

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1a in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant explains why construction and other typical costs are unnecessary.

- The applicant explains how it determined the cost to equip each individual room.

In Section F, page 56, the applicant states there will be no working capital costs because DUH is an existing and operational facility that currently offers the services proposed in this application. This information is reasonable and adequately supported because DUH is an existing hospital and will continue to operate during and after development of the proposed project.

Availability of Funds – In Section F, pages 54-55, the applicant states the entire projected capital expenditure of $4,828,000 will be funded by Duke's accumulated reserves.

In Exhibit F.2(a), the applicant provides a letter dated April 7, 2022, from the Senior Vice President, Chief Financial Officer & Treasurer for Duke, stating that Duke has sufficient accumulated reserves to fund all projected capital costs and committing to providing that funding to develop the proposed project.

Exhibit F.2(b) contains a copy of the audited Consolidated Financial Statements and Supplemental Information for Duke University Health System, Inc. and Affiliates for the years ending June 30, 2021, and 2020. According to the audited Consolidated Financial Statements, as of June 30, 2021, Duke had adequate cash and assets to fund all the capital needs of the proposed project.

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

- The applicant provides a letter from the appropriate Duke official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.

- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

Financial Feasibility – The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. On Form F.2b in Section Q, the applicant projects operating expenses will exceed revenues in each of the first three full fiscal years following project completion, as shown in the table below.

DUH Revenues and Operating Expenses – Adult Inpatient Beds			
	1st Full FY SFY 2024	2nd Full FY SFY 2025	3rd Full FY SFY 2026
Number of Discharges	37,222	37,780	38,347
Total Gross Revenues (Charges)	$3,501,033,221.11	$3,553,517,680.23	$3,606,848,662.88
Total Net Revenue	$1,139,164,151.04	$1,167,737,968.06	$1,197,065,445.03
Total Net Revenue per Discharge	$30,604.59	$30,908.90	$31,216.66
Total Operating Expenses (Costs)	$1,379,150,007.25	$1,432,676,730.65	$1,488,469,720.18
Total Operating Expense per Discharge	$37,052.01	$37,921.57	$38,815.81
Net Income/(Losses)	**($239,985,856.20)**	**($264,938,762.59)**	**($291,404,275.15)**

The applicant also provides pro formas for the entire Duke system for the first three full fiscal years of operation following project completion. The applicant projects revenues for the entire Duke system will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the table below.

Duke System Revenues and Operating Expenses (in thousands)			
	1st Full FY SFY 2024	2nd Full FY SFY 2025	3rd Full FY SFY 2026
Total Gross Revenues (Charges)	$15,357,606	$16,077,027	$16,829,388
Total Net Revenue	$4,750,949	$4,953,979	$5,173,504
Total Operating Expenses (Costs)	$4,656,472	$4,780,806	$4,914,982
Net Income/(Losses)	**$94,447**	**$173,173**	**$258,522**

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Forms F.2b and F.3b for both DUH and the entire Duke system in Section Q.

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported because projected utilization is questionable. 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.

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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

Capital and Working Capital Costs – On Form F.1b in Section Q, the applicant provides the original approved capital expenditure for Project ID #J-12065-21, the proposed capital expenditure for the current proposal, and the combined total capital expenditure, as shown in the table below.

UNC Hospitals-RTP Previously Approved & Newly Projected Capital Expenditures			
	Previously Approved (J-12065-21)	**Newly Proposed (J-12214-22)**	**Total**
Purchase Price of Land	$35,000,000	$0	$35,000,000
Closing Costs	$184,000	$0	$184,000
Site Preparation	$26,868,714	$7,395,138	$34,263,852
Construction Contracts	$126,448,482	$197,034,266	$323,482,748
Landscaping	$398,401	$302,690	$701,091
Architect/Engineering Fees	$14,846,480	$18,607,294	$33,453,774
Medical Equipment	$22,833,519	$26,882,730	$49,716,249
Non-Medical Equipment	$8,924,842	$10,507,540	$19,432,382
Furniture	$3,880,484	$4,568,635	$8,449,119
Consultant Fees*	$2,203,391	$309,801	$2,513,192
Other**	$10,320,216	$13,698,075	$24,018,291
Total	**$251,908,529**	**$279,306,169**	**$531,214,698**

*Third-party inspections, commissioning authority fees
**Contingency, permits/fees inspection

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1b in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides assumptions about costs included in the calculation of each line item in the projected capital cost.

- The applicant states much of the projections are based on UNC's history or the project architect's history in developing similar projects.

In Section F, page 91, the applicant states that working capital costs are projected to increase and provides the following information:

UNC Hospitals-RTP Previously Approved & Newly Projected Working Capital Costs	
New total estimated start-up costs	$5,831,936
New total estimated initial operating costs	$8,747,905
New total working capital	$14,579,841
Previously approved total working capital (J-12065-21)	$6,143,566
Difference	$8,436,275

In Section F, page 91, the applicant provides the assumptions used to project the increase in working capital costs. The information is reasonable and adequately supported based on the following:

- The applicant states the updated utilization projections are part of the increase in working capital costs.

- The applicant states the additional capital cost with the change of scope is also part of the increase in working capital costs.

Availability of Funds – In Section F, pages 89-91, the applicant states the entire projected capital expenditure of $279,306,169 and the entire working capital cost of $14,579,841 will be funded with UNC's accumulated reserves.

In Exhibit F.5-2, the applicant provides a letter dated April 15, 2022, from the Chief Financial Officer for UNC Hospitals, stating that UNC Hospitals has sufficient accumulated reserves to fund the projected capital and working capital costs and committing to providing that funding to develop the proposed project.

Exhibit F.5-3 contains a copy of UNC's Financial Statement Audit Report for the year ending June 30, 2021, completed by the State Auditor. According to the Financial Statement Audit Report, as of June 30, 2021, UNC had adequate cash and assets to fund all the capital and working capital needs of the proposed project.

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 provides a letter from the appropriate UNC official confirming the availability of the funding proposed for the capital and working capital needs of the project and the commitment to use those funds to develop the proposed project.

- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital and working capital needs of the project.

Financial Feasibility – The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. In Form F.2b, the applicant projects operating expenses will exceed revenues in the first full fiscal year following project completion, but revenues will exceed operating expenses in the

second and third full fiscal year following project completion, as shown in the table below.

Revenues and Operating Expenses – UNC Hospitals-RTP			
	1st Full FY SFY 2030	2nd Full FY SFY 2031	3rd Full FY SFY 2032
Total Discharges	8,038	8,161	8,277
Total Gross Revenues (Charges)	$251,449,915	$361,378,755	$429,396,602
Total Net Revenue	$88,830,807	$127,740,417	$151,898,157
Total Net Revenue per Discharge	$11,051	$15,653	$18,352
Total Operating Expenses (Costs)	$95,022,529	$122,954,094	$141,129,372
Total Operating Expenses per Discharge	$11,822	$15,066	$17,051
Net Income/(Losses)	**($6,191,722)**	**$4,786,323**	**$10,768,785**

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in forms immediately prior to Forms F.2b and F.3b in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant clearly details the sources of data used to project revenues and expenses.

- The applicant bases its projections on its own historical experience at UNC Hillsborough, a satellite campus of UNC Hospitals in Orange County with 83 acute care beds.

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.

- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

(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 – Duke University Hospital
C – UNC Hospitals-RTP

The 2022 SMFP includes a need determination for 68 acute care beds in the Durham/Caswell multicounty service area.

On page 33, the 2022 SMFP defines the service area for acute care beds as *"... the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 38, shows Durham and Caswell counties in a multicounty grouping. Thus, the service area for these facilities is the Durham/Caswell multicounty service area. Facilities may also serve residents of counties not included in their service area.

As of the date of this decision, there are 1,442 existing and approved acute care beds, allocated between four existing and approved hospitals owned by three providers in the Durham/Caswell multicounty service area, as illustrated in the following table.

Durham/Caswell Multicounty Service Area Acute Care Hospital Campuses	
Facility	**Existing/(Approved) Beds**
Duke University Hospital*	1,048 (+14)
Duke Regional Hospital	316
Duke Total	**1,364 (+14)**
North Carolina Specialty Hospital	18 (+6)
UNC Hospitals-RTP**	0 (+40)
Durham/Caswell Multicounty Service Area Total	**1,382 (+60)**

Source: Table 5A, 2022 SMFP; applications under review; 2022 LRAs; Agency records.
Note: Numbers in parentheses reflect approved changes in bed inventory which have not yet been developed.
*Includes 14 Policy AC-3 NICU beds that are not included in Table 5A or the planning inventory for DUH.
**As of the date of this decision, the 40 acute care beds have been awarded to UNC Hospitals-RTP; however, the decision is under appeal and no CON has been issued at this time.

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

In Section G, pages 62-63, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved acute care beds in the Durham/Caswell multicounty service area. The applicant states that North Carolina Specialty Hospital offers primarily surgical services in a limited number of specialties and serves a much different patient population than DUH. The applicant states DRH's capacity is restricted by facility limitations, and it does not offer the same tertiary or quaternary care services as DUH, but despite that its utilization is growing. The applicant states the beds awarded to UNC Hospitals-RTP are under appeal but that regardless they have already been subtracted from the Durham/Caswell multicounty service area's need determination and so would not be duplicative. On page 62, the applicant states:

> *"…the need for additional inpatient capacity was driven by the demand for DUH's highly specialized services. The proposed 68 additional acute care beds are specifically needed at DUH to expand access to the hospital's well-utilized inpatient acute care services which do not duplicate the services provided by any other facility. …, DUH patients come from across the state, and it is their need that drives the demand for additional capacity."*

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 based on the following analysis:

- The applicant did not adequately demonstrate the need it has for the proposed project or that its projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference.

- The applicant did not demonstrate in the application as submitted that it was conforming with the Criteria and Standards for Acute Care Beds promulgated in 10A NCAC 14C .3803(a). The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference.

- Because the applicant did not demonstrate the need to develop 68 new acute care beds, it cannot demonstrate that the 68 new acute care beds are needed in addition to the existing and approved acute care beds in the Durham/Caswell multicounty service area.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

In Section G, page 94, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved acute care bed services in the Durham/Caswell multicounty service area. On page 94, the applicant states:

> *"All service components involved in the proposed change of scope project were included in the previously approved Project ID # J-12065-21. Further, the 2022 SMFP includes a need for 68 additional acute care beds in the Durham/Caswell service area, of which this project proposes to develop only 34. ..., the proposed project will better optimize UNC Hospitals-RTP by enhancing capacity and ensuring sufficient resources to provide all the services required to support the provision of high-quality care.*
>
> *In addition, all of the services to be offered at UNC Hospitals-RTP, 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 both the previously approved application and the proposed change of scope and are essential to the development and operation of the previously approved facility as a full service hospital. Other existing outpatient services in the market, such as imaging or surgical services, do not offer services to inpatients as proposed at UNC Hospitals-RTP."*

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

- There is a need determination in the 2022 SMFP for the proposed acute care beds.

- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved acute care beds in the Durham/Caswell multicounty service area.

- The applicant adequately demonstrates that the proposed acute care beds are needed in addition to the existing and approved acute care beds. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

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 all the reasons described 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 – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

On Form H in Section Q, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

DUH Current & Projected Staffing				
Position	Current	Projected		
	SFY 2022	FY 1 SFY 2024	FY 2 SFY 2025	FY 3 SFY 2026
Nurse Practitioners	5.0	5.2	5.4	5.7
Registered Nurses	1,869.9	1,926.4	2,014.4	2,138.0
Licensed Practical Nurses	4.6	4.7	4.9	5.2
Certified Nurse Aides/ Nursing Assistants	457.3	471.1	492.6	522.9
Surgical Technicians	2.7	2.8	2.9	3.1
Clerical	5.7	5.9	6.2	6.5
Nurse Manager	26.0	26.0	26.0	26.0
Physician	2.3	2.4	2.5	2.7
Total Staffing	**2,373.5**	**2,444.5**	**2,554.9**	**2,710.1**

The assumptions and methodology used to project staffing are provided on Form H Assumptions immediately following Form H in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In Section H, pages 65-66, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. The applicant provides supporting documentation in Exhibit H-3.

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

- The applicant adequately demonstrates it has experience in acquiring sufficient personnel to provide services and provides documentation about the ways it has done so in the past that will be used for the proposed project.

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.

- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3b in Section Q.

- The applicant provides adequate documentation of its policy for continuing education programs, leave, and financial assistance associated with continuing education for nurses.

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 described above.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

UNC Hospitals-RTP Projected Staffing			
Position	**FY 1 (SFY 2030)**	**FY 2 (SFY 2031)**	**FY 3 (SFY 2032)**
Registered Nurses	89.6	128.8	153.0
Director of Nursing	1.0	1.0	1.0
Surgical Technicians	19.9	28.6	34.0
Lab Technicians	7.1	10.3	12.2
Radiology Technologists	12.6	18.1	21.5
Pharmacists	3.0	4.4	5.2
Pharmacy Technicians	4.0	5.7	6.8
Physical Therapists	1.9	2.7	3.2
Speech Therapists	1.2	1.2	1.2
Occupational Therapists	1.3	1.9	2.2
Respiratory Therapists	6.4	9.3	11.0
Dieticians	1.9	1.9	1.9
Cooks	5.9	8.4	10.0
Dietary Aides	3.3	4.7	5.6
Social Workers	2.0	2.0	2.0
Housekeeping	17.5	25.1	29.8
Bio-medical Engineering	2.0	2.0	2.0
Maintenance/ Engineering	14.0	14.0	14.0
Chief Operating Officer	1.0	1.0	1.0
Clerical	13.9	19.9	23.7
Other*	72.4	101.8	118.0
Total	**284.9**	**392.6**	**459.3**

*The applicant lists the positions and FTEs in the "Other" category on Form H in Section Q.

The assumptions and methodology used to project staffing are provided on Form H Assumptions immediately following Form H in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q.

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

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.

- The applicant's projections for FTEs are based on its own historical experience at other UNC facilities.

- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3b in Section Q.

- The methods to be used by the applicant to recruit or fill new positions and its proposed training and continuing education programs were found conforming with this criterion in Project ID #J-12065-21 and the applicant proposes no changes in the application as submitted that would affect that determination.

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 described 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 – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

Ancillary and Support Services – In Section I, page 67, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, page 67, the applicant explains how each ancillary and support service will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because it currently provides those services for its existing acute care beds and will continue to do so for its proposed acute care beds.

Coordination – In Section I, pages 67-68, the applicant describes Duke's existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is part of a large and existing healthcare system in the Durham/Caswell multicounty service area.

- On page 68, Duke provides a link to its 2021 Report on Community Benefit which describes its community investment.

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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

Ancillary and Support Services – In Section I, page 98, the applicant states that the proposed change of scope project will not change its commitment to the provision of necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- In Exhibit I.3-1, the applicant provides a letter from the President of UNC Hospitals, committing to provide the necessary ancillary and support services for the proposed project.

- Project ID #J-12065-21 was found conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

Coordination – In Section I, page 99, the applicant states the proposed change of scope project will not result in changes to coordination with the existing health system described in the application for Project ID #J-12065-21. The applicant adequately

demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant provides letters of support from local physicians and healthcare providers documenting their support for UNC Hospitals-RTP in Exhibit I.3-2.

- Project ID #J-12065-21 was found conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

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.

(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 – Both Applications

Neither of the applicants 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, neither of the applicants project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

(i) would be available under a contract of at least 5 years duration;

(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA – Both Applications

Neither of the applicants are HMOs. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective July 1, 1987.

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

NA – Duke University Hospital
C – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

The applicant does not propose to construct any new space or make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

In Section K, page 104, the applicant states that the project involves constructing an additional 251,580 square feet of space in addition to the previously approved 189,838 square feet of space for a combined total construction of 441,418 square feet of space. Line drawings are provided in Exhibit C.8-1.

In Section K, pages 104-105, the applicant adequately 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 designed to provide the most efficient circulation and throughput for patients and caregivers.

- The applicant states adding the 34 acute care beds to the proposed facility while it is still under development is more financially prudent and better for patients because it will reduce later costs associated with demolition and renovation and reduce patient disruptions.

- The applicant details proposals to use sustainable strategies in developing the facility.

On page 105, 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 additional acute care capacity is needed in the proposed location of the proposed project.

- The applicant states conservative fiscal management has allowed UNC to set aside past excess revenues to pay for the proposed project without necessitating an increase in costs or charges.

In Section B, page 32, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

(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 – Duke University Hospital
NA – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

In Section L, page 74, the applicant provides the historical payor mix during SFY 2021 for the proposed services, as shown in the table below.

DUH Historical Payor Mix – SFY 2021	
Payor Category	**% of Total Patients Served**
Self-Pay	2.2%
Charity Care	2.6%
Medicare*	37.8%
Medicaid*	10.9%
Insurance*	43.3%
Workers Compensation	0.2%
TRICARE	1.4%
Other	1.5%
Total	**100.0%**

*Including any managed care plans.

In Section L, page 75, the applicant provides the following comparison.

DUH	Percentage of Total Patients Served During SFY 2021	Percentage of the Population of Durham County
Female	58.7%	52.3%
Male	41.3%	47.7%
Unknown	0.0%	0.0%
64 and Younger	65.3%	84.4%
65 and Older	34.7%	13.6%
American Indian	0.5%	0.9%
Asian	3.3%	5.5%
Black or African-American	26.4%	36.9%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	61.5%	54.0%
Other Race	3.9%	0.0%
Declined / Unavailable	4.1%	0.0%

Source: US Census Bureau

Conclusion – 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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

UNC Hospitals-RTP is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

(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 – Duke University Hospital
NA – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 76, the applicant states it satisfied the requirements of providing uncompensated care in exchange for Hill Burton funds previously received, and has no other such obligation.

In Section L, page 77, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

UNC Hospitals-RTP is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

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

C – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

In Section L, page 78, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

DUH Projected Payor Mix – FY 3 (SFY 2026)		
Payor Category	**Entire Facility**	**Adult Acute Care Services**
Self-Pay	1.9%	2.5%
Charity Care	2.4%	3.0%
Medicare*	38.2%	46.2%
Medicaid*	12.3%	14.1%
Insurance*	41.8%	29.9%
Workers Compensation	0.2%	0.3%
TRICARE	1.4%	1.3%
Other	1.7%	2.7%
Total	**100.0%**	**100.0%**

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 1.9% of total services and 2.5% of adult acute care services will be provided to self-pay patients, 2.4% of total services and 3.0% of adult acute care services to charity care patients, 38.2% of total services and 46.2% of adult acute care services to Medicare patients, and 12.3% of total services and 14.1% of adult acute care services to Medicaid patients.

On pages 78-79, 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. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the historical payor mix from the first six months of SFY 2022.

- The applicant explains a one-time shift of managed care patients to Medicare during SFY 2023 to reflect the aging of DUH population projections.

- The applicant clearly explains how it calculated the charity care payor mix.

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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

In Section L, pages 112-113, the applicant states:

> *"Projected access by medically underserved groups will not change from the previously approved Project ID J-12065-21 in terms of the percentage of care provided to underserved groups. As previously stated, UNC Hospitals 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 the UNC Hospitals-RTP upon completion of the proposed change of scope project. ..., UNC Hospitals' charity care program ensures that all eligible individuals receive medically necessary care at UNC Hospitals regardless of their ability to pay. No citizen of North Carolina is refused non-elective treatment at UNC Hospitals because of his/her inability to pay. .... As noted in the previously approved project, although a separately licensed hospital, the previously approved UNC Hospitals-RTP will be developed under the provider number for UNC Hospitals and will use UNC Hospitals' policies. However, the proposed project will increase access to the medically underserved by expanding the capacity of the previously approved project to all patients, including the medically underserved groups."*

Project ID #J-12065-21 was found conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

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.

(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 – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

In Section L, page 80, the applicant adequately describes the range of means by which patients will 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 conforming to this criterion.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

Project ID #J-12065-21 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination. Therefore, the application is conforming to this criterion.

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

C – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

In Section M, pages 81-82, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes because it is an academic medical center teaching hospital.

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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

In Section M, page 114, the applicant states the proposed project does not involve any changes to the information provided in the application for Project ID #J-12065-21.

Project ID #J-12065-21 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination. Therefore, the application is conforming to this criterion.

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 – Duke University Hospital
C – UNC Hospitals-RTP

The 2022 SMFP includes a need determination for 68 acute care beds in the Durham/Caswell multicounty service area.

On page 33, the 2022 SMFP defines the service area for acute care beds as *"... the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 38, shows Durham and Caswell counties in a multicounty grouping. Thus, the service area for these facilities is the Durham/Caswell multicounty service area. Facilities may also serve residents of counties not included in their service area.

As of the date of this decision, there are 1,442 existing and approved acute care beds, allocated between four existing and approved hospitals owned by three providers in the the Durham/Caswell multicounty service area, as illustrated in the following table.

Durham/Caswell Multicounty Service Area Acute Care Hospital Campuses	
Facility	**Existing/(Approved) Beds**
Duke University Hospital*	1,048 (+14)
Duke Regional Hospital	316
Duke Total	**1,364 (+14)**
North Carolina Specialty Hospital	18 (+6)
UNC Hospitals-RTP**	0 (+40)
Durham/Caswell Multicounty Service Area Total	**1,382 (+60)**

Source: Table 5A, 2022 SMFP; applications under review; 2022 LRAs; Agency records.
Note: Numbers in parentheses reflect approved changes in bed inventory which have not yet been developed.
*Includes 14 Policy AC-3 NICU beds that are not included in Table 5A or the planning inventory for DUH.
**As of the date of this decision, the 40 acute care beds have been awarded to UNC Hospitals-RTP; however, the decision is under appeal and no CON has been issued at this time.

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 83, the applicant states:

> *"..., DUH is a crucial provider of tertiary and quaternary care to patients from not only the Triangle and surrounding counties, but across the state and nation. By ensuring sufficient capacity to meet demand for DUH's specialized inpatient services, this project will increase patient choice for patients throughout this region.*
>
> *DUH currently operates on divert status a significant percentage of the time, which affects its ability to accept transfers and potentially limits access for patients."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 83, the applicant states:

> *"This project will not affect the cost to patients or payors for the services provided by DUH because reimbursement rates are set by the federal government and commercial insurers. The capital expenditure for this project is necessary to ensure that DUHS will continue to provide high quality services that are accessible to patients. Also, DUHS will continue to participate in initiatives aimed at promoting cost effectiveness and optimizing quality healthcare."*

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

Regarding the impact of the proposal on quality, in Section N, pages 83-84, the applicant states:

> *"The US News and World Report ranks Duke University Hospital as the best hospital in the state. DUH has existing quality-related policies and procedures, and its quality management programs emphasize a customer-oriented perspective that is used to determine the needs of patients, physicians, and others who utilize hospital services. ...*
>
> *All clinical and technical staff will be required to maintain appropriate and current licensure and continuing education. Expanding capacity to improve access also benefits quality of care for patients, who might otherwise face delays or inability to receive DUH's highly specialized care."*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 84, the applicant states:

> *"By expanding inpatient capacity, DUH strives to reduce the time that it must operate on divert status and therefore to increase access to all patients needing its services.*
>
> *As previously stated, DUHS will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved."*

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

However, the applicant does not adequately demonstrate how any enhanced competition in the service area will have a positive impact on the cost-effectiveness of the proposed services. The applicant did not adequately demonstrate the need to develop 68 new acute care beds or that the project is the least costly or most effective alternative. The discussions regarding analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference. A project that cannot demonstrate the need for the services proposed and a project that cannot demonstrate it is the least costly or most effective alternative cannot demonstrate how any enhanced competition will have a positive impact on the cost-effectiveness of the proposal.

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 not conforming to this criterion based on all the reasons stated above.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

Regarding the expected effects of the proposal on competition, cost-effectiveness, quality, and access by medically underserved groups in the service area, in Section N, page 116, the applicant states:

> *"The proposed project will continue to stimulate competition and will appropriately balance access, quality, and cost-effectiveness of health services for Durham and Caswell County patients and will not result in changes to the expected effects of the proposal on competition in the proposed service area from what was stated in the previously approved application. ..., UNC Hospitals believes that, at this time, a 74-bed hospital is well suited to deliver the much-needed lower acuity hospital services to Durham and Caswell County patients. Further, UNC Hospitals believes that the additional 34 acute care beds and the proposed augmentation of multiple other ancillary and support services to support the acute care beds, including additional observation beds, labor and delivery recovery beds, procedure rooms, emergency department bays, and imaging equipment, will improve access to the lower acuity community hospital services to be provided at UNC Hospitals-RTP upon completion of the proposed project while also allowing UNC Hospitals to remain good stewards of the resources available to serve the residents of Durham County and the surrounding area."*

See also Sections B, C, F, K, L, O, and Q of the application and any exhibits.

Project ID #J-12065-21 was found conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

1) The proposal is cost effective because the applicant adequately demonstrated in this application and in Project ID #J-12065-21: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

2) Quality care would be provided based on the applicant's representations in this application and in Project ID #J-12065-21 about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.

3) Medically underserved groups will have access to the proposed services based on the applicant's representations in this application and in Project ID #J-12065-21 about access by medically underserved groups and the projected payor mix.

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 based on all 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 – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

On Form O in Section Q, the applicant identifies hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identified three other existing and approved hospitals in North Carolina. The applicant is also part of a joint venture, Duke LifePoint Healthcare, which owns, operates, or manages nine additional existing hospitals in North Carolina.

In Section O, page 87, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in a finding of immediate jeopardy at any of the hospitals. 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, there were incidents related to quality of care in four of the hospitals. Two of the hospitals, Duke University Hospital and Duke Raleigh Hospital, are back in compliance at this time. Two of the hospitals, DLP Frye Regional Medical Center and DLP Wilson Medical Center, are not in compliance with all Medicare Conditions of Participation as of the date of these findings. 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 11 existing hospitals, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

On Form O in Section Q, the applicant identifies the hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identified a total of 13 hospitals in North Carolina.

In Section O, page 118, the applicant states that during the 18 months immediately preceding the submittal of the application, there were two incidents resulting in an Immediate Jeopardy finding – one incident each at Onslow Memorial Hospital and UNC Health Blue Ridge. The applicant states both facilities are back in compliance and provides supporting documentation in Exhibit O.4. The applicant states that no other facilities had immediate jeopardy findings during the 18 months immediately preceding the submittal of the application. 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, there were incidents related to quality of care that occurred in nine of the 13 hospitals. All nine hospitals are back in compliance as of the date of these findings. 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 13 hospitals, 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 – Duke University Hospital
C – UNC Hospitals-RTP

SECTION .3800 – CRITERIA AND STANDARDS FOR ACUTE CARE BEDS are applicable to both projects. The specific criteria are discussed below.

10A NCAC 14C .3803 PERFORMANCE STANDARDS

(a) An applicant proposing to develop new acute care beds shall demonstrate that the projected average daily census (ADC) of the total number of licensed acute care beds proposed to be licensed within the service area, under common ownership with the applicant, divided by the total number of those licensed acute care beds is reasonably projected to be at least 66.7 percent when the projected ADC is less than 100 patients, 71.4 percent when the projected ADC is 100 to 200 patients, and 75.2 percent when the projected ADC is greater than 200 patients, in the third operating year following completion of the proposed project or in the year for which the need determination is identified in the State Medical Facilities Plan, whichever is later.

-NC- **Duke University Hospital.** The applicant proposes to develop 68 acute care beds at DUH. The projected ADC of the total number of acute care beds proposed to be licensed at Duke is greater than 200. The applicant projects a utilization rate of 83% by the end of the third operating year following completion of the proposed project.

However, the applicant does not adequately demonstrate that the projected utilization of the total number of acute care beds proposed to be licensed within the service area and which are owned by Duke is reasonably projected to be at least 75.2% by the end of the third operating year following completion of the proposed project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this Rule.

-C- **UNC Hospitals-RTP.** The applicant proposes to develop 34 additional acute care beds at UNC Hospitals-RTP. The projected ADC of the total number of acute care beds proposed to be licensed within the service area and owned by UNC is less than 100. The applicant projects a utilization rate of 69.9% by the end of the third operating year following completion of the proposed project.

The applicant adequately demonstrates that the projected utilization of the total number of acute care beds proposed to be licensed within the service area and which are owned by UNC is reasonably projected to be at least 66.7% by the end of the third operating year following completion of the proposed project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(b) An applicant proposing to develop new acute care beds shall provide all assumptions and data used to develop the projections required in this rule and demonstrate that they support the projected inpatient utilization and average daily census.

-NC- **Duke University Hospital.** See Section C, pages 32-38, for the applicant's discussion of need, and Section Q, for the applicant's data, assumptions, and methodology used to project utilization. The applicant does not adequately demonstrate that the assumptions and data used to develop the projections required in this rule are reasonable and adequately support the projected inpatient utilization and average daily census. 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.

-C- **UNC Hospitals-RTP.** See Section C, pages 52-65, for the applicant's discussion of need, and Section Q for the applicant's data, assumptions, and methodology used to project utilization. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

COMPARATIVE ANALYSIS FOR ACUTE CARE BEDS

Pursuant to G.S. 131E-183(a)(1) and the 2022 State Medical Facilities Plan, no more than 68 acute care beds may be approved for the Durham/Caswell multicounty service area in this review. Because the applications in this review collectively propose to develop 102 additional acute care beds in the Durham/Caswell multicounty service area, all applications cannot be approved for the total number of beds proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in the Acute Care Bed Comparative Analysis.

- Project ID #J-12211-22 / **Duke University Hospital** / Develop 68 additional acute care beds pursuant to the 2022 SMFP need determination
- Project ID #J-12214-22 / **UNC Hospitals-RTP** / Develop 34 additional acute care beds pursuant to the 2022 SMFP Need Determination

The table below summarizes information about each application.

	Duke University Hospital	**UNC Hospitals-RTP**
Hospital Level of Care	Quaternary Academic Medical Center	Community
Number of Existing Beds*	1,062	40
Beds Proposed to be Added	68	34
Total Number of Proposed Beds**	1,130	74
Third Full Fiscal Year	SFY 2026	SFY 2032
Projected Acute Care Days – FY 3	343,639	18,869
Projected Discharges – FY 3	45,591	3,858
% of Beds Compared to Quaternary Hospital***	NA	6.5%

*Includes beds previously approved but not yet developed and excludes beds approved to be relocated away from the facility
**Proposed Beds = Number of existing beds + Number of beds requested in the application
***Assuming all beds requested by each applicant are approved

Because of the significant differences in types of facilities, numbers of total acute care beds, numbers of projected acute care days and discharges, levels of patient acuity which can be served, total revenues and expenses, and the differences in presentation of pro forma financial statements, some comparatives may be of less value and result in less than definitive outcomes than if both applications were for like facilities of like size proposing like services and reporting in like formats.

The inequity in a comparison of the two hospitals is highlighted by the applicants themselves. Both applications call attention to the dissimilarity of the two hospitals.

Duke University Hospital. In Section E, page 52, the applicant states:

> *"Additional capacity is currently needed in the service area for the tertiary and quaternary care services provided by DUH and which are not readily duplicated at another facility."*

And in Section G, page 63, the applicant states:

> *"UNC's approved Durham County hospital project under appeal is for a small community hospital that would not offer the scope of services provided by DUH."*

UNC Hospitals-RTP. In Section C, page 47, the applicant states:

> *"…, UNC Hospitals-RTP is expected to focus on a broad range of community hospital services in contrast to the academic medical center, tertiary, and specialty acute care hospitals that already exist in Durham County."*

Further, the analysis of comparative factors and what conclusions the Agency reaches (if any) with regard to specific comparative analysis factors is determined in part by whether or not the applications included in the review provide data that can be compared and whether or not such a comparison would be of value in evaluating the competitive applications.

Conformity with Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

Table 5B on page 47 of the 2022 SMFP identifies a need for 68 additional acute care beds in the Durham/Caswell multicounty service area. As shown in Table 5A, page 40, the Duke health system shows a projected deficit of 141 acute care beds for 2024, which in combination with the need determinations from the 2021 and 2022 SMFPs results in the Durham/Caswell multicounty service area need determination for 68 acute care beds. However, the application process is not limited to the provider (or providers) that show a deficit and create the need for additional acute care beds. Any qualifying provider can apply to develop the 68 acute care beds in the Durham/Caswell multicounty service area. Furthermore, it is not necessary that an existing provider have a projected deficit of acute care beds to apply for more acute care beds. However, it is necessary that an applicant adequately demonstrate the need to develop its project, as proposed.

Duke University Hospital's application, **Project ID #J-12211-22**, is not conforming to all applicable statutory and regulatory review criteria. **UNC Hospitals-RTP's** application, **Project ID #J-12214-22**, is conforming to all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with review criteria, the application submitted by **UNC Hospitals-RTP** is a more effective alternative than the application submitted by **Duke University Hospital**.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

One application involves an existing acute care hospital which provides numerous types of medical services. Another application involves an approved acute care hospital proposing to offer numerous types of medical services. However, **Duke University Hospital** is a Level I trauma center, a quaternary care center, and an academic medical center. **UNC Hospitals-RTP** will be a smaller community hospital that does not propose to offer all of the same types of services and will not offer services for high acuity patients.

Therefore, **Duke University Hospital** is the more effective alternative with respect to this comparative factor and **UNC Hospitals-RTP** is a less effective alternative.

Geographic Accessibility

As of the date of this decision, there are 1,402 existing and approved acute care beds, allocated between three existing hospitals owned by two providers in the the Durham/Caswell multicounty service area, as illustrated in the following table.

Durham/Caswell Multicounty Service Area Acute Care Hospital Campuses	
Facility	**Existing/(Approved) Beds**
Duke University Hospital*	1,048 (+14)
Duke Regional Hospital	316
Duke Total	**1,364 (+14)**
North Carolina Specialty Hospital	18 (+6)
Durham/Caswell Multicounty Service Area Total	**1,382 (+60)**

Source: Table 5A, 2022 SMFP; applications under review; 2022 LRAs; Agency records.
Note: Numbers in parentheses reflect approved changes in bed inventory which have not yet been developed.
*Includes 14 Policy AC-3 NICU beds that are not included in Table 5A or the planning inventory for DUH.

In Project ID #J-12065-21, **UNC Hospitals-RTP** was approved by the Agency to develop 40 acute care beds at a new hospital in southern Durham County. However, as of the date of these findings, that decision is under appeal and no CON has been issued. Since no CON has been issued and it is unclear where the beds will ultimately be located, they are not considered for purposes of this comparative analysis factor.

The following table illustrates where the existing and approved (CON issued) acute care beds are located within Durham County.

Facility	Total AC Beds	Address	Location
Duke University Hospital	1,062	2301 Erwin Rd, Durham 27710	Central Durham County
Duke Regional Hospital	316	3643 N. Roxboro Rd, Durham 27704	Central Durham County
North Carolina Specialty Hospital	24	3916 Ben Franklin Blvd, Durham 27704	Central Durham County

As shown in the table above, the three existing hospitals are all located in the central part of Durham County, within approximately five miles of one another.

Duke University Hospital proposes to add 68 acute care beds at its existing facility in the central part of Durham County. **UNC Hospitals-RTP** proposes to develop acute care beds in the southern part of Durham County where there are currently no existing acute care beds. Therefore, **UNC Hospitals-RTP** is a more effective alternative with regard to geographic accessibility and **Duke University Hospital** is a less effective alternative.

Historical Utilization

The table below shows acute care bed utilization for existing facilities based on acute care days as reported in Table 5A of the 2022 SMFP. Generally, the applicant with the higher historical utilization is the more effective alternative with regard to this comparative analysis factor.

Historical Utilization – Hospitals in the Durham/Caswell Multicounty Service Area					
Facility	**FFY 2021 Days**	**ADC**	**Total Beds***	**Utilization**	**Projected (Surplus)/Deficit**
Duke University Hospital	303,671	832	946	87.9%	141
Duke Regional Hospital	69,486	190	316	60.1%	(33)
NC Specialty Hospital	2,905	8	18	44.4%	(11)

Sources: Table 5A, 2022 SMFP; Agency records

*Existing acute care beds during FFY2021 only. While Duke University Hospital brought 88 beds online in June 2021, they were not available for use during most of the reporting period.

As shown in the table above, **Duke University Hospital** has a higher historical utilization than the other two acute care facilities in Durham County. However, **Duke University Hospital** is the only existing facility applying to add acute care beds in Durham County. **UNC Hospitals-RTP** is not an existing facility and thus has no historical utilization.

Therefore, a comparison of historical utilization cannot be effectively evaluated.

Competition (Patient Access to a New or Alternate Provider)

Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer acute care beds than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

As of the date of this decision, there are 1,442 existing and approved acute care beds in the Durham/Caswell multicounty service area. **Duke University Hospital** and Duke Regional Hospital are affiliated with Duke, which currently controls 1,378 of the 1,442 acute care beds in the Durham/Caswell multicounty service area, or 95.6%. **Duke University Hospital** alone controls 73.6% of the existing and approved acute care beds in the Durham/Caswell multicounty service area.

If **Duke University Hospital's** application to add 68 beds is approved, **Duke University Hospital** would control 1,130 of the 1,510 existing and approved acute care beds in the Durham/Caswell multicounty service area, or 74.8%, with the Duke health system controlling 95.8% of all the Durham/Caswell multicounty service area acute care beds. If **UNC Hospitals-RTP's** application is approved, **UNC Hospitals-RTP** would control 74 of the 1,510 existing and approved acute care beds in the Durham/Caswell multicounty service area, or 4.9% of the Durham/Caswell multicounty service area acute care beds.

Therefore, with regard to patient access to a new or alternate provider, the application submitted by **UNC Hospitals-RTP** is the more effective alternative, and the application submitted by **Duke University Hospital** is the less effective alternative.

Access by Service Area Residents

On page 31, the 2021 SMFP defines the service area for acute care beds as *"... the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on page 36, shows Durham and Caswell counties in a multicounty grouping. Thus, the service area for this facility is the Durham/Caswell multicounty service area. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional acute care beds in the service area where they live.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

Projected Service to Durham/Caswell Multicounty Service Area Residents (FY3)		
Applicant	**# Durham/Caswell Residents**	**% Durham/Caswell Residents**
Duke University Hospital	10,939	28.5%
UNC Hospitals-RTP	3,291	85.3%

Sources: Project ID #J-12211-22 p.30, Project ID #J-12214-22 p.67

As shown in the table above, **Duke University Hospital** projects to serve the highest number of Durham/Caswell multicounty service area residents and **UNC Hospitals-RTP** projects to serve the highest percentage of Durham/Caswell multicounty service area residents.

However, the acute care bed need determination methodology is based on utilization of all patients that utilize acute care beds in the Durham/Caswell multicounty service area and is not only based on patients originating from the Durham/Caswell multicounty service area. Durham County is also a relatively large urban county currently served by the Duke health system and its two hospitals. Further, **Duke University Hospital** is a Level I trauma quaternary care academic medical center which, because of its numerous advanced specialties and extremely specialized level of care, pulls in many patients from significant distances who are seeking the specialized level of health care offered by **Duke University Hospital**. **UNC Hospitals-RTP** will be a small community hospital. Obviously the two hospitals are different types of facilities and offer a different scope of services.

Considering the discussion above, the Agency believes that in this specific instance attempting to compare the applicants based on the projected acute care bed access of residents of the Durham/Caswell multicounty service area would be ineffective. Therefore, the result of this analysis is inconclusive.

Access by Underserved Groups

"Underserved groups" is defined in G.S. 131E-183(a)(13) as follows:

> *"Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority."*

For access by underserved groups, the applications in this review are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients, and Medicaid patients. Access by each group is treated as a separate factor.

Projected Charity Care

The following table shows projected charity care during the third full fiscal year following project completion for each facility. Generally, the application projecting to provide the most charity care is the more effective alternative with regard to this comparative factor.

Projected Charity Care Inpatient Services – 3rd Full FY			
Applicant	**Total Charity Care**	**Average Charity Care per Discharge**	**% of Gross Revenue**
Duke University Hospital	$106,030,462	$2,765	2.9%
UNC Hospitals-RTP	$20,692,825	$5,364	8.8%

Sources: Forms C and F.2 for each applicant

In Section L, page 79, **Duke University Hospital** defines charity care as free or discounted care provided to persons in medical need who are unable to financially afford to pay for their care, and who do not qualify for public or private assistance.

In its Form F.2 Assumptions, **UNC Hospitals-RTP** states that projected charity care is the difference between projected gross revenue and projected net revenue for self-pay patients.

Based on the differences in how each applicant categorizes charity care and the differences in presentation of pro forma financial statements, the Agency determined it could not make a valid comparison of the charity care provided by each applicant for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to add acute care beds to an approved but not yet

developed relatively small community hospital.

However, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility and the level of care (community hospital, quaternary care academic medical center) at each facility would make any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Medicare

The following table shows projected Medicare revenue during the third full fiscal year following project completion for each facility. Generally, the application projecting the highest Medicare revenue is the more effective alternative with regard to this comparative factor to the extent the Medicare revenue represents the number of Medicare patients served.

Projected Medicare Revenue – 3rd Full FY			
Applicant	**Total Medicare Rev.**	**Av. Medicare Rev./Discharge**	**% of Gross Rev.**
Duke University Hospital	$1,780,560,702	$46,533	49.4%
UNC Hospitals-RTP	$120,659,542	$31,275	51.2%

Sources: Forms C and F.2 for each applicant

Based on the differences in presentation of pro forma financial statements, the number of patients, and the level of care at each facility, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to add acute care beds to an approved but not yet developed relatively small community hospital.

Further, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility and the level of care (community hospital, quaternary care academic medical center) at each facility would make any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Medicaid

The following table shows projected Medicaid revenue during the third full fiscal year following project completion for each facility. Generally, the application projecting the highest Medicaid revenue is the more effective alternative with regard to this comparative factor to the extent the Medicaid revenue represents the number of Medicaid patients served.

Projected Medicaid Revenue – 3rd Full FY			
Applicant	**Total Medicaid Rev.**	**Av. Medicaid Rev./Discharge**	**% of Gross Rev.**
Duke University Hospital	$426,696,656	$11,127	11.8%
UNC Hospitals-RTP	$36,194,498	$9,382	15.4%

Sources: Forms C and F.2 for each applicant

Based on the differences in presentation of pro forma financial statements, the number of patients, and the level of care at each facility, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to add acute care beds to an approved but not yet developed relatively small community hospital.

Further, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility and the level of care (community hospital, quaternary care academic medical center) at each facility would make any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Average Net Revenue per Patient

The following table shows the projected average net revenue per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average net revenue per patient is the more effective alternative with regard to this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per Discharge – 3rd Full FY			
Applicant	**Total # of Discharges**	**Net Revenue**	**Average Net Revenue / Discharge**
Duke University Hospital	38,347	$1,197,065,445	$31,217
UNC Hospitals-RTP	3,858	$92,650,396	$24,015

Sources: Forms C and F.2 for each applicant

Based on the differences in presentation of pro forma financial statements, the number of patients, and the level of care at each facility, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to add acute care beds to an approved but not yet developed relatively small community hospital.

Further, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility and the level of care (community hospital, quaternary care

academic medical center) at each facility would make any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Average Operating Expense per Patient

The following table shows the projected average operating expense per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense per patient is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Projected Operating Expense per Discharge – 3rd Full FY			
Applicant	**Total # of Discharges**	**Operating Expense**	**Average Operating Expense / Discharge**
Duke University Hospital	38,347	$1,488,469,720	$38,816
UNC Hospitals-RTP	3,858	$79,776,658	$20,678

Sources: Forms C and F.2 for each applicant

Based on the differences in presentation of pro forma financial statements, the number of patients, and the level of care at each facility, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to add acute care beds to an approved but not yet developed relatively small community hospital.

Further, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility and the level of care (community hospital, quaternary care academic medical center) at each facility would make any comparison of little value. Therefore, the result of this analysis is inconclusive.

SUMMARY

Due to significant differences in the size of hospitals, levels of acuity each hospital proposes to serve, total revenues and expenses, and the differences in presentation of pro forma financial statements, some of the comparatives may be of less value and result in less than definitive outcomes than if all applications were for like facilities of like size and reporting in like formats.

The following table lists the comparative factors and states which application is the more effective alternative with regard to that particular comparative factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	Duke University Hospital	UNC Hospitals-RTP
Conformity with Review Criteria	Less Effective	**More Effective**
Scope of Services	**More Effective**	Less Effective
Geographic Accessibility	Less Effective	**More Effective**
Historical Utilization	Inconclusive	Inconclusive
Competition/Access to New/Alternate Provider	Less Effective	**More Effective**
Access by Service Area Residents	Inconclusive	Inconclusive
Access by Underserved Groups		
Projected Charity Care	Inconclusive	Inconclusive
Projected Medicare	Inconclusive	Inconclusive
Projected Medicaid	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive

- With respect to Conformity with Review Criteria, **UNC Hospitals-RTP** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Scope of Services, **Duke University Hospital** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Geographic Accessibility, **UNC Hospitals-RTP** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Competition/Access to New Provider, **UNC Hospitals-RTP** offers the more effective alternative. See Comparative Analysis for discussion.

CONCLUSION

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of acute care beds that can be approved by the Healthcare Planning and Certificate of Need Section. Approval of all applications submitted during this review would result in acute care beds in excess of the need determination for the Durham/Caswell multicounty service area.

However, the application submitted by **Duke University Hospital** is not approvable and therefore cannot be considered an effective alternative. Consequently, the application submitted by **Duke University Hospital, Project ID #J-12211-22**, is denied.

The application submitted by **UNC Hospitals-RTP** is conforming to all applicable statutory and regulatory review criteria and is approvable. Further, based on the applications as submitted and the Comparative Analysis, the application submitted by **UNC Hospitals-RTP** is comparatively superior to the application submitted by **Duke University Hospital**, even if **Duke University Hospital's** application could be approved. The application submitted by **UNC Hospitals-RTP** is a more effective alternative for three comparative analysis factors, while the application submitted by **Duke University Hospital** is a more effective alternative for only one comparative analysis factor.

The application submitted by **UNC Hospitals-RTP**, **Project ID #J-12214-22**, is comparatively superior and is approved as submitted, subject to the following conditions.

1. University of North Carolina Hospitals at Chapel Hill and University of North Carolina Health Care System (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.

2. The certificate holder shall develop no more than 34 acute care beds at UNC Hospitals-RTP pursuant to the need determination in the 2022 SMFP.

3. The certificate holder shall also develop no more than two additional unlicensed procedure rooms, 10 additional unlicensed observation beds, two additional unlicensed labor and delivery room beds, eight additional emergency department bays, one additional fixed CT scanner, and one additional ultrasound unit at UNC Hospitals-RTP.

4. Upon completion of this project and Project ID #J-12065-21, UNC Hospitals-RTP shall be licensed for no more than 74 acute care beds.

5. Progress Reports:
   a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
   b. The certificate holder shall complete all sections of the Progress Report form.
   c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
   d. The first progress report shall be due on July 1, 2023.

6. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.

7. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.

8. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
   a. Payor mix for the services authorized in this certificate of need.
   b. Utilization of the services authorized in this certificate of need.
   c. Revenues and operating costs for the services authorized in this certificate of need.
   d. Average gross revenue per unit of service.

e. Average net revenue per unit of service.
f. Average operating cost per unit of service.

9. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.