ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS C = Conforming

CA = Conditional NC = Nonconforming

NA = Not Applicable

Decision Date: March 26, 2018 Findings Date: March 26, 2018

Project Analyst: Celia C. Inman Team Leader: Fatimah Wilson

COMPETITIVE REVIEW

Project ID #: J-11422-17

Facility: North Carolina Specialty Hospital

FID #: 943374 County: Durham

Applicant: North Carolina Specialty Hospital, LLC

Project: Add 6 acute care beds pursuant to the Durham/Caswell need determination in

the 2017 SMFP for a total of 24 acute care beds

Project ID #: J-11426-17

Facility: Duke University Hospital

FID #: 943138 County: Durham

Applicant: Duke University Health System, Inc.

Project: Add 96 acute care beds pursuant to the Durham/Caswell need determination in

the 2017 SMFP for a total of 1,034 acute care beds

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility,

health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C – NCSH CA – DUHS

Need Determination

Chapter 5 of the 2017 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional acute care (AC) hospital beds by service area. Application of the standard need methodology in the 2017 SMFP identifies a need for ninety-six (96) additional acute care beds in the Durham/Caswell multicounty acute care bed service area (Durham/Caswell service area).

Chapter 5, page 41, states that any qualified applicant may apply for acute care beds and describes a qualified applicant as any 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 major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services (CMC) as listed on page 41.

Two applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency), each proposing to develop new acute care beds at existing acute care hospitals in Durham County. Pursuant to the need determination in Table 5B, page 52 of the 2017 SMFP, 96 acute care beds may be approved in this review for the Durham/Caswell multicounty acute care bed service area.

Policies

There are two policies in the 2017 SMFP which are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3, on page 33 of the 2017 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, on page 33 of the 2017 SMFP, states:

"Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

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

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

North Carolina Specialty Hospital, LLC, "the applicant", proposes to develop six additional acute care beds pursuant to the Durham/Caswell service area need determination in the 2017 SMFP for a total of 24 acute care beds at the North Carolina Specialty Hospital (NCSH), "the facility".

Need Determination. In Section B.1, pages 14-15, the applicant documents that it is a qualified applicant, stating:

 The existing facility has emergency services with 24-hour staffing. In addition, NCSH plans to implement Level III Emergency Services. Exhibit B.1 contains a copy of the applicant's No Review determination request, stating its intent to implement the services, along with the Agency's response acknowledging that the

- applicant's proposal to offer Level III Emergency Services is not governed by, and therefore, does not currently require a certificate of need.
- NCSH has 18 licensed inpatient acute care beds and currently provides inpatient
 medical services to both surgical and non-surgical patients and is committed to
 using the proposed additional inpatient acute care beds to serve inpatient medical
 services to both surgical and non-surgical patients.
- The hospital currently provides medical and surgical services on a daily basis within more than five of the major diagnostic categories as listed on page 41 of the 2017 SMFP.

Based on NCSH's 2017 License Renewal Application (LRA), NCSH did not provide Emergency services 24 hours a day 7 days per week in FY2016. However, as the applicant stated, NCSH provided the Agency with a letter dated September 7, 2017, indicating its intent to implement Level III hospital emergency services. Based on the applicant's project scope in Section C.1, page 28, the proposed beds will "serve medical and surgical patients". Because the applicant is not proposing a new licensed hospital, the third requirement above for "medical and surgical services on a daily basis within at least five of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services (CMC) as listed on page 41" is not applicable.

Therefore, based on the information provided by the applicant and other data available to the Agency, NCSH is a qualified applicant.

The applicant does not propose to develop more new acute care beds than are determined to be needed in the 2017 SMFP for the Durham/Caswell service area.

Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> – The applicant describes how it believes the proposed project would promote safety and quality in Section B.10(a), pages 24-25, Section N.2(b), page 93, Section O, pages 95-96, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

<u>Promote Equitable Access</u> – The applicant describes how it believes the proposed project would promote equitable access in Section B.10(b), page 25, Section L, pages 87-90, Section N.2(c), page 94, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

<u>Maximize Healthcare Value</u> – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.10(c), pages 25-26 and Section K.4 (a) and (b), page 83. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value and that the applicant's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2017 SMFP. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is less than \$2 million; therefore, Policy GEN-4 is not applicable to this application.

Conclusion. The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant demonstrates it is a "qualified applicant",
- the applicant does not propose to develop more new acute care beds than are determined to be needed in the 2017 SMFP for the Durham/Caswell service area,
- the applicant demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
 - the applicant uses existing policies, historical data, and verifiable sources to project utilization, and
 - o the applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need.

Duke University Health System, Inc. (DUHS), "the applicant", proposes to develop 96 additional acute care beds pursuant to the Durham/Caswell service area need determination in the 2017 SMFP for a total of 1,034 acute care beds at Duke University Hospital (DUH), "the facility".

Need Determination. In Section B.1(b), page 12, the applicant documents that it is a qualified applicant, stating:

"As documented in its 2017 License Renewal Application provided in exhibit 2, DUH:

• provides a 24-hour emergency department, and

• provides inpatient medical services to both surgical and non-surgical patients."

Based on DUH's 2017 LRA, DUH provides emergency services 24 hours a day 7 days per week and had both surgical and non-surgical inpatient cases in 2016. Because the applicant is not proposing a new licensed hospital, the third requirement above for "medical and surgical services on a daily basis within at least five of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services (CMC) as listed on page 41" is not applicable.

Therefore, based on the information provided by the applicant and other data available to the Agency, DUHS is a qualified applicant.

The applicant does not propose to develop more new acute care beds than are determined to be needed in the 2017 SMFP for the Durham/Caswell service area.

Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> – The applicant describes how it believes the proposed project would promote safety and quality in Section N.2(b), pages 106-107 and referenced exhibits. The applicant also refers to its website at https://www.dukehealth.org/quality-and-safety/awards for a list or the patient safety and health care quality awards, including its current rank as the #1 Best Hospital in North Carolina. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

<u>Promote Equitable Access</u> – The applicant describes how it believes the proposed project would promote equitable access in Section N.2(c), pages 107-108. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

<u>Maximize Healthcare Value</u> – The applicant describes how it believes the proposed project would maximize healthcare value in Section N.2(a), page 106, where it states:

"Addition of acute care beds represents increased economy of scale and efficiency. Therefore, DUH will be able to most cost-effectively increase its inpatient capacity."

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value and that the applicant's projected volumes incorporate the concepts of quality, equitable access and

maximum value for resources expended in meeting the need identified in the 2017 SMFP. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4. DUHS addresses Policy GEN-4 as follows:

The proposed capital expenditure for this project is greater than \$5 million; therefore, Policy GEN-4 is applicable to this application. In Section B.11, pages 25-26, and Section K.4 (c), page 92, the applicant describes its plan to assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4, subject to the condition that the applicant shall develop 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.

Conclusion. The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on the review, the Agency concludes that the application is conforming to this criterion, subject to the development and implementation of an Energy Efficiency and Sustainability Plan, for the following reasons:

- the applicant demonstrates it is a "qualified applicant",
- the applicant does not propose to develop more new acute care beds than are determined to be needed in the 2017 SMFP for the Durham/Caswell service area,
- the applicant demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
 - o the applicant uses existing policies, historical data, and verifiable sources to project utilization, and
 - o the applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need, and
- the applicant provides a written statement that demonstrates that the project includes an a plan for energy efficiency and water conservation.

Decision. The applications submitted by NCSH and DUHS are conforming or conditionally confroming to the need determination in the 2017 SMFP, which identifies

the need for 96 additional acute care beds in the Durham/Caswell service area. However, the limit on the number of acute care beds that can be approved is 96. Collectively, the two applicants propose a total of 102 additional acute care beds. Therefore, both applications cannot be approved even if both applications are conforming to all statutory and regulatory review criteria. See the Conclusion following the Comparative Analysis for the decision.

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

C – Both Applications

NCSH. The applicant proposes to develop six additional acute care beds pursuant to the Durham/Caswell service area need determination in the 2017 SMFP for a total of 24 acute care beds at NCSH in Durham County.

In Section C.1, page 28, the applicant describes the proposed project, stating:

"North Carolina Specialty Hospital proposes to expand its existing facility capacity at the main campus location at 3916 Ben Franklin Blvd in Durham to add 6 inpatient acute care beds for a total of 24 beds upon completion. The proposed additional licensed acute care beds will be located in private patient rooms to serve medical and surgical patients including orthopedics, ophthalmology, ear, nose and throat, sports medicine, oral, podiatry, general, bariatric, interventional radiology, pain management, plastic and reconstructive surgery, neurosurgery, gynecology, and vascular procedures."

The applicant states that NCSH has 18 licensed acute care beds and 6 unlicensed observation beds on the second floor of the hospital and the scope of the project involves converting observation bed space on the existing nursing unit to house the acute care beds. The applicant further states:

- NCSH has the administrative, clinical and ancillary services already in place to support the licensure, accreditation and regulatory compliance for the existing and proposed additional licensed acute care beds,
- no new construction or renovations are involved because the observation rooms were designed and built to meet or exceed the construction standards for acute care beds,
- the observation rooms are outfitted as private patient rooms with fixtures and furnishings, including oxygen, suction, and a nurse call system,

- NCSH is not proposing to acquire additional major medical equipment or to develop any other health services as part of this proposed project, and
- the proposed project is independent and not contingent upon other planned renovations and new construction for which NCSH has previously obtained CON exemption.

Patient Origin

On page 38, the 2017 SMFP states, "An acute care bed's service area is the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1." In Figure 5.1, page 42 of the 2017 SMFP, Durham County and Caswell County are shown as a multicounty acute care bed service area. Thus, in this review, the service area is Durham and Caswell counties. Providers may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 31-33, the applicant provides NCSH's historical patient origin for FY2016 and the projected patient origin for the first three fiscal years of operation following project completion, by number and percentage of patients, as summarized below.

Historica Oct. 1, 201 30, 2		15 to Sept.	Oct. 1, 201 30, 2	2021	Second Oct. 1, Sept. 3	2021 to 0, 2022	Oct. 1, 202 30, 2	
G 4	#	% of	#	% of	// TD -4* - 4	% of	#	% of
County	Patients	Total	Patients	Total	# Patients	Total	Patients	Total
Durham	569	34.61%	639	34.61%	678	34.61%	719	34.61%
Wake	208	12.65%	234	12.65%	248	12.65%	263	12.65%
Orange	128	7.79%	144	7.79%	152	7.79%	162	7.79%
Granville	125	7.60%	140	7.60%	149	7.60%	158	7.60%
Alamance	106	6.45%	119	6.45%	126	6.45%	134	6.45%
Vance	76	4.62%	85	4.62%	91	4.62%	96	4.62%
Person	59	3.59%	66	3.59%	70	3.59%	75	3.59%
Johnston	29	1.76%	33	1.76%	35	1.76%	37	1.76%
Chatham	24	1.46%	27	1.46%	29	1.46%	30	1.46%
Franklin	22	1.34%	25	1.34%	26	1.34%	28	1.34%
Halifax	18	1.09%	20	1.09%	21	1.09%	23	1.09%
Harnett	18	1.09%	20	1.09%	21	1.09%	23	1.09%
Wayne	18	1.09%	20	1.09%	21	1.09%	23	1.09%
Caswell	15	0.91%	17	0.91%	18	0.91%	19	0.91%
Wilson	15	0.91%	17	0.91%	18	0.91%	19	0.91%
Warren	12	0.73%	13	0.73%	14	0.73%	15	0.73%
Nash	10	0.61%	11	0.61%	12	0.61%	13	0.61%
Cumberland	9	0.55%	10	0.55%	11	0.55%	11	0.55%
Guilford	9	0.55%	10	0.55%	11	0.55%	11	0.55%
Moore	8	0.49%	9	0.49%	10	0.49%	10	0.49%
Lee	6	0.36%	7	0.36%	7	0.36%	8	0.36%
Lenoir	6	0.36%	7	0.36%	7	0.36%	8	0.36%
Sampson	6	0.36%	7	0.36%	7	0.36%	8	0.36%
Northampton	5	0.30%	6	0.30%	6	0.30%	6	0.30%
Pitt	5	0.30%	6	0.30%	6	0.30%	6	0.30%
Robeson	4	0.24%	4	0.24%	5	0.24%	5	0.24%
Beaufort	4	0.24%	4	0.24%	5	0.24%	5	0.24%
Mecklenburg	3	0.18%	3	0.18%	4	0.18%	4	0.18%
Other NC Counties*	22	1.34%	25	1.34%	26	1.34%	28	1.34%
Virginia	85	5.17%	95	5.17%	101	5.17%	107	5.17%
Georgia	2	0.12%	2	0.12%	2	0.12%	3	0.12%
South Carolina	1	0.06%	1	0.06%	1	0.06%	1	0.06%
Tennessee	1	0.06%	1	0.06%	1	0.06%	1	0.06%
Other States	16	0.97%	18	0.97%	19	0.97%	20	0.97%
Total	1,644	100.00%	1,847	100.00%	1,958	100.00%	2,076	100.00%

*Other NC Counties include Anson, Avery, Brunswick, Carteret, Dare, Duplin, Edgecombe, Forsyth, Gaston, Iredell, McDowell, New Hanover, Pender, Rockingham, Scotland, Stanly and Yancey.

As shown in the table above, and on page 33, the applicant identifies the first full fiscal year as Oct. 1, 2010 to Sept. 30, 2021, the second full fiscal year as Oct. 1, 2021 to Sept. 30, 2022, and the third full fiscal year as Oct. 1, 2022 to Sept. 30, 2023. However, the projected utilization on page 59 and in Form D, page 109, and Section P, page 97, confirm the project begins January 1, 2019, with the first three fiscal years following project completion being calendar years: CY2019, CY2020 and CY2021.

In Section C.3(c), page 34, with regard to the assumptions for projected patient origin, the applicant states:

"NCSH assumes that the projected future patient origin will have the same percentages as the historical because no change in facility location is proposed and the future medical staff will include many of the current medical staff. Referral relationships are expected to continue with physicians in the primary and secondary counties where NCSH patients have historically originated."

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 35-51, the applicant describes the need for the proposed project and states that the need for additional acute care bed capacity is supported by the factors as listed below and discussed thereafter:

- the need for additional acute care beds in the service area of Durham and Caswell counties as identified in the 2017 SMFP (page 35),
- the growth and aging of the population in Durham and other counties in the region (pages 36-37),
- the growth of the medical staff and an increased number of specialties at NCSH (pages 38-43),
- the need for additional inpatient bed capacity to accommodate the high inpatient surgery utilization (page 44),
- the need for additional inpatient bed capacity to respond to daily and weekly fluctuations in census (pages 44-45),
- the increased demand for admissions related to NCSH Emergency Services (pages 47-49), and
- providing increased access to cost effective inpatient acute care services (pages 51-52).

2017 State Medical Facilities Plan

The applicant states that the 2017 SMFP includes an acute care bed need determination for 96 additional acute care beds in the Durham/Caswell multicounty service area.

Population Growth and Aging

On page 36, the applicant states that Durham County has the sixth largest population of all counties in North Carolina and its population is projected to grow by more than 25,000 between 2017 and 2022. The applicant further states that NCSH serves patients from multiple counties in the region where high growth rates are projected.

The applicant provides a table on page 36 showing projected population growth for the counties where the majority of NCSH acute care patients have originated, stating that the five year projected population growth for the counties contributes to increased demand for healthcare services, including acute care admissions.

The applicant states that aging of the population is significant because, typically, older residents utilize healthcare services at a higher rate than those who are younger. The applicant further states:

"Unlike the two neighboring hospitals in Durham County, NCSH does not provide obstetrics and neonatal inpatient acute care. Therefore, the NCHS patient population includes a larger percentage of older adults."

The applicant provides data on page 36 showing the projected increase in the aged population in the counties where the majority of its patients originate and states that the continued growth and aging of the population in its market counties contributes to the expected increase in demand for hospital admissions at NCSH.

Medical Staff Growth and Added Specialties

On pages 38-43, the applicant provides data illustrating the continued growth and changes in the NCSH medical staff that the applicant states, "result in a greater depth of medical and surgical services and expected future patient admissions." On page 43, the applicant states anticipated growth in the medical staff over the next three years includes a total of 26 physicians in 16 different specialties, not including additions to the anesthesia, pathology and radiology staff.

On page 47, the applicants discuss the opening of NCSH's Wound Healing and Hyperbaric Center and implementing High Intensity Focused Ultrasound for the treatment of prostate cancer as two examples of NCSH's increased provision of medical services.

High Inpatient Surgery Utilization

The applicant provides a table on page 44 with calculations showing that NCSH, with its 18 existing acute care beds, has higher inpatient surgery utilization than most area acute care hospitals with 25 to 179 licensed beds.

The applicant discusses Durham County's total acute care bed and operating room capacity to serve inpatients. The table on page 44 shows that NCSH has 6.78% of the inpatient OR capacity with only 1.43% of the inpatient licensed beds. The applicant states:

"The limited acute bed capacity at NCSH is a serious constraint because inpatient surgery requires the availability of inpatient beds."

Weekly Census Fluctuations

On pages 44-45, the applicant discusses its census fluctuations, stating, "During weekdays, the inpatient census at NCSH frequently reaches peak capacity on Tuesdays through Thursdays when the majority of admissions and discharges occur.

. . .

NCSH has a shortage of inpatient beds during the week due to the very high inpatient surgery utilization."

On page 5 of its response to written comments, the applicant states, "Based on the small number of licensed beds, very short average length of stay, and the peak capcity constraints that occur on Tuesdays through Thursdays, the NCSH occupancy rate that is calculated based on the midnight census figures does not accurately reflect the hospital's utilization."

Growth in Orthopedic and Spine Surgery

The applicant states (page 45) that the majority of the inpatient surgery cases at NCSH have been orthopedic and spine cases, with total inpatient surgery cases increasing from 810 cases in 2006 to 1,629 cases in 2016, which is a compound annual growth rate of 7.24% over the ten year period. On page 47, the applicant further states that while orthopedic and spine surgeries comprise a large portion of the operating room utilization, the NCSH operating rooms serve numerous surgical specialties for both inpatient and ambulatory cases, with NCSH ORs being staffed and utilized 10 hours per day and 266 days during FY2016.

Increased Demand for NCSH Emergency Services

The applicant states that the emergency department will be managed and operated in full compliance with local, state and federal hospital regulations and that NCSH will work collaboratively with Durham County Emergency Medical Services. On pages 48-49 of the application, the applicant projects a conservative ramp up in utilization in 2018 and 2019, reaching 1,387 annual visits and 42 admissions in FY2021.

Increased Access to Cost Effective Inpatient Acute Care Services

The applicant states that NCSH strives to provide highly cost effective acute care services, using special efforts to contain capital costs and operating costs. On page 51, the applicant further states:

"NCSH can more effectively compete in terms of cost, quality and access with additional inpatient bed capacity. The proposed additional 6 acute care beds at NCSH will improve patient access to cost-effective inpatient care because the total projected capacity of 24 licensed inpatient acute care beds is necessary to support timely access and quality of care for patients following surgery as well as pending medical admission."

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

- the applicant uses historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served, and
- the applicant uses Agency accepted methodologies and reasonable assumptions to demonstrate the need the population projected to be served has for the proposed services.

Projected Utilization

In Section Q, Form C - Methodology and Assumptions, pages 102-109, the applicant provides the projected utilization and methodology for the existing and proposed beds for the first three years of operation following completion of the project, as summarized below.

North Carolina Specialty Hospital Projected Utilization (CY2019-CY2021)

	PY 1 CY2019	PY 2 CY2020	PY 3 CY2021
Number of Acute Care Beds	24	24	24
Number of Discharges	1,847	1,988	2,076
Number of Patient Days	4,747	5,287	5,894
Average Length of Stay	2.57	2.70	2.84
Annual Occupancy	54.19%	60.35%	67.29%

Totals may not sum due to rounding

As shown in the above table, the applicant projects NCSH will provide 5,894 patient days with an average daily census (ADC) of 16.14 or 67.29% occupancy (5,894/365=16.14/24=67.29) in the proposed 24 acute care beds in the third operating year (CY2021), which exceeds the annual occupancy standard of 66.7%, as required in 10A NCAC 14C.3803(a) when the projected ADC is less than 100 patients.

The applicant's methodology, along with support for its assumptions for projecting acute care bed utilization, begins on page 102 of Section Q of the application, as summarized below.

Assumptions/Methodology

- NCSH's project year is the calendar year January 1 to December 31.
- PY1 is CY2019 from January 1, 2019 December 31, 2019.
- CY2018 utilization is based on 8 months of actual 2017 data annualized
 - o the applicant states that it is reasonable to project 548 discharges in the remaining 4 months of 2017, based on the 1,096 discharges during the initial eight months of 2017
 - o the applicant states that it is reasonable to project 1,280 patient days in the remaining 4 months of 2017, based on the 2,559 patient days during the initial eight months of 2017
 - Average length of stay for 2017 is 2.33 days based on the eight months of 2017 annualized data.
- Admissions and discharges are projected to increase 6% annually due to the expectation of strong growth in the medical staff and implementation of Level III Emergency Services, reaching 2,076 discharges in CY2021.

January 1, 2017-December 31, 2017	1,644 current year
January 1, 2018-December 31, 2018	1,743 (1,644 x 1.06)
January 1, 2019-December 31, 2019	1,847 (1,743 x 1.06)
January 1, 2020-December 31, 2020	1,959 (1,847 x 1.06)
January 1, 2021-December 31, 2021	2,076 (1,959 x 1.06)

In its response to written comments, the applicant discusses the 6% annual growth rate and why it should be considered reasonable and even conservative, with discharges increasing at just over 2.0 discharges per week.

 Average length of stay (ALOS) is projected to increase by 5% annually, reaching 2.84 ALOS in CY2021, due to increased complexity of high acuity patients.

January 1, 2017-December 31, 2017	2.33 current year
January 1, 2018-December 31, 2018	2.45 (2.33 x 1.05)
January 1, 2019-December 31, 2019	2.57 (2.45 x 1.05)
January 1, 2020-December 31, 2020	2.70 (2.57 x 1.05)
January 1, 2021-December 31, 2021	2.84 (2.70 x 1.05)

In support of the reasonableness of the projection, the applicant states that other area hospitals have higher ALOS, including Durham Regional Hospital, with a 2017 ALOS of 4.27.

• Patient days reach 5,894 in CY2021 (2,076 x 2.84).

	Discharges	ALOS	Patient Days
January 1, 2017-December 31, 2017	1,644	2.33	3,838
January 1, 2018-December 31, 2018	1,743	2.45	4,269
January 1, 2019-December 31, 2019	1,847	2.57	4,747
January 1, 2020-December 31, 2020	1,959	2.70	5,287
January 1, 2021-December 31, 2021	2,076	2.84	5,894

• Occupancy reaches 67.29% in CY2021 (5,894 / (365 days x 24 beds) = 0.6729).

		Available	Patient	
	Beds	Days	Days	Occupancy
January 1, 2017-December 31, 2017	18	6,570	3,838	58.42%
January 1, 2018-December 31, 2018	18	6,570	4,269	64.98%
January 1, 2019-December 31, 2019	24	8,760	4,747	54.19%
January 1, 2020-December 31, 2020*	24	8,784	5,287	60.35%
January 1, 2021-December 31, 2021	24	8,760	5,894	67.29%

^{*}Leap Year

Thus, the applicant demonstrates that the projected acute care bed utilization is based on reasonable and adequately supported assumptions.

The applicant also provides the projected utilization and related assumptions for its emergency services and observation beds in Section Q.

The applicant states that the projections for the ED are based on the historical experience of "similar" surgical specialty hospitals with 31 or fewer inpatient beds that provide emergency services and are managed by National Surgical Hospitals: specifically, El Paso Specialty Hospital in Texas and Mountain View Regional Hospital in Wyoming. The applicant states that the two hospitals averaged 3 to 7 emergency department visits per day with most patients having need for treatment for orthopedic- musculoskeletal pain or injuries, gastrointestinal – abdominal pain, nausea/vomiting, and neurological symptoms. On pages 105-106, the applicant states:

"Based on this historical data and the applicant's knowledge and experience regarding the local service area, the following utilization projections, methodology and assumptions are provided for the NCSH Level III Emergency Department:

	2018	2019	2020	2021
NCSH ED Visits/Day	2.6	3.0	3.4	3.8
Annual Visits	949	1,095	1,241	1,387
% Admissions from ED	0.45%	1.00%	2.00%	3.00%
Annual Admissions	4	11	25	42

"NCSH conservatively projects that the ED visits per day will gradually ramp up from 2.3 visits per day in 2018, 3.0 visits per day in 2019, 3.4 visits per day in 2020, and 3.8 visits per day in 2021. The utilization projections are reasonable and conservative as compared to the combined experience of the other two National Surgical Hospitals that are similar to NCSH."

The applicant further states that as with the other two hospitals, most emergency patients at NCSH will be walk-in patients presenting with orthopedic musculoskeletal pain or injuries.

On page 106, the applicant states that NCSH bases projected observation patients on the current year's ratio of observation patients to inpatient discharges and states that this is a reasonable assumption because the overall composition of the hospital is not expected to change drastically and the proportion of observation patient to inpatient discharges is a reflection of the NCSH physician practice patterns.

Projected utilization is reasonable and adequately supported for the following reasons:

- the applicant bases projected utilization upon historical data and the applicant's experience in providing the proposed service, and
- the applicant applies reasonable growth assumptions.

<u>Access</u>

Underserved groups is defined in Criterion (13), as:

"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."

The 2017 SMFP (page 2) states, "The SHCC assigns the highest priority to a need methodology that favors providers delivering services to a patient population representative of all payer types in need of those services in the service area."

In Section C.10, pages 55-56, the applicant states that NCSH complies with all federal and state regulations and does not exclude people or treat them differently due to race, color, national origin, religion, age, disability, or sex. On page 56, the applicant states that NCSH consistently serves a wide variety of patient groups and provides the following statistical information.

	NCSH % of Total Patients	Durham County Population	
Women	55.0%	52.3%	
65+	45.0%	11.9%	
Racial Minorities	32.0%	46.9%	

In Section L.3(b), page 89, the applicant projects that over 50% of its medical/surgical inpatient bed revenue will be from Medicare or Medicaid recipients, as shown below.

North Carolina Specialty Hospital As a Percent of Total Gross Revenue 1/1/20-12/31/20

Payor Source	Entire Facility	Acute Care
Self-Pay / Indigent / Charity	1.2%	0.2%
Medicare	43.0%	48.7%
Medicaid	2.8%	1.9%
Commercial Insurance/ Managed Care	46.4%	44.3%
Workers Compensation	4.2%	2.5%
TRICARE	2.4%	2.4%
Total	100.0%	100.0%

Totals may not sum due to rounding

The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant uses historical data with regard to access to project the extent to which
 all residents of the area, including underserved groups are likely to have access to
 the services proposed, and
- the applicant adequately demonstrates that its proposed project delivers services to a service area patient population representative of all payor types in need of those services.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,

- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

DUHS. The applicant proposes to develop 96 additional acute care beds pursuant to the Durham/Caswell service area need determination in the 2017 SMFP for a total of 1,034 acute care beds at DUH upon project completion. In Section C.1, the applicant states that the proposed project does not involve development of new services or reduction in existing services, but rather will expand DUH's acute care bed capacity to accommodate growing inpatient volumes. On page 28, the applicant states that the proposed project does not include the development of new ICU beds or neonatal beds, only general acute care beds. The applicant further states:

"The proposed 96 new general acute care beds will serve the needs of DUH's adult routine and intermediate patient population throughout its various existing service lines."

In Section C.1, pages 27-28, the applicant explains that the development of the 96 beds will be in stages, beginning with the immediate development, upon project approval, of 22 of the proposed beds in existing vacated patient room spaces within the hospital. On June 9, 2017, DUH notified the Agency of its plans to construct a new patient bed tower addition (BTA) to accommodate the relocation of 350 of DUH's existing licensed beds from Duke North. The proposed BTA is exempt from CON review per Section 131E-184(g). The applicant further states:

"Upon completion of the BTA and relocation of existing beds into that space, DUH will backfill some of the space vacated by the BTA bed relocation project with the remaining 74 proposed new acute care beds (96 - 22 = 74). Reflecting the need to renovate Duke North without delaying access to the proposed new acute care beds, DUH will commence renovation of backfill space to operate the 74 beds in their long-term location in the 100 Tower, but in the interim will be able to operate these beds in other existing space vacated by the relocation of beds to the BTA."

Patient Origin

On page 38, the 2017 SMFP states, "An acute care bed's service area is the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1." In Figure 5.1, page 42 of the 2017 SMFP, Durham County and Caswell County are shown as a multicounty acute care bed service area. Thus, in this review, the service area is Durham and Caswell counties. Providers may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 30 and 31, the applicant provides the historical and projected patient origin, respectively, by percent of total patients.

DUH Historical and Projected Patient Origin

Dell'Institute	Percent of Total Patients				
County	FY2017	FY2024-2026			
Durham	29.1%	29.1%			
Wake	12.3%	12.3%			
Person	3.8%	3.8%			
Granville	3.7%	3.7%			
Orange	3.6%	3.6%			
Alamance	3.4%	3.4%			
Vance	2.9%	2.9%			
Cumberland	2.7%	2.7%			
Robeson	1.6%	1.6%			
Guilford	1.4%	1.4%			
Franklin	1.3%	1.3%			
Johnston	1.2%	1.2%			
Harnett	1.0%	1.0%			
Nash	1.0%	1.0%			
Other NC Counties*	19.3%	19.3%			
Virginia	6.1%	6.1%			
Other States	5.4%	5.4%			
Total	100.0%	100.0%			

^{*}Other NC counties includes <1% patient origin from each of the remaining counties in NC, including Caswell County.

In Section C.3(c), page 32, with regard to the assumptions for projected patient origin, the applicant states:

"The projected patient origin is consistent with DUH's historical experience providing acute care services. ... DUH does not anticipate a substantial change in patient origin as a result of the proposed project."

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.1, page 28, the applicant states that the proposed project is needed to expand capacity at DUH and more effectively manage growing inpatient volumes. In Section C.4, pages 33-50, the applicant discusses the project and states the need is based on and supported by the following:

- the need for 96 additional acute care beds, as identified in the 2017 SMFP and generated by DUH's utilization (pages 33-35),
- the growing inpatient volume at DUH (pages 35-40),
- the growing number of inpatient discharges treated at academic medical centers (AMC) and teaching hospitals in North Carolina (pages 40-41),
- DUHS strategic growth (pages 41-43), and
- projected population growth and aging in DUH's primary service area (pages 43-50).

2017 SMFP Acute Bed Methodology

On page 33, the applicant states that Chapter 5 of the 2017 SMFP identifies a need for 96 additional acute care beds in the Durham/Caswell service area, which is triggered by the utilization of the total number of existing and approved acute care beds in the service area. On pages 34-35, the applicant provides the methodology calculations showing the projected deficits and surpluses at DUH, Duke Regional Hospital (DRH) and NCSH; and resulting in the SMFP's identified need for 96 acute care beds.

As shown on page 35 of the application, the SMFP acute care bed methodology shows DUH has a deficit of 145 beds and DRH has a surplus of 49 beds. Per the methodology, if two or more hospitals in the same service area are under common ownership, the surpluses and deficits of beds are totaled to determine the surplus or deficit of beds for the hospital system, which results in the need determination of 96 beds in the 2017 SMFP. On page 35, the applicant states:

"... the need for additional acute care bed capacity in Durham County is driven solely by the inpatient utilization at DUH and not by any other hospital."

While discussing the acute care bed need methodology and recognizing that the SMFP groups DUH and DRH as a hospital system within the Durham/Caswell service area to determine the need, it should be noted that DUHS leases and operates DRH; therefore, by definition, DRH is not a healthcare facility owned by DUHS. Furthermore, because of its status as an AMC teaching hospital, DUH is not required to document or project the utilization of any other facility in the service area, including related entities, pursuant to N.C. Gen. Stat. §131E-183(b).

DUH Inpatient Utilization

On page 35, the applicant states that the completion of the Duke Medical Pavilion (DMP) in 2013 brought DUH's staffed and operational inpatient beds to its full licensed complement and added 16 licensed operating rooms, which has enabled DUH to continue to grow its inpatient volumes and maximize its inpatient capacity. On page 36, the applicant further states:

"Today, the need for additional inpatient bed capacity is the result of year-overyear volume increases at DUH. Between FY2013 and FY2017 annualized, inpatient discharges at DUH increased by 13.5%, or a compound annual growth rate of 3.2%."

On pages 36-38, the applicant discusses the increase of transfers into DUH from other facilities, its management of what it calls extremely high occupancy rates (93% at its highest peak during FY2017) and its persistent diversion hours, in which it informs local emergency medical services that its beds are full and it cannot take new patients. On pages 38-40, the applicant further discusses its inpatient utilization needs in relation to DUH's increase in average daily census, its maximization of access for surgical patients, and DUH's increase in case mix index which results in a growing number of complex acute care patients, as they step down to lower levels of care.

Academic Medical Centers/Teaching Hospitals

On page 41, the applicant states that while inpatient discharges in North Carolina have declined by 1% since 2010, the volume of inpatient discharges treated at academic medical centers and teaching hospitals has risen by 7.4%. The applicant further states that on average, community hospitals in North Carolina have seen a 2.4% decline in inpatient discharges over the same period. The applicant provides a comparison chart of inpatient discharges from community hospitals versus AMC hospitals on page 41. This being said, in its discussion of scope on page 28 of the application, the applicant makes a point of stating that the proposed new beds do not include ICU or neonatal and will serve adult routine and intermediate patients.

DUHS Strategic Growth

On page 41 of the application, the applicant states that primary care providers serve as a primary entry point for health care services for DUH patients. The applicant further states that as part of its physician recruitment plan, Duke Primary Care will add a total of 186 new providers during the next five years.

On page 42, the applicant states:

"Aligning specialty practice sites in the community with primary care sites and newly established tertiary care capacity creates a strong care continuum in DUH's primary service area."

The table on page 43 shows the incremental specialty provider counts expected across DUH's primary market area to serve secondary, tertiary, and quaternary care needs.

DUHS Service Area Population Growth and Aging

On pages 44-50, the applicant discusses DUH's primary and secondary market areas, their current population, their projected growth and aging, and the impact on DUH's inpatient utilization and need for additional acute care capacity.

In summary and based on the factors discussed above, on page 50, the applicant states:

"The proposed 96 additional acute care beds are needed at DUH to expand access to the hospital's well-utilized acute care services."

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

- the applicant uses historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served, and
- the applicant uses Agency accepted methodologies and reasonable assumptions to demonstrate the need the population projected to be served has for the proposed services.

Projected Utilization

In Section Q, beginning on page 114, the applicant provides the methodology and assumptions for its projected utilization for the first three years of operation following completion of the project, summarized in the table on page 119, and below.

Duke University Hospital Projected Acute Care Bed Utilization (FY2024-FY2026)

	PY1 FY2024 (7/1/23-6/30/24)	PY2 FY2025 (7/1/24-6/30/25)	PY3 FY2026 (7/1/25-6/30/26)	
Acute Days of Care	308,896	310,440	311,993	
Acute Discharges	46,705	46,939	47,174	
Licensed AC Beds	1,034	1,034	1,034	
Percent Occupancy	81.8%	82.3%	82.7%	
ALOS	6.61	6.61	6.61	

As shown in the above table, the applicant projects the proposed facility will provide 311,993 patient days of care with an occupancy of 82.7% in the third operating year (FY2026), which exceeds the utilization standard of 75.2%, as required in 10A NCAC 14C .3803(a) when ADC is greater than 200 patients. The assumptions regarding patient days, discharges, ALOS, ADC, and percent occupancy are stated and discussed throughout the methodology in Section Q, as summarized below.

Step 1: Identify Historical DUH Acute Bed Utilization

In Section Q, page 114, the applicant provides the historical DUH acute care bed utilization from FY2013 through FY2017 and calculates the four-year compound annual growth rate for acute days of care at 3.9%.

Duke University Hospital Historical Patient Days of Care

======================================								
	FY2013	FY2014	FY2015	FY2016	FY2017	4-yr CAGR		
Acute Days of Care	241,580	256,456	268,103	273,758	281,394	3.9%		
Licensed AC Beds	938	938	938	938	938			
ADC	662	703	735	750	771			
Percent Occupancy	70.6%	74.9%	78.3%	80.0%	82.2%			
ALOS	6.44	6.58	6.78	6.68	6.61			

Step 2: Project DUH Acute Bed Utilization during Interim Project Years

In Section Q, pages 115-118, the applicant provides its assumptions for the phased development and ramp-up for the utilization of the proposed beds, resulting in the table on page 118 showing the projected acute days of care for the interim years FY2018-FY2023, as summarized below.

Duke University Hospital Interim Project Years Patient Days of Care

	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023
Acute Days of Care	281,394	287,311	287,818	287,818	291,975	302,318
Acute Discharges	42,547	43,442	43,518	43,518	44,147	48,711
Licensed AC Beds	938	960	960	960	994	1,011
Percent Occupancy	82.2%	82.0%	82.1%	82.1%	80.5%	81.9%
ALOS	6.61	6.61	6.61	6.61	6.61	6.61

Step 3: Project DUH's Acute Care Utilization during Project Years 1-3

In Section Q, pages 118-120, the applicant provides its assumptions for the development and ramp-up of the final 23 of 96 beds and shows the utilization of the proposed beds on page 119 as summarized below.

Duke University Hospital
Projected Acute Care Bed Utilization (FY2024-FY2026)

	PY1 FY2024 (7/1/23-6/30/24)	PY2 FY2025 (7/1/24-6/30/25)	PY3 FY2026 (7/1/25-6/30/26)
Acute Days of Care	308,896	310,440	311,993
Acute Discharges	46,705	46,939	47,174
Licensed AC Beds	1,034	1,034	1,034
Percent Occupancy	81.8%	82.3%	82.7%
ALOS	6.61	6.61	6.61

On page 119, the applicant states that DUH's methodology for projecting acute care bed utilization results in a CAGR of only 1.2% from FY2017 to FY2026, when DUH, in fact, anticipates greater demand for its services based on its 3.9% four-year CAGR for 2013-2017.

Projected utilization is reasonable and adequately supported for the following reasons:

- the applicant bases projected utilization upon historical data and the applicant's experience in providing the proposed service, and
- the applicant applies reasonable growth assumptions.

<u>Access</u>

Underserved groups is defined in Criterion (13), as:

"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."

The 2017 SMFP (page 2) states, "The SHCC assigns the highest priority to a need methodology that favors providers delivering services to a patient population representative of all payer types in need of those services in the service area."

In Section C.10, page 55, the applicant states DUH is opened to all residents and non-area residents for inpatient, outpatient and other healthcare services on a walk-in, emergency, appointment, or referral basis. The applicant states there is no discrimination of the basis of race, ethnicity, age, gender, or disabilities. In Section L, page 99, the applicant provides a table which illustrates that DUH (entire hospital) provided services to women (52.2%), those 65+ (32.4%) and racial minorities (40.8%) during the last full fiscal year.

In Section L.3, page 102, the applicant projects that 65.9 percent of patients will have some or all of their inpatient services paid for by Medicare and/or Medicaid during the second full fiscal year, FY20205, as shown below.

DUH Historical Payor Mix FY2025						
Payor Source	Entire Facility	Acute Days of Care				
Self-Pay*	1.9%	2.2%				
Medicare	44.1%	47.1%				
Medicaid	18.1%	18.8%				
Insurance	30.9%	28.3%				
Other**	5.0%	3.7%				
Total	100.0%	100.0%				

^{*}Includes Charity Care

The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant uses historical data with regard to access to project the extent to which all residents of the area, including underserved groups are likely to have access to the services proposed, and
- the applicant adequately demonstrates that its proposed project delivers services to a service area patient population representative of all payor types in need of those services.

Conclusion

^{**}Includes Out-of-State Medicaid, Workers Comp, TRICARE, other gov't, other non-gov't

Totals may not sum due to rounding

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

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

NA-Both Applications

Neither of the proposed projects in this review involves the reduction or elimination of a service, or the relocation of a facility or service. Therefore, this criterion is not applicable to this review.

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

CA – Both Applications

NCSH. In Section E, pages 65-66, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintaining the Status Quo –The applicant states that there are currently days of the week when NCSH reaches peak occupancy which means that patient admissions from surgery recovery are delayed. NCSH has already implemented strategies to maximize the use of the existing licensed 18 beds and NCSH intends to increase its medical staff and scope of services, which means more patients and physicians will utilize the facility. Therefore, the applicant states that maintaining the status quo is not the most effective alternative.
- Adding 8 to 10 Acute Care Beds The applicant states that the existing nursing unit with 18 licensed acute care beds and six observation rooms has a compact and efficient design that provides for staff productivity. Adding 8 or 10 acute care beds to the present facility would be more costly and less effective because the proposal would require facility changes that could disrupt the operation of the existing 18 licensed acute care beds, disrupt patient care, and could limit capacity of NCSH during project development.
- Adding 6 Acute Care Beds as Proposed The applicant states that developing the
 additional six beds for a total of 24 acute care beds will add the needed inpatient
 capacity to accommodate future utilization without major capital cost and with no
 disruption to current services. This alternative does not require any changes to
 building systems that would require renovation or new construction that could
 interrupt the delivery of excellent quality of care. The applicant states that

without the additional bed capacity, NCSH will be extremely limited in its ability to accommodate additional surgeons in future years.

On page 66, the applicant states that its proposal is the most effective alternative because NCSH needs six additional acute care beds in order to effectively compete, provide cost effective services, and provide access to physician-directed, high quality services.

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

- Maintaining the status quo does not alleviate the acute care bed capacity constraints, causes use of additional staff resources, and continues to foster increased patient wait times for rooms.
- Adding more than six patient rooms would create the need for major construction causing disruption of patient care and increasing capital costs.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

DUHS. In Section E, pages 64-66, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo / Pursue No Additional Inpatient Bed Expansion —The
 applicant states that by Fall 2017, DUH will have conducted small renovations on
 all feasible bed spaces within its facilities and be at maximum inpatient capacity
 and future growth will be difficult to accommodate. The applicant further states
 that the year-over-year inpatient utilization increases, coupled with the current
 occupancy rate at DUH are evidence that the status quo is not a realistic
 alternative.
- Construct an Off-Site Facility in Durham County The applicant states that
 developing a new inpatient hospital at an off-site location is not an effective
 alternative because it would require site preparation of land, incremental utility
 and infrastructure construction, construction permits and other timely and costly
 challenges. The applicant also states that it would not capitalize on the current

resource-intense DUH facilities, and would increase fixed costs; therefore the applicant does not consider this alternative the least costly or most effective alternative at this time.

- Renovate Existing Space at Duke Regional Hospital The applicant states that DUHS is evaluating renovation plans that would enable DRH to operate and staff more of its licensed beds as private rooms. However, the applicant states that such a project would not address the need for additional inpatient capacity within the Duke University Health System, particularly for the specialized services at DUH; therefore this was not considered the most effective alternative to meet the DUH identified need.
- Renovate Existing Spaces for Incremental Beds The applicant has plans to construct a new patient bed tower at DUH to accommodate the relocation of 350 existing licensed beds from Duke North. That project affords an opportunity for the efficient and cost-effective development of additional acute care bed capacity in vacated space at DUH. DUH will be able to backfill existing vacated space with the proposed additional 96 beds.

On page 66, the applicant states that its proposal is the most effective alternative because the proposed project represents the most effective alternative for development of additional acute care capacity at DUH in a manner that is also cost effective.

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

- Maintaining the status quo would cause DUH to be unable to accommodate inpatient volume growth.
- Building offsite would not capitalize on the current resource-intense DUH facilities and increase fixed costs for providing the additional bed capacity.
- Adding capacity at DRH would not alleviate capacity constraints at DUH.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C – Both Applications

NCSH. The applicant proposes to add six additional acute care beds in existing space that was built to meet or exceed acute care bed requirements.

Capital and Working Capital Costs

In Form F.1a in Section Q, page 110, the applicant states the total capital cost is projected as follows:

Proposed Project Capital Cost

	Total Project Costs
Contingency	\$ 100,000
Total Capital Cost	\$ 100,000

In Section C.1, pages 28-29, the applicant states that no new construction or renovations are involved in the proposed plan to add six licensed acute care beds by converting existing unlicensed observation bed space located on the existing nursing unit. The applicant further states:

"This proposed project is independent and not contingent upon other planned renovations and new construction at NCSH; the renovations and construction have obtained CON exemption with no changes in the total licensed capacity of the hospital's licensed acute care beds and operating rooms."

In July 2017, the applicant requested and received an "Exempt from Review" letter from the Agency confirming that NCSH's proposal to renovate and expand its facility, including adding space for five unlicensed observation beds, is exempt from CON review. In addition, in September 2017, the applicant notified the Agency of its intent to implement Level III emergency services at NCSH in early 2018, which the Agency acknowledged in October 2017 with a "No Review" letter stating that the proposal to implement the proposed services was not governed by, and therefore, does not currently require a certificate of need.

In Section F.3, pages 68-70, the applicant states that there will be no start-up costs or initial operating expenses associated with the proposed project because the hospital currently provides inpatient acute care services.

Availability of Funds

In Section F.2, page 67, the applicant states that the projected capital costs will be funded through NCSH's accumulated reserves and owner's equity, including cash on hand. Exhibit F.1, page 123, contains a letter from NCSH's Chief Financial Officer documenting NCSH's intent to use current assets, including cash, to fund the proposed project. NCSH's 2016 balance sheet provided in Exhibit F.1, page 124, shows \$12,217,687 in total current assets and \$3,215,237 in cash.

Financial Feasibility

In the pro forma financial statements for NCSH, Form F.4 in Section Q, the applicant projects that revenues from acute care inpatient services will exceed operating expenses in each of the first three operating years of the project, as shown in the following table.

North Carolina Specialty Hospital Acute Inpatient Services

	CY2019	CY2020	CY2021
Projected # of Patient Days	4,747	5,287	5,894
Projected Average Charge	\$ 14,700	\$ 14,700	\$ 14,700
Gross Patient Revenue	\$69,785,308	\$77,714,223	\$86,648,480
Deductions from Gross Patient			
Revenue	\$36,988,307	\$41,190,870	\$45,926,294
Net Patient Revenue	\$32,797,001	\$36,523,353	\$40,722,186
Total Expenses	\$27,055,608	\$30,539,490	\$34,501,843
Net Income	\$ 5,741,394	\$ 5,983,863	\$ 6,220,343

Totals may not sum due to rounding

Furthermore, the projected revenues, operating expenses and number of patient days results in the following net revenue and expense per patient day for the first three operating years.

North Carolina Specialty Hospital Acute Inpatient Services

	(CY2019	CY2020	CY2021
Net Revenue per Patient Day	\$	6,909	\$ 6,908	\$ 6,909
Total Expense per Patient Day	\$	5,699	\$ 5,777	\$ 5,853

In addition, in Form F.3, the applicant provides the projected revenue and expenses for the entire facility, which results in a net income of more than \$12 million in each of the first three years of operation following project completion.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the pro forma financials in Section Q of the application for the assumptions used regarding costs

and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

DUHS. The applicant proposes to develop 96 additional acute care beds for a total of 1,034 acute care beds at DUH.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant states the total capital cost is projected to be as follows:

Project Capital Cost

Site Costs	\$ 29,720
Construction Contract	\$ 19,668,125
Equipment	\$ 5,157,392
Furniture	\$ 2,164,173
Consultant Fees	\$ 295,860
Architect / Engineering Fees	\$ 1,784,730
TOTAL CAPITAL COST	\$ 29,100,000

Exhibit 4 contains a renovation/construction cost estimate prepared by a North Carolina licensed architect, stating that the total cost of the renovation required for the addition of 74 beds is \$19,668,125, as stated on Form F.1a. The first 22 beds to be developed will

fill existing vacated space that does not require any renovation. Exhibit 9 contains the line drawings showing the spaces to be vacated and/or renovated for the proposed beds. In Section F.3, page 69, the applicant states that the project does not involve any working capital because the hospital currently provides inpatient acute care services.

Availability of Funds

In Section F.2, page 68, the applicant states that the capital cost of the project will be funded with accumulated reserves or owner's equity. Exhibit 11 contains a letter dated October 6, 2017 from the Senior Vice President, Chief Financial Officer and Treasurer of DUHS committing up to \$32,000,000 in accumulated reserves to the capital cost of the proposed project. Exhibit 11 also contains the Duke University Health System, Inc. and Affiliates consolidated balance sheet for the years ending June 30, 2017 and 2016. As of June 30, 2017, DUHS had \$181,939,000 in cash and cash equivalents, \$5,641,206,000 in total assets, and \$2,930,216,000 in net assets.

Financial Feasibility

In Section Q, Form F.4 the applicant projects that acute care inpatient operating expenses will exceed revenues in each of the first three full fiscal years of operation following completion of the project, as shown in the table below.

Duke University Hospital Acute Care Beds

	FY2024	FY2025	FY2026
Projected # of Patient Days	308,950	310,495	312,048
Projected Average Charge	\$ 13,142	\$ 13,405	\$ 13,673
Gross Patient Revenue	\$4,060,237,250	\$ 4,162,149,205	\$ 4,266,619,150
Deductions from Gross Patient Revenue	\$2,835,679,927	\$ 2,906,855,493	\$ 2,979,817,566
Net Patient Revenue	\$1,224,557,323	\$ 1,255,293,712	\$ 1,286,801,584
Total Expenses	\$1,366,436,757	\$ 1,407,613,226	\$ 1,450,101,241
Net Income (Loss)	\$(141,879,434)	\$ (152,319,514)	\$ (163,299,657)

Totals may not sum due to rounding

Furthermore, the projected revenues, operating expenses and number of patient days results in the following net revenue and expense per patient day for the first three operating years.

	FY2024	FY2025	FY2026
Net Revenue per Patient Day	\$ 3,964	\$ 4,043	\$ 4,124
Total Expense per Patient Day	\$ 4,422	\$ 4,534	\$ 4,647

As shown in the tables above, the applicant expects its acute care inpatient service to continue to show an operating loss through FY2026. However, Form F.3, Duke

University Health Systems Statement of Revenues & Expenses, projects the system's overall Excess of Revenue over Expenses from Continuing Operations to be \$301,557, \$315,251, and \$329,662 in FY2024, FY2025, and FY2026, respectively. Furthermore, based on a comparison of the applicant's Form F-3 to DUHS Consolidated Statements of Operations (Exhibit 11, page 4), the Project Analyst has reason to believe the figures provided in Form F-3 should have been labeled "in 000's", which would result in the excess of revenue over expenses being \$301,557,000, \$315,251,000, and \$329,662,000 in FY2024, FY2025, and FY2026, respectively.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

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

C – Both Applications

On page 38, the 2017 SMFP states, "An acute care bed's service area is the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1." In Figure 5.1, page 42 of the 2017 SMFP, Durham County and Caswell County are shown as a multicounty acute care bed service area. Thus, in this review, the service area is Durham and Caswell counties. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved acute care inpatient beds located in the multicounty acute care bed service area of Durham and Caswell counties, per page 45 of the 2017 SMFP.

Durham/Caswell Acute Care Bed Service Area

	# of Existing and Approved Acute Care Beds
Duke Regional Hospital	316
Duke University Hospital	924
Duke/Duke Regional Total	1,240
North Carolina Specialty Hospital	18
Total Acute Care Beds	1,258

Source: Table 5A, 2017 SMFP, based on 2015 Truven Data

As the table above indicates, there are three hospitals in the Durham/Caswell service area and a total of 1,258 acute care beds.

Table 5B, page 52 of the 2017 SMFP, identifies a need for 96 additional acute care beds in the Durham/Caswell service area.

NCSH. The applicant does not propose to develop more acute care beds than are determined to be needed in the service area. In Section G, pages 73-74, the applicant discusses why it believes its proposal would not result in the unnecessary duplication of existing or approved services in the Durham/Caswell service area. The applicant states:

"NCSH, as a physician-owned surgical hospital, is different than both Duke Regional and Duke University Hospital. The proposed six additional beds at NCSH will not replicate or diminish the capabilities of Duke Regional and Duke University Hospital to provide inpatient acute care services."

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

- There is a need determination in the 2017 SMFP.
- The applicant adequately demonstrates the need the population proposed to be served has for six additional acute care beds at NCSH in addition to the existing and approved acute care beds.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

DUHS. The applicant does not propose to develop more acute care beds than are determined to be needed in the service area. In Section G, pages 75-78, the applicant discusses why it believes its proposal would not result in the unnecessary duplication of existing or approved services in the Durham/Caswell service area. The applicant states that while the average annual occupancy of 52%-53% at DRH appears low, the hospital's potential capacity is restricted by semi-private beds and facility limitations. The applicant describes DUH as serving a fundamentally different patient population compared to DRH because DUH is a full-service tertiary and quaternary care hospital and Academic Medical Center and DRH is a community hospital. The applicant further states:

"The scope of acute care services at DUH cannot efficiently be duplicated at DRH. Therefore, any available licensed bed capacity at DRH cannot effectively meet the need that DUH has for additional acute care bed capcity."

The applicant states that NCSH is a private, physician-owned medical center, which the applicant states also serves a fundamentally different patient population compared to DUH. Furthermore, the applicant states:

"The scope of acute care services at DUH cannot be replicated at NCSH. Any available licensed bed capacity at NCSH cannot effectively meet the need that DUH has for additional acute care bed capacity."

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

- There is a need determination in the 2017 SMFP.
- The applicant adequately demonstrates the need the population proposed to be served has for 96 additional acute care beds at DUH in addition to the existing and approved acute care beds.

Conclusion

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

(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

NCSH. In Section Q, Form H, page 128 of its application, the applicant provides the proposed staffing for the facility's proposed 24-bed nursing unit in the second full fiscal year of operation (CY2020), as shown in the table below.

Position	Number of Full-Time Equivalent (FTE) Positions
Physician (Hospitalist)	2.50
Registered Nurse	28.00
Licensed Practical Nurse	4.20
Aide/Orderly	14.00
Clerical	1.25
TOTAL	49.95

Source: Form H in Section Q of the application

On page 129, the applicant provides the staffing assumptions and methodology, stating that the projected staffing is based on the 2017 NCSH acute inpatient staffing with incremental additions for the proposed addition of beds. The applicant further states that the level of staffing provides continuous 24 hour coverage for the licensed inpatient beds and includes coverage for staff vacation, holidays and sick time. Exhibit H.1 contains NCSH's Nursing Staffing Plan. In Section H.2, pages 75-78, the applicant describes its experience and process for recruiting and retaining staff and discusses the experience of the physicians from several of the medical groups who will provide services at NCSH. In Section H.4, pages 76-77, the applicant lists the current and projected number of physicians on its medical staff, along with their specialties. Exhibit C.4 contains a letter from the NCSH CEO documenting the hospital's commitment to support physician recruitment. The applicant lists David Musante, MD as the Hospital Medical Director. Exhibit H.4 contains NCSH's Medical Director Agreement. Exhibit C.1 contains support letters from physicians practicing at NCSH.

Conclusion

- application,
- exhibits to the application,

- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

DUHS. In Section Q, Form H, of its application, the applicant provides the proposed incremental staffing for acute inpatient services for the project in the second year of operation (FY2025), as shown in the table below.

	Number of Full-Time
	Equivalent (FTE)
Position	Positions
Physician Assistant	1.90
RN	223.33
Aides/Orderlies	0.32
Cert. Med Assistant	4.20
LPN	0.30
Nurse Practitioner	6.47
Patient Service Associate	8.34
Nursing Assistant	31.53
Social Workers	4.24
Dieticians	3.82
Pharmacists	11.61
Pharmacy Technicians	11.41
Lab Technicians	6.84
Radiology Technologists	27.48
Physical Therapists	5.59
Speech Therapists	1.04
Occupational Therapists	2.24
Respiratory Therapists	15.19
Surgery Technicians	6.48
Surgery CRNA	9.54
Surgery Anes. Tech	3.58
Central Sterile Technicians	8.43
Administrative Manager	10.99
Clerical	15.86
Patient Services	43.49
IT	0.08
Other*	35.72
	500.03

^{*}Includes various positions from different departments

Totals may not sum due to rounding

Source: Form H in Section Q of the application

The assumptions and methodology used to project staffing are provided in Sections H and Q of the application. Adequate costs for health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H.2, page 81, the applicant discusses its process for recruiting and retaining staff. In Section H.4(b), page 84, the applicant states that Lisa Pickett, MD is the Chief Medical Officer for DUH. Exhibit 12 contains a letter from Dr. Pickett documenting her willingness to continue to serve in that capcity at DUH. In Section H.4, page 82, the

applicant states that DUH has 1,968 physicians on the active Medical Staff, as shown on page 83. Supporting documentation is provided in Exhibits 6 and 12.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

C – Both Applications

NCSH. In Section I, pages 79-80, the applicant discusses the necessary ancillary and support services to support the hospital. On page 79, the applicant states,

"NCSH currently has all ancillary and support services in place necessary to support hospital operations. These existing ancillary and support services will also support the six additional beds to be developed as proposed in this application."

The applicant states that it has existing agreements for professional services that include anesthesia, radiology, pathology, physical therapy and occupational therapy. Exhibit I.1 contains documentation of these agreements. Exhibit I.2 contains copies of the facility's transfer agreements with both Rex Hospital and University of North Carolina Hospitals. Exhibit C.1 contains copies of support letters from physicians and surgeons.

Conclusion

- application,
- exhibits to the application,
- written comments,

- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant adequately demonstrates the availability of the necessary ancillary and support services required for the provision of the proposed services, and
- the applicant identifies relationships with the existing medical community, including physicians and hospitals, demonstrating the proposed service will be coordinated with the existing health care system.

DUHS. DUH is a full-service tertiary and quaternary care hospital. In Section I, page 86, the applicant states that DUH will continue to operate as a licensed acute care hospital following completion of the proposed project and has all the necessary ancillary and support services currently available. The applicant further states that DUH is a part of the DUHS which includes inpatient acute care, psychiatric and rehabilitation services, primary care, home health and hospice services; and DUH works closely with Private Diagnostic Clinic, PLLC, which provides a range of specialty physician services across the Triangle.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- the applicant adequately demonstrates the availability of the necessary ancillary and support services required for the provision of the proposed services, and
- the applicant identifies relationships with the existing medical community, including physicians and hospitals, demonstrating the proposed service will be coordinated with the existing health care system.
- (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

The applicants in this review do not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, this criterion 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 applicant is an HMO. Therefore, this criterion 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 – NCSH C – DUHS

NCSH. The applicant proposes to add six additional acute care beds in existing space that was built to meet or exceed acute care bed requirements. The applicant does not

propose to construct new space or renovate existing space. Therefore, Criterion (12) is not applicable to the review of NCSH's application.

DUHS. The applicant proposes to add 96 acute care beds to be developed in phases, with the first 22 beds being developed in existing vacated space that requires no renovation. Exhibit 4 contains a renovation/construction cost estimate prepared by a North Carolina licensed architect, stating that the total cost of the renovation required for the 74 additional beds is \$19,668,125, as stated on Form F.1a. Exhibit 9 contains the line drawings showing the spaces to be vacated and renovated for the proposed beds. In Section K.4, page 91, the applicant explains why it believes that the cost, design and means of construction represents the most reasonable alternative for the proposal, stating:

"DUH's architect has experience in developing hospital facility projects, and worked with hospital staff to design the facility renovation to maintain a cost-effective and energy efficient facility design which enables operational efficiency and enhances the patient experience, thus maximizing the affordability and accessibility of DUH to patients."

On page 91, 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.

On page 92, 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,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of

determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C – Both Applications

The 2017 SMFP (page 2) states, "The SHCC assigns the highest priority to a need methodology that favors providers delivering services to a patient population representative of all payer types in need of those services in the service area."

NCSH. In Section L.1, page 88, the applicant reports the payor mix for the entire facility and for acute care inpatient beds during the last full fiscal year (CY2016), as summarized below.

North Carolina Specialty Hospital Last Full FY 1/1/16-12/31/16 As a Percent of Total Gross Revenue

Payor Source	Entire Facility	Medical/Surgical Inpatient Beds
Self-Pay / Indigent / Charity	1.2%	0.2%
Medicare	43.0%	48.7%
Medicaid	2.8%	1.9%
Commercial Insurance/ Managed Care	46.4%	44.3%
Workers Compensation	4.2%	2.5%
TRICARE	2.4%	2.4%
Total	100.0%	100.0%

Totals may not sum due to rounding

As the table above demonstrates, NCSH served "a patient population representative of all payer types".

In Section C.10, page 56, the applicant states that NCSH consistently serves a wide variety of patient groups and provides the following statistical information the last full fiscal year in comparison to the Durham County population.

	NCSH % of Total Patients	Durham County Population
Women	55.0%	52.3%
65+	45.0%	11.9%
Racial Minorities	32.0%	46.9%

In Section L.3, pages 89-90 the applicant discusses its financial assistance policies regarding patients who are uninsured, ineligible for governmental assistance, with incomes at percentages of the Federal Poverty Level, and the homeless. Exhibit B.10 contains a copy of NCSH's Charity Care policy.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

DUHS. In Section L.1(b), page 100, the applicant provides the payor source for DUH and for the inpatient services provided at DUH for FY2017, as follows:

DUH Historical Payor Mix FY2017			
Payor Source	Entire Facility	Acute Days of Care	
Self-Pay*	1.9%	2.2%	
Medicare	42.3%	44.4%	
Medicaid	18.1%	18.8%	
Insurance	32.6%	31.0%	
Other**	5.0%	3.7%	
Total	100.0%	100.0%	

Totals may not sum due to rounding

As the table above demonstrates, DUH served "a patient population representative of all payer types".

^{*}Includes Charity Care

^{**}Includes Out-of-State Medicaid, Workers Comp, TRICARE, other gov't, other non-gov't

In Section L.1, page 99, the applicant provides the following statistical information on the inpatient groups it served in the last full fiscal year in comparison to the Durham County population.

	DUH % of Total Patients	Durham County Population
Women	52.2%	52.3%
65+	32.4%	11.9%
Racial Minorities	40.8%	57.6%

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

C – Both Applications

NCSH. Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2(b), page 88, the applicant states that the facility is not obligated under any applicable federal regulation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L.3, pages 89-90 the applicant discusses its financial assistance policies regarding patients who are uninsured; ineligible for governmental assistance, with incomes at percentages of the Federal Poverty Level; and the homeless. Exhibit B.10 contains a copy of NCSH's Charity Care policy.

In Section L.2(c), page 88, the applicant states that no civil rights equal access complaints have been filed against the hospital and/or any similar facilities owned by a related entity within the last five years.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- 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.

DUHS. Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 100, the applicant states that DUHS has no obligation under applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons other than those obligations which apply to private, not-for-profit, acute care hospital which participate in Medicare, Medicaid and Title V programs.

On page 101, the applicant states no civil rights access complaints were filed against DUHS in the last five years.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- 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.

(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

NCSH. In Section L of the application, the applicant provides the information required by this criterion. The following table illustrates the projected payor mix for the entire facility, and its acute care inpatient services for the second full fiscal year following completion of the project, CY2020.

North Carolina Specialty Hospital As a Percent of Total Gross Revenue 1/1/20-12/31/20

-,-,-,,-,-				
Payor Source	Entire Facility	Acute Care		
Self-Pay / Indigent / Charity	1.2%	0.2%		
Medicare	43.0%	48.7%		
Medicaid	2.8%	1.9%		
Commercial Insurance/ Managed Care	46.4%	44.3%		
Workers Compensation	4.2%	2.5%		
TRICARE	2.4%	2.4%		
Total	100.0%	100.0%		

Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.2% of total services will be provided to self-pay/charity care patients, 43.0% to Medicare patients and 2.8% to Medicaid patients.

In Section L, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year. On page 89, the applicant states:

"The projected payor percentages are based on the NCSH 2016 Actual Fiscal Year Data. The applicant assumes no changes in the payor percentages for each payor category for future years."

The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant bases future payor mix on historical payor mix, and
- the proposed project does not change the underserved's access to the proposed services.

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,

- responses to comments, and
- 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.

DUHS. In Section L of the application, the applicant provides the information required by this criterion. The following table illustrates the projected payor source for DUH and for the acute care inpatient services provided at DUH for the second full fiscal year of operation following completion of the project, FY2025.

DUH Historical Payor Mix FY2025			
Payor Source	Entire Facility	Acute Days of Care	
Self-Pay*	1.9%	2.2%	
Medicare	44.1%	47.1%	
Medicaid	18.1%	18.8%	
Insurance	30.9%	28.3%	
Other**	5.0%	3.7%	
Total	100.0%	100.0%	

Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.9% of total services will be provided to self-pay/charity care patients, 44.1% to Medicare patients and 18.1% to Medicaid patients.

In Section L, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year. On page 102, the applicant states that DUH projects the inpatient payor mix based on the FY2017 inpatient payor mix, adjusted for a shift of managed care patients to Medicare due to the aging of the population. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant bases future payor mix on the historical adjusted payor mix,
- the proposed project does not change the underserved's access to the proposed services.

- application,
- exhibits to the application,
- written comments,

^{*}Includes Charity Care

^{**}Includes Out-of-State Medicaid, Workers Comp, TRICARE, other gov't, other non-gov't

- remarks made at the public hearing,
- responses to comments, and
- 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.

(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

NCSH. In Section L.5, page 90, the applicant describes the range of means by which a person will have access to its services, including by physician order and referral from other healthcare providers and community organizations. The applicant states that the implementation of Level III emergency services will also expand patient access to NCSH.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- 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.

DUHS. In Section L.5, page 103, the applicant states that access to inpatient services at DUH will continue to be by physician admission, or via admission through the Emergency Department.

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- 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.

(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

NCSH. In Section M.1, page 91, the applicant states that NCSH has existing agreements with clinical training programs at North Carolina Central University, Keiser University, and Lenoir Rhyne University. Exhibit M.1 contains copies of the above clinical training agreements.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

DUHS. In Section M, page 105, the applicant states that as an AMC teaching hospital, DUH serves as a primary teaching location for medical students, residents, fellows, nurses, and other health care professionals. The applicant further states that the proposed project will increase capacity at DUH, and thus will enhance Duke's ability to fulfill its educational mission. The applicant states that members of Duke University Schools of Medicine and Nursing and DUH's staff work closely with faculties of other schools and universities, community colleges and clinics in the area to provide health professional training programs including specialized training.

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

C – Both Applications

On page 38, the 2017 SMFP states, "An acute care bed's service area is the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1." In Figure 5.1, page 42 of the 2017 SMFP, Durham County and Caswell County are shown as a multicounty acute care bed service area. Thus, in this review, the service area is Durham and Caswell counties. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved acute care inpatient beds located in the service area of Durham and Caswell counties, per page 45 of the 2017 SMFP.

Durham/Caswell Acute Care Bed Service Area

	# of Existing and Approved Acute Care Beds
Duke Regional Hospital	316
Duke University Hospital	924
Duke/Duke Regional Total	1,240
North Carolina Specialty Hospital	18
Total Acute Care Beds	1,258

Source: Table 5A, 2017 SMFP, based on 2015 Truven Data

As the table above indicates, there are three hospitals in the Durham/Caswell service area and a total of 1,258 acute care beds.

Table 5B, page 52 of the 2017 SMFP, identifies a need for 96 additional acute care beds in the Durham/Caswell service area.

NCSH. The applicant proposes to add six acute care inpatient beds for a total of 24 acute care inpatient beds. The applicant does not propose to develop more acute care beds than are determined to be needed in the service area. The applicant adequately demonstrates the need the population proposed to be served has for the six additional acute care beds at NCSH.

In Section N of the application, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

The applicant states:

"The proposed project will enhance competition because NCSH needs additional licensed bed capacity to provide timely patient admissions in response to the growth of the medical staff, the offering of more medical and surgical services and the implementation of Level III emergency services.

...

NCSH is committed to achieve cost effectiveness and maximize healthcare value based on multiple strategies.

...

This NCSH project will promote patient safety and quality in the delivery of healthcare services through its continued compliance with accreditation standards, as well as NCSH's Competency Assessment Policy, Performance Improvement Program Utilization Management Plan, and Risk Management Program and Safety Policies.

. . .

North Carolina Specialty Hospital complies with applicable federal civil rights laws and does not discriminate on the Basis of race, color, national origin, religion, age, disability, or sex.

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

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

DUHS. The applicant proposes to add 96 acute care beds for a total of 1,034 acute care beds at DUH. The applicant does not propose to develop more acute care beds than are determined to be needed in the service area. The applicant adequately demonstrates the need the population proposed to be served has for the proposed additional acute care beds at DUH.

In Section N, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

The applicant states:

"Addition of acute care beds represents increased economy of scale and efficiency. Therefore, DUH will be able to most cost-effectively increase its inpatient capacity.

...

DUH is committed to delivering high-quality care, and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its illustrious history of providing patients care. DUH has 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.

. . .

... DUH 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."

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

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

C – Both Applications

NCSH. In Section O.3(a), page 96, the applicant states that NCSH is the only acute care hospital in North Carolina that is owned, operated or managed by the applicant and its related entities. The applicant states:

"At no time during the 18 month look-back period has NCSH been determined by the Division of Health Service Regulation or the Centers for Medicare and Medicaid Services to have operated out of compliance with any Medical Conditions of participation. No survey deficiencies have been noted for NCSH."

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred at NCSH during the 18 months immediately preceding the submittal of the application through the date of the decision. 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, the

applicant provided sufficient evidence that quality care has been provided in the past and adequately demonstrated that there is no pattern of substandard quality of care. Therefore, the application is conforming to this criterion.

DUHS. In Section O.3, page 110, the applicant states that the healthcare facilities owned by Duke University Health System include Duke University Hospital. Duke Raleigh Hospital, Duke Home Health, Duke Home Infusion, Duke Hospice (Durham office), Duke Hospice (Raleigh office), Hock Family Pavilion, and Duke Hospice at the Meadowlands. Duke University Health System also leases and operates Duke Regional Hospital. On page 111, the applicant states:

"No Duke facilities have been out of compliance with any Medicare Conditions of Participation during the 18 months prior to submission of this CON application."

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred at any of three hospitals owned and/or operated by DUHS during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 nine facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C- Both Applications

The Criteria and Standards for Acute Care Beds, promulgated in 10A NCAC 14C.3800, are applicable to this review. The specific criteria are discussed below.

SECTION .3800 - CRITERIA AND STANDARDS FOR ACUTE CARE BEDS

.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.
- -C- **NCSH** In Section C.11(b), pages 58-59, and Section Q, pages 99 and 102-109, the applicant provides the projected utilization, methodology and assumptions for the proposed 24 acute care beds for the first three years following completion of the project, as summarized in the following table.

North Carolina Specialty Hospital Projected Utilization (CY2019-CY2021)

Trojected Chiletton (C1201) C12021)			
	PY 1 CY2019	PY 2 CY2020	PY 3 CY2021
Number of Acute Care Beds	24	24	24
Number of Discharges	1,847	1,988	2,076
Number of Patient Days	4,747	5,287	5,894
Average Daily Census	13	14	16
Percent Occupancy	54.19%	60.35%	67.29%

Totals may not sum due to rounding

As shown in the above table, the applicant projects that NCSH will provide 5,894 patient days of care at 67% occupancy in the third operating year (CY2021), which exceeds the utilization standard of 66.7%, as required in 10A NCAC 14C .3803(a) when the ADC is less than 100 patients.

-C- **DUHS** - In Section C.9(c), page 54, and Section Q, the applicant provides the projected utilization for Duke University Hospital as summarized below.

Duke University Hospital Projected Acute Care Bed Utilization (FY2024-FY2026)

	PY1 FY2024 (7/1/23-6/30/24)	PY2 FY2025 (7/1/24-6/30/25)	PY3 FY2026 (7/1/25-6/30/26)
Number of Beds	1,034	1,034	1,034
Number of Discharges	46,705	46,939	47,174
Number of Patient Days	308,896	310,440	311,993
Average Daily Census	846	851	855
Percent Occupancy	81.8%	82.3%	82.7%

As shown in the above table, the applicant projects that DUH will provide 311,993 patient days of care at 83% occupancy in the third operating year (FY2026), which exceeds the utilization standard of 75.2%, as required in 10A NCAC 14C .3803(a) when the ADC is greater than 200 patients.

- (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.
- -C- **NCSH.** See Section Q, Form C, page 99, and pages 102-109. The applicant's assumptions and data used to project utilization support the projected utilization, average daily census, and percent of occupancy.
- -C- **DUHS.** See Section Q, pages 114-120 and Form C. The applicant's assumptions and data used to project utilization support the projected utilization, average daily census, and percent of occupancy.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2017 State Medical Facilities Plan, no more than 96 new acute care beds may be approved for the Durham/Caswell multicounty acute care bed services area in this review. Because the two applications in this review collectively propose 102 new acute care beds, both applications cannot be approved as proposed. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst also conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, both applications are conditionally approved: the application submitted by North Carolina Specialty Hospital, Project I.D. J-11422-17, is conditionally approved to develop six acute care beds and the application submitted by Duke University Health Systems, Inc., Project I.D. J-11426-17, is conditionally approved to develop 90 acute care beds.

Conformity with Applicable Statutory and Regulatory Review Criteria

Both applications are conforming or conditionally conforming with the Review Criteria as discussed throughout the Findings. Therefore, with regard to conformity with the Review Criteria, the two proposals are comparable.

Geographic Accessibility

The 2017 SMFP identifies the need for 96 new acute care beds in the Durham/Caswell service area. The following table identifies the three existing acute care hospitals in the service area, their location and number of existing acute care beds.

Durham/Caswell Acute Care Bed Service Area

		# of Existing and Approved Acute Care Beds
Duke Regional Hospital	3643 N. Roxboro St, Durham	316
Duke University Hospital	2301 Erwin Road, Durham	924
Duke/Duke Regional Total		1,240
North Carolina Specialty Hospital	3916 Ben Franklin Blvd, Durham	18
Total Durham/Caswell Service Area		1,258

All three of the existing acute care hospitals are located in the city limits of Durham, within a five mile radius of each other. Neither applicant proposes to expand geographic access to acute care services in Durham County or the Durham/Caswell service area by developing acute care services in a new location within the service area. Therefore, because both applicants propose to locate additional acute care beds at their existing hospitals in Durham, the two applications are comparable with regard to geographic access.

Demonstration of Physician Support

NCSH. In Section H, pages 75-78, the applicant discusses the current and projected number of physicians on its medical staff, along with their specialties. The applicant lists 154 physicians in 17 specialties that are on the current medical staff and projects the medical staff will grow by 26 physicians over the next three years. Exhibit C.1 contains 41 physician support letters.

DUHS. In Section H.4, pages 82-83, the applicant provides a table showing DUH currently has 1,968 physicians on its active Medical Staff providing services in 17 listed specialties. Exhibit 12 contains support letters for the proposed project from DUHS' physicians and area hospitals. The applicant discusses attention to physician demand/supply and recruitment, as needed on page 84.

Both applications document adequate physician support of their proposed projects. Therefore, with regard to demonstration of physician support, the two proposals are comparable.

Patient Access to a Broad Range of Medical and Surgical Specialties

NCSH. In Section B.1, page 15, the applicant states that the hospital currently provides medical and surgical services on a daily basis in 15 of the 25 major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services, including diseases and disorders of the following systems: nervous, eye, ear, nose, mouth and throat, respiratory, circulatory, digestive, hepatobiliary and pancreas, musculoskeletal and connective tissue, skin, subcutaneous tissue and breast, endocrine, nutritional and metabolic, kidney and urinary tract, male reproductive, female reproductive, myeloproliferative and poorly differentiated neoplasms, and infectious and parasitic diseases.

In Section C.1, page 28, the applicant states that its licensed acute care beds will serve medical and surgical patients including, "orthopedics ophthalmology, ear, nose and throat, sports medicine, oral, podiatry, general, bariatric, interventional radiology, pain management, plastic and reconstructive surgery, neurosurgery, gynecology, and vascular procedures."

DUHS. In Section B.1, page 12, the applicant states that DUH provides medical and surgical services on a daily basis in all of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services, including obstetrics, neonatal and pediatric services, and seven other specialties.

In Section C.1, page 28, the applicant states, "The proposed 96 new general acute care beds will serve the needs of DUH's adult routine and intermediate patient population throughout its various existing service lines."

Both applications document intent to serve patients across a broad spectrum of medical and surgical specialties, with DUHS stating a limitation to its adult routine and intermediate patient population. Both applicants propose that patients from Durham and Wake counties make up approximately 30% and 12%, respectively, of the proposed patients to be served, with the same five counties making up the next highest percentage of patients served at each facility. Thus, approximately the same service area patients appear to have the same percent access to the proposed services. Therefore, with regard to demonstration of patient access to a broad range of medical and surgical specialties, the two proposals are comparable.

Access by Underserved Groups

Underserved groups is defined in Criterion (13), as:

"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."

The 2017 SMFP (page 2) states, "The SHCC assigns the highest priority to a need methodology that favors providers delivering services to a patient population representative of all payer types in need of those services in the service area."

The following table shows each applicant's percentage of care currently provided to women, persons 65 and older and racial minorities, as compared to the percentages of services provided.

Percent of All Patients Served Last Full Year

Applicant	Women	65 and Older	Racial Minorities		
NCSH	55%	45%	32%		
DUHS	52%	32%	41%		

Sources: Section L.1 of each application

As shown in the table above, NCSH projects serving the higher percentage of women and persons 65 and older, while DUHS projects the higher percentage of racial minorities served.

Medicare

The following table shows each applicant's total number of projected acute care patient days and the percent of days projected to be provided to Medicare recipients in the second full year of operation following completion of each of the projects, CY2020 for NCSH and FY2025 for Duke, based on the information provided in each applicant's pro forma financial statements.

Projected Medicare Days of Care Year Two Following Project Completion

Applicant	Operating Year 2	Total Patient Days of Care	Total Medicare Days of Care	Percentage of Medicare Days	
NCSH	2020	5,287	2,575	48.7%	
DUHS	2025	310,495	146,272	47.1%	

Source: Form F.5 of each application

As shown in the table above, NCSH projects the higher percentage of Medicare days of care as a percent of total patient days of care.

Medicaid

The following table shows each applicant's total number of projected acute care patient days and the percent of days projected to be provided to Medicaid recipients in the second full year of operation following completion of each of the projects, CY2020 for NCSH and FY2025 for Duke, based on the information provided in each applicant's pro forma financial statements.

Year Two Following Project Completion

Applicant	Operating Year 2	Total Patient Days of Care	Total Medicaid Days of Care	Percentage of Medicaid Days	
NCSH	2020	5,287	100	1.9%	
DUHS	2025	310,495	58,363	18.8%	

Source: Form F.5 of each application

As shown in the table above, DUHS projects the higher percentage of Medicaid days of care as a percent of total days of care.

Charity Care / Bad Debt

Both applicants consider charity care and bad debt allowances as reductions to gross revenue in the calculation of net patient revenue, per Form F.5 of each application. Charity care and bad debt are often self-pay write-offs, or uncollectable self-pay charges. NCSH includes charity care in its total bad debt write off of 0.62% percent of gross revenues. DUHS calculates charity care and bad debt as 2.8% and 0.49% of gross revenue, respectively, and are included in the payor contractual adjustments in the income statement. A direct comparison of charity care and bad debt as presented by the applicants cannot be made. The following calculations add DUH's charity care and bad debt together in order to compare the total amount of charity care and bad debt provided by both applicants per patient day of care.

Projected Charity Care/Bad Debt as a Percent of Patient Days of Care Year Two Following Project Completion

Applicant	Operating Year 2	Total Patient Days of Care	Total Charity Care / Bad Debt	Charity Care/Bad Debt Per Patient Day
NCSH	2020	5,287	\$ 481,828	\$ 91
DUHS	2025	310,495	\$ 140,264,428	\$ 452

Source: Forms F.4 and F.5 of each application

As is shown in the table above, DUHS projects the higher charity care / bad debt combination per patient day of care.

However, the two hospitals differ in several characteristics that significantly affect the comparison of the applications to one another. For example, DUH is currently licensed for 938 acute care beds and NCSH is licensed for 18 acute care beds, or 1.9% of DUH's capacity. In the third year of operations following completion of the projects, DUHS is projecting 312,048 acute days of care at DUH; NCSH is projecting 1.9% of that number or 5,894 acute days of care. DUHS projects its third year of operation following completion of its project to be FY2026, beginning July 1, 2025; NCSH projects its third year of operation following completion of its project to be CY2021, beginning a full four and one-half years earlier than DUHS. DUH is an Academic Medical Center Teaching Hospital; NCSH is not.

DUH provides the typically high Medicaid services of obstetrics, neonatal and pediatrics; NCSH does not. Further, DUH is a full-service tertiary and "quaternary care referral center that serves patients from all over North Carolina, the Southeast, and beyond. ... Duke is routinely referred patients from across the state and region for specialized and/or complex acute care services." (page 89 of the DUHS application) Because of these significant differences, a comparison of the two applications with regard to the care provided to underserved groups is inconclusive. Thus, this comparative factor may be of little value.

Acute Care Inpatient Charges

The following table shows the projected average gross and net revenue per acute days of care in the third year of operation following completion of each project, based on the information provided in the applicants' pro forma financial statements.

Revenue per Acute Days of Care Third Operating Year Following Project Completion

	NCSH CY2021			DUHS FY2026				
	Gross Revenue Net Revenue		Gro	ss Revenue	Revenue Net Revenue			
Patient Revenue	\$	86,648,480	\$	40,722,186	\$ 4	,266,619,150	\$	1,286,801,584
Days of Care		5,894		5,894		312,048		312,048
Revenue/Days of Care	\$	14,701	\$	6,909	\$	13,673	\$	4,124

Source: Pro Forma Financials of each application

Totals may not sum due to rounding

As shown in the table above, DUHS projects the lower average gross and net revenue. However, the two hospitals differ in several characteristics that could significantly affect the comparison of the applications to one another. For example, DUH is currently licensed for 938 acute care beds and NCSH is licensed for 18 acute care beds, or 1.9% of DUH's capacity. In the third year of operations following completion of the projects, DUHS is projecting 312,048 acute days of care at DUH; NCSH is projecting 1.9% of that number or 5,894 acute days of care. DUHS projects its third year of operation following completion of its project to be FY2026, beginning July 1, 2025; NCSH projects its third year of operation following completion of its project to be CY2021, beginning a full four and one-half years earlier than DUHS. DUH is an Academic Medical Center Teaching Hospital and NCSH is not. Further, DUH is a full-service tertiary and "quaternary care referral center that serves patients from all over North Carolina, the Southeast, and beyond. ... Duke is routinely referred patients from across the state and region for specialized and/or complex acute care services (page 89 of the DUHS application)." Revenue from surgical and ancillary services is not included in DUH's revenue projections; surgical and ancillary revenue is included in NCSH's revenue projections. The comparison of hospital charges per inpatient day could be affected by the differences in presentation of revenues, differences in volumes; differences in medical and surgical subspecialties and critical care for trauma patients; the extent to which DUH provides teaching and medical education activities; as well as the differences in reimbursement agreements that a hospital system of the size and influence of DUHS can command. Because of these significant differences, a comparison of the two applications

with regard to acute care inpatient charges is inconclusive. Thus, this comparative factor may be of little value.

Acute Care Inpatient Operating Expense

The following table compares the projected average operating expense per acute days of care in the third year of operation following completion of each project, based on the information provided in the applicants' pro forma financial statements.

Operating Expense per Patient Days of Care Third Operating Year Following Project Completion

	NCSH Y2021	DUHS FY2026		
Inpatient Operating Expense	\$ 34,501,843	\$ 1,43	50,101,241	
Inpatient Days	5,894		312,048	
Operating Expense/Patient Days of Care	\$ 5,853	\$	4,647	

Source: Pro Forma Financials of each application

Totals may not sum due to rounding

As shown in the table above, DUHS projects the lower average operating expense per acute care patient days of care in the third operating year. However, the two hospitals differ in several characteristics that could significantly affect the comparison of the applications to one another. For example, DUH is currently licensed for 938 acute care beds and NCSH is licensed for 18 acute care beds, or 1.9% of DUH's bed capacity. In the third year of operations following completion of the projects, DUHS is projecting 312,048 acute days of care at DUH; NCSH is projecting 1.9% of that number or 5,894 acute days of care. DUHS projects its third year of operation following completion of its project to be FY2026, beginning July 1, 2025; NCSH projects its third year of operation following completion of its project to be CY2021, beginning a full four and one-half years earlier than DUHS. DUH is an Academic Medical Center Teaching Hospital and NCSH is not. Further, DUH is a fullservice tertiary and "quaternary care referral center that serves patients from all over North Carolina, the Southeast, and beyond. ... Duke is routinely referred patients from across the state and region for specialized and/or complex acute care services." (Page 89 of the DUHS application). Expenses for surgical and ancillary services are not included in DUH's expense projections, while both are included in NCSH's expense projections. The comparison of hospital costs per inpatient day could be affected by the differences in presentation of expenses, differences in volumes; differences in medical and surgical subspecialties and critical care for trauma patients; the extent to which DUH provides teaching and medical education activities; as well as the differences in buying contracts that a hospital system of the size and influence of DUHS can negotiate. Because of these significant differences, comparison of the two applications with regard to acute care inpatient operating costs is inconclusive. Thus, this comparative factor may be of little value.

SUMMARY

As discussed in the comparative analysis above, with regard to conformity with Review Criteria, geographic accessibility, physician support, and patient access to a broad range medical and surgical specialties, the two applications are comparable. Furthermore, because of the significant differences in the number of inpatient beds operated by the applicants, the differences in the number of beds being proposed, the differences is the acuity level of care provided, the number of years between the third full operating year after completion of the two projects, and the differences in the reimbursement/buying negotiating power, comparisons with regard to access to the underserved, projected average charges per inpatient day, and projected average operating expense per inpatient day are inconclusive and of little value.

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.

NCSH. In Section A.10, page, the applicant states:

"As a physician-owned medical facility, NCSH has the means to provide specialized care and resources to best fit the needs of all patients."

In Section C, the applicant states that it is a surgical specialty hospital with the majority of its surgeries being orthopedic and spinal. On page 36, the applicant further states:

"Unlike the two neighboring hospitals in Durham County, NCSH does not provide obstetrics and neonatal inpatient acute care. Therefore, the NCSH patient population includes a larger percentage of older adults."

In Section G, page 74, the applicant states:

"NCSH, as a physician-owned surgical hospital, is different than both Duke Regional and Duke University Hospital. The proposed six additional beds at NCSH will not replicate or diminish the capabilities of Duke Regional and Duke University Hospital to provide inpatient acute care services."

DUHS.

Throughout its application and in its comments at the public hearing, the applicant states that DUHS is a not-for-profit health system with DUH being a full-service tertiary and quaternary care hospital and academic medical center / teaching hospital, composed of a network of over 2,500 physicians offering almost every medical and surgical specialty.

In Section G, page 78, the applicant states:

"DUH serves a fundamentally different patient population compared to NCSH. The scope of acute care services at DUH cannot be replicated at NCSH."

CONCLUSION

Both applications proposing to add acute care beds are individually conforming to the need determination in the 2017 SMFP for 96 additional acute care beds in the Durham/Caswell multicounty acute care bed service area. However, N.C. Gen. Stat. §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 Certificate of Need Section. Therefore, given all of the above factors, the Agency determines that NCSH should be approved to develop six additional acute care beds and DUHS should be approved to develop 90 additional acute care beds, for a total of 96 new acute care beds in the Durham/Caswell service area. The approval of both applications, as conditioned, provides access to a broader base of patients and projects the availability of 28 acute care beds (six for NCSH and DUH's initial 22 beds) by January 1, 2019, making more acute care beds operational sooner than the approval of either application alone. The decision also promotes competition and enhances patient choice in the service area.

The application submitted by NCSH is approved subject to the following conditions.

- 1. North Carolina Specialty Hospital, LLC shall materially comply with all representations made in the certificate of need application.
- 2. North Carolina Specialty Hospital, LLC shall acquire shall develop no more than six additional acute care beds for a total of 24 acute care beds.
- 3. North Carolina Specialty Hospital, LLC as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, North Carolina Specialty Hospital, LLC 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.

5. North Carolina Specialty Hospital, LLC 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.

The application submitted by DUHS is approved subject to the following conditions.

- 1. Duke University Health System, Inc. d/b/a Duke University Hospital shall materially comply with all representations made in the certificate of need application.
- 2. Duke University Health System, Inc. d/b/a Duke University Hospital shall acquire shall develop no more than 90 additional acute care beds for a total of 1,028 acute care beds.
- 3. Duke University Health System, Inc. d/b/a Duke University Hospital as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Duke University Health System, Inc. d/b/a Duke University Hospital 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.
- 5. Duke University Health System, Inc. d/b/a Duke University Hospital 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.
- 6. Duke University Health System, Inc. d/b/a Duke University Hospital 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.