December 1, 2017

Celia Inman, Project Analyst
Health Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Comments on Durham County Acute Care Bed CON Applications

Dear Ms. Inman:

Enclosed please find comments prepared by Duke University Health System regarding the competing CON application by North Carolina Specialty Hospital to develop new acute care beds in Durham County, pursuant to the need identified in the *2017 State Medical Facilities Plan*. We trust that you will take these comments into consideration during your review of both applications.

If you have any questions about the information presented here, please feel free to contact me at (919) 668-0857. I look forward to seeing you at the public hearing.

Sincerely,

Catharine W. Cummer

Catharine W. Cummer
Regulatory Counsel, Strategic Planning

COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS
DURHAM COUNTY ACUTE CARE BEDS

Submitted by Duke University Health System
December 1, 2017

Two applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2017 State Medical Facilities Plan (SMFP)* for 96 additional acute care beds in Durham County; Duke University Hospital (DUH) and North Carolina Specialty Hospital (NCSH). In accordance with N.C.G.S. §131E-185(a.1)(1), this document includes comments relating to the representations made by NCSH, and a discussion about whether the material in their application complies with the relevant review criteria, plans, and standards. These comments also address the determination of which of the two competing proposals represents the most effective alternative for development of additional acute care beds in Durham County.

Specifically, the Healthcare Planning and Certificate of Need Section, in making the decision, should consider several key issues, including the extent to which each proposed project:

(1) Represents the most effective alternative for development of the need-determined acute care beds;
(2) Demonstrates conformity with applicable review criteria and standards;
(3) Reasonably demonstrates the need the population has for the proposed services;
(4) Does not represent unnecessary duplication of existing services; and
(5) Maximizes healthcare value in the delivery of health care services.

The Agency typically performs a comparative analysis when evaluating applications in a competitive batch review. The purpose is to help identify the proposal that would bring the greatest overall benefit to the community. The table on the following page summarizes 13 objective metrics that the Agency should use for comparing the two applications in this Durham County acute care bed batch review.

Durham County Acute Care Bed Batch Review
Application Comparative Analysis

Metrics		
Comparative	**DUH**	**NCSH**
Enhance Market Competition	No change	No change
Improve Geographic Access	No change	No change
Meeting Need for Additional Acute Care Beds	82.1% occupancy rate last full fiscal year, FY2016	55.1% occupancy rate last full fiscal year, CY2016
Demonstration of MD Support	Yes	Yes
Operational Date	7/1/2018	1/1/2019
Patient Access to Medical & Surgical Specialties	All major diagnostic categories	Post-surgical only, plus limited # of major diagnostic categories
PY2 Gross Revenue/Patient Day	$13,407	$14,699
PY2 Net Revenue/Patient Day	$4,044	$6,908
PY2 Operating Cost/Patient Day	$4,534	$5,776
Self-Pay/Charity Care %	2.20%	0.20%
Medicare %	47.10%	48.70%
Medicaid %	18.80%	1.90%
RN Salary	$89,056	$75,491

Rankings		
Comparative	**DUH**	**NCSH**
Enhance Market Competition	1	1
Improve Geographic Access	1	1
Meeting Need for Additional Acute Care Beds	1	2
Demonstration of MD Support	1	1
Operational Date	1	2
Patient Access to Medical & Surgical Specialties	1	2
PY2 Gross Revenue/Patient Day	1	2
PY2 Net Revenue/Patient Day	1	2
PY2 Operating Cost/Patient Day	1	2
Self-Pay/Charity Care %	1	2
Medicare %	2	1
Medicaid %	1	2
RN Salary	1	2
Average	**1.08**	**1.69**
Total	**14**	**22**

Based on this comparative analysis, which shows DUH ranks more favorably (lower average) on the head-to-head comparison, and considering that the DUH application conforms to the Review Criteria and best achieves the Basic Principles of the 2017 SMFP (Policy Gen-3), DUH represents the most effective alternative for development of the need-determined acute care beds in Durham County.

Comparative Analysis

Meeting the Need for Additional Acute Care Beds

The 2017 SMFP includes tiered target occupancy rates for acute care beds based on average daily census. Specifically, for hospitals with an average daily census of less than 100 inpatients, the target occupancy rate is 66.7%; for hospitals with an average daily census of 100 to 200 inpatients, the target occupancy rate is 71.4%; for hospitals with an average daily census of more than 200 but less than 400 inpatients, the target occupancy rate is 75.2%; and for hospitals with an average daily census of more than 400 inpatients, the target occupancy rate is 78.0%. According to the 2017 SMFP, in FFY2015, DUH had an average daily census of more than 400. Thus, its target occupancy rate is 78.0%. NCSH had an average daily census of less than 100 inpatients, therefore its target occupancy rate is 66.7%.

As shown below, Table 5A of the 2017 SMFP indicates that Durham County is projected to have a deficit of 96 acute care beds in 2019. DUH is projected to have a deficit of 145 beds, Duke Regional Hospital (DRH) is projected to have a surplus of 49 beds and NCHS is projected to have a surplus of two (2) beds.

2017 SMFP, Table 5A Acute Care Bed Need Projections

Facility Name	Licensed Acute Care Beds	2015 Acute Care Days	Projected 2019 Acute Care Days	2019 Projected ADC	2019 Adjusted for Target Occupancy	Projected 2019 Deficit or (Surplus)
Duke University Hospital	924*	272,459	304,873	835	1,069	145
Duke Regional Hospital	316	62,280	69,689	191	267	-49
DUH/DRH Total		334,739	374,452	1,026	1,336	**96**
North Carolina Specialty Hospital	18	3,580	4,006	11	16	-2

*The 924 beds reported for DUH in the planning inventory in the SMFP does not include 14 NICU beds developed pursuant to Policy AC-3

Source: 2017 SMFP

As shown in the table on the previous page, of the two competing applicants that propose to add acute care beds, DUH is the only one projected to have a deficit (145 beds) in 2019 (per the 2017 SMFP). NCSH is projected to have a surplus of two (2) beds by 2019.

Upon CON approval by the Agency, DUH would immediately develop 22 of the proposed new 96 acute care beds in existing spaces within the hospital (July 1, 2018). The remainder of the beds will be developed in phases. NCSH projects its project will be complete such that CY2019 will be the first operating year; however, NCSH proposes to develop only six (6) additional acute care beds.

With regard to meeting a need for additional beds, the application submitted by DUH is the most effective alternative because a) DUH is the only applicant projected to have a deficit of acute care beds (145 beds) by 2019 and b) DUH will develop a larger complement of acute care beds that will be available to service area residents as early as July 1, 2018.

Access for Medically Underserved

Medicaid Access

A key factor in considering the relative accessibility of the alternative proposals is the extent to which each applicant expands access to the medically underserved, particularly self-pay/indigent/charity patients and Medicaid recipients. Generally, the application proposing to serve the higher percent of total patients who are self-pay and Medicaid patients is the more effective alternative with regard to this comparative factor. The table below summarizes the projected self-pay and Medicaid payor mixes for the competing applicants.

Projected Medicaid Payor Mix, PY2

Payor Type	DUH	NCSH
Self-pay/ charity/indigent	2.2%	0.2%
Medicaid	18.8%	1.9%
Combined	**21.0%**	**2.1%**

Source: CON Applications

As indicated in the table, in terms of access for the medically underserved self-pay and Medicaid populations, DUH's proposal represents the most effective alternative, as DUH projects to serve a far greater percentage of both self-pay/charity/indigent patients and Medicaid recipients.

Medicare Access

DUH projects to serve a substantial Medicare percentage, comparable to the NCSH Medicare percentage, as shown on the table below.

Projected Medicare Payor Mix, PY2

Payor Type	DUH	NCSH
Medicare	**47.1%**	**48.7%**

Source: CON Applications

What is not reflected in the Medicare payor mix percentage is the volume of patients projected to be served. Notably, DUH proposes to serve the greatest number of Medicare patients of the competing applications, i.e. over 145,000 patient days in Project Year 2, compared to 2,575 patient days in Project Year 2 for NCSH.

In summary, DUH's proposal for service to self-pay/charity/indigent, Medicaid and Medicare recipients will provide the best and most appealing projection of access for medically underserved patients of the competing proposals. Therefore, the DUH application is the most effective alternative with respect to access.

Maximize Healthcare Value

Average Charges, Reimbursement and Cost per Patient Day

An essential issue to consider when evaluating the competing applications is the extent to which each proposed project represents a cost-effective alternative for development of additional acute care beds. In the current healthcare marketplace, where cost of care is a major concern with payors and consumers, the projected average charges, average

reimbursement and average cost per patient day are all important measures of healthcare value. In this Durham County batch review, DUH projects the lowest charges and costs, with lower gross charges, lower average reimbursement, and lower average costs per patient day than NCSH. Please see the following tables.

Projected Average Charge per Patient Day*

Project Year	DUH	NCSH
1	$13,144	$14,701
2	$13,407	$14,699
3	$13,675	$14,701

Source: CON Applications
*Reflects only technical charges.

Projected Average Reimbursement per Patient Day*

Project Year	DUH	NCSH
1	$3,964	$6,909
2	$4,044	$6,908
3	$4,124	$6,909

Source: CON Applications
*Reflects only technical charges.

Projected Average Cost per Patient Day

Project Year	DUH	NCSH
1	$4,424	$5,700
2	$4,534	$5,776
3	$4,648	$5,854

Source: CON Applications

This comparative analysis demonstrates DUH's commitment to competitive pricing and greater cost-effectiveness. In Project Year 3, NCSH projects average reimbursement per patient day 68 percent higher than DUH, and a 26 percent higher average cost per patient day. Clearly, DUH most effectively satisfies the value requirement of Policy GEN-3, and is a comparatively superior application.

Quality in Delivery of Services

Clinical Staff Salaries

In recruitment and retention of high quality clinical personnel, salaries are a significant factor. Both applicants provided salary information in Form H. As the largest employer in Durham County, DUH has long demonstrated that its clinical staff salaries are competitive in the local marketplace.

RN, LPN & Nurse Aide Salaries, YR 2

	DUH	NCSH
Registered Nurse	$89,056	$75,491
LPN	$54,465	$58,777
Nurse Aide	$47,403	$31,909

Source: CON Applications

Specific comments regarding the NCSH application

Comments specific to Criterion 3

NCSH does not demonstrate the need it has for additional acute care beds. As indicated in Form C, Section Q, NCSH's occupancy rate during CY2016 was only 55.13% which is well below the SMFP target occupancy rate of 66.7% for hospitals with less than 100 ADC. Even with the addition of 12 physicians to its Medical Staff during CY2017 (see page 29 of NCSH application), NCSH's CY2017 annualized occupancy rate is just 58.42%, still well below the SMFP target occupancy rate of 66.7%. In addition, NCSH has several deficiencies in the specific methodology and assumptions it used to project acute care utilization.

Acute Care Discharges

NCSH's assumption that patient discharges are projected to increase by six percent annually is not reasonable and is not supported by the applicant's historical experience. On page 102 of its application NCSH states, "*[H]ospital admissions and discharges are projected to increase at six percent annually in the future years (2018 through 2021) due the [sic] strong growth of the medical staff and the planned implementation of Level III Emergency Services.*" Based on a review of recent NCSH Medical Staff additions and annual NCSH discharge data, there is not a direct correlation associated with additions to the NCSH Medical Staff and increased acute care discharges. Please see the following table.

North Carolina Specialty Hospital
Comparison of Medical Staff Additions & Patient Discharges

	2014	2015	2016	2017
NCSH Medical Staff Additions (page 43 NCSH CON application)	6	15	17	19
NCSH FFY Discharges Obtained from License Renewal Applications	1,692	1,607	1,644	Data not available
NCSH CY Discharges Obtained from NCSH CON Application, From C	Data not available	1,568	1,651	1,644

The data in the previous table indicates there is not a direct correlation between Medical Staff Additions and patient discharges at NCSH. For example, from 2014 to

2016 NCSH increased its Medical Staff by a total of 38 physicians (6 + 15 + 17); however, the number of patient discharges actually decreased during the same time period (FY2014: 1,692; FY2016 1,644). Furthermore, based on annualized 2017 data, NCSH anticipates it will experience a decrease in patient discharges (1,644) compared to the prior year, despite the addition of 19 physicians to the medical staff in 2017. Therefore, the mere addition of physicians to the NCSH Medical Staff is not sufficient evidence to support the projected annual growth of patient discharges at NCSH by six percent. NCSH failed to provide any historical information regarding the historical acute care patient utilization or inpatient surgical utilization for the physicians who have recently and/or will soon join the NCSH Medical Staff. Furthermore, NCSH projects only 42 ED admissions in 2021, which is insufficient to support the aggressive annual growth rate. For these reasons, NCHS's projected patient discharge growth rate of six percent is not supported.

Average Length of Stay

NCSH's assumption that average length of stay (ALOS) is projected to increase by five percent annually is unreasonable and is not supported by the applicant's historical experience. On page 103 of its application NCSH states, "*NCSH reasonably expects that the growth in the medical staff combined with the aging population will support continued increases in the complexity of nursing care in future years…The aging of the population and the expansion of NCSH supports further increases in patient acuity.*"

North Carolina Specialty Hospital
Comparison of Medical Staff Additions & Patient Average Length of Stay

	2014	**2015**	**2016**	**2017**
NCSH Medical Staff Additions (page 43 NCSH CON application)	6	15	17	19
NCSH FY Discharges Obtained from License Renewal Applications	1,692	1,607	1,644	Data not available
NCSH FY Days of Care Obtained from License Renewal Applications	4,084	3,727	3,690	Data not available
NCSH FY ALOS Obtained from License Renewal Applications (FY Days of Care ÷ FY Discharges)	**2.41**	**2.32**	**2.24**	Data not available
NCSH CY ALOS Obtained from CON Application, From C	Data not available	2.20	2.19	2.33

Source: NCSH License Renewal Application and NCSH CON application

The data in the previous table indicates there is not a direct correlation between Medical Staff Additions and increased ALOS at NCSH. For example, from 2014 to 2016 NCSH increased its Medical Staff by a total of 38 physicians (6 + 15 + 17); however, the ALOS actually decreased during the same time period (FY2014: 2.41; FY2016 2.24). Therefore, mere addition of physicians to the NCSH Medical Staff is not sufficient evidence to support the projected annual increase of patient ALOS at NCSH by five percent. NCSH failed to provide any historical information regarding the historical acute care patient utilization, inpatient surgical utilization, and/or patient acuity for the physicians who have recently and/or will soon join the NCSH Medical Staff. NCSH compares its projected ALOS to Duke Regional Hospital in an attempt to justify its projections; however, Duke Regional Hospital is a full-service hospital whose scope of acute care services and patient acuity mix is not comparable to NCSH. The projected annual ALOS increase of five percent is an assumption that is essential for NCSH to achieve the minimum performance standard of 66.7 percent per 10A NCAC 14C .3803(a); however, the applicant failed to demonstrate the projected days of care are based on reasonable and supported assumptions. Therefore, the application is non-conforming to Review Criterion 3.

Emergency Department Visits

NCSH's website states NCSH does not currently provide full-service ED services. NCSH actually reported zero ED visits on its most recent license renewal application, along with only 32 urgent care visits. NCSH has no historical experience operating an ED or providing ED services.

NCSH bases its projected ED visits on the experience of two specialty hospitals in Texas and Wyoming. The two referenced hospitals averaged three to seven ED visits per day for the reporting periods provided on page 48 of the NCSH application. The review of 12-months historical data for the two specialty hospitals in Texas and Wyoming was the only analysis NCSH described in its application. NCSH failed to provide any information regarding ED visit use rates in Durham County or North Carolina, or how the ED visits for the referenced specialty hospitals in Texas and Wyoming compared to ED visits for other hospitals in their respective service areas. NCSH failed to provide any information regarding ED benchmarks or ED use by specialty area, e.g. orthopaedics. Furthermore, NCSH did not adequately show evidence of the availability of health manpower for the ED services proposed (see Criterion 7). Therefore, NCSH failed to demonstrate projected ED utilization is based on reasonable and supported assumptions and that there will be sufficient manpower available to accommodate projected utilization.

Comments specific to Criterion 4

NCSH failed to demonstrate that its proposal represents the least costly or most effective alternative, and is not conforming to Review Criterion 4.
As described previously, NCSH does not demonstrate that projected acute care utilization is based on reasonable and supported assumptions. Therefore, because the application does not demonstrate need for the proposed services, it is not an effective alternative, and the application is thus not conforming to Criterion 4.

Comments specific to Criterion 5

Because NCSH did not reasonably demonstrate the need for the proposed bed addition (see Criterion 3), and because NCSH does not appear to have shown evidence of the availability of health manpower (see Criterion 7), NCSH did not demonstrate the financial feasibility of the proposal, and the NCSH application is therefore non-conforming to Review Criterion 5.

Comments specific to Criterion 6

NCSH failed to demonstrate the need it has to increase its acute care bed capacity by 33 percent. As indicated in Form C, Section Q, NCSH's occupancy rate during CY2016 was only 55.13%, which is well below the SMFP target occupancy rate of 66.7% for hospitals with less than 100 ADC. Even with the addition of 12 physicians to its Medical Staff during CY2017 (see page 29 of NCSH application), NCSH's CY2017 annualized occupancy rate is just 58.42%, still well below the SMFP target occupancy rate of 66.7%.

As described in the comments related to Criterion 3, NCSH failed to demonstrate in its application that the new acute care beds it proposes to develop are needed. Therefore, the NCSH application does not demonstrate that it is not unnecessarily duplicative, and is non-conforming to Review Criterion 6.

Comments specific to Criterion 7

As previously noted, NCSH does not currently operate an Emergency Department, and is proposing to offer a 24/7 ED at the hospital as part of its

CON application. This represents a substantive increase in the scope of services of the hospital, and requires careful consideration vis-à-vis staffing, especially clinical staff. NCSH did not adequately show evidence of the availability of health manpower for the ED services proposed. Specifically, NCSH provided no information in its application about physician on-call staffing for the ED. As a proposed new provider of ED services, the burden is on NCSH to specifically document physician on-call staffing for ED coverage.

And for clinical staffing, on page 75 of its application, NCSH states "*the project will not involve the addition of any new positions because the staff positions for the service are already in place, as the services are operational.*" This statement is not accurate, as NCSH currently does not offer ED services, and has had zero ED visits in the past; therefore, ED services are not currently operational. More significantly, on page 128 of the application, NCSH shows its current and projected staffing for the hospital. On Form H, in the first full fiscal year, NCSH projects to add 2.9 RNs, 0.8 LPNs, 2.95 aides/orderlies, and 0.25 clerical staff. It is not clear if any of these staff are to be used for the proposed ED, or if they all are related solely to the proposed 33% increase in the acute care bed total. The staffing appears to be only for the NCSH acute care beds. Regardless, given that an ED needs to be staffed 24/7/365, NCSH's proposed incremental staffing appears to be inadequate. For example, to provide one RN always on duty in the ED would necessitate 4.21 FTEs (365x24=8,760/2,080=4.21). This is much greater staffing than the modest incremental staffing that NCSH projects on page 128. Therefore, the NCSH application is non-conforming to Review Criterion 7.

Comments specific to Criterion 18a

As the NCSH application is non-conforming with Criteria (3), (4), (5), (6) and (7), it should also be found non-conforming with Criterion (18a). NCSH did not reasonably demonstrate the need the population projected to be served has for the proposed project, and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of services in Durham County. NCSH did not adequately demonstrated the financial feasibility of the proposal. Thus, the proposed NCSH project will not have a positive impact on competition.

And with regard to cost effectiveness, NCSH did not demonstrate how any enhanced competition will have a positive impact upon the cost effectiveness to the services proposed. In fact, the NCSH application is the least cost-effective option of the two applicants. Specifically, as shown in the table on the following page, NCSH projects the highest charges, reimbursement and cost between the two applicants.

Comparison of Projected Charges, Reimbursement and Costs

Third Project Year	NCSH	DUH
Per Patient Day:		
Gross Revenue	**$14,701**	$13,144
Net Revenue	**$6,909**	$4,124
Cost	**$5,854**	$4,648

Source: CON applications

With regard to access, NCSH did not demonstrate how any enhanced competition will have a positive impact upon access to the services proposed. In fact, for this metric as well, the NCSH application is the least effective alternative of the two applicants. Specifically, as shown in the table below, NCSH projects to serve a much lower percentage of medically underserved patients than DUH.

Comparison of Projected Payor Mix, PY2

Payor Type	NCSH	DUH
Self-pay/charity/indigent	**2.2%**	**0.2%**
Medicare	**47.1%**	**48.7%**
Medicaid	**18.8%**	**1.9%**
Combined	**68.1%**	**50.8%**

Source: CON applications

10A NCAC 14C .3803 (a)&(b) Performance Standard

The NCSH application does not conform to 10A NCAC 14C .3803(a)&(b) because the NCSH acute days of care are not based on reasonable and supported assumptions. Please see discussion regarding Criterion 3.

CONCLUSION

For all of the foregoing reasons, the NCSH application should be disapproved. It fails to satisfy multiple CON review criteria, and it is also comparatively inferior to the DUH application. The DUH application should be approved because it satisfies all the applicable CON review criteria and is comparatively superior to the NCSH application.