ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: September 25, 2012

PROJECT ANALYST: Mike McKillip
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: G-8842-12 / North Carolina Baptist Hospital / Add four burn intensive care services beds for a total 12 burn intensive care services beds / Forsyth County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, North Carolina Baptist Hospital **[NCBH]** proposes to add four new burn intensive care services beds to its existing burn intensive care unit for a total of 12 burn intensive care services beds upon project completion.

The 2012 State Medical Facilities Plan (SMFP) identifies a statewide need determination for eight new burn intensive care services beds. The applicant proposes to add no more than four burn intensive care services beds. Thus, the application is conforming to the need determination in the 2012 SMFP.

Additionally, Policy GEN-3 of the 2012 SMFP is applicable to this review. Policy GEN-3: Basic Principles 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."

Maximize Healthcare Value

In Section III.2, page 44, the applicant states the following regarding how the proposal maximizes healthcare value:

> *"The application seeks to provide an efficient burn intensive care environment for patients on 10 North Tower. The result will be a more efficient allocation of resources and the ability to share infrastructure, supplies, and staffing."*

The applicant adequately demonstrates that the proposed project will maximize health care value.

Promote Safety and Quality

In Section III.2, page 44, the applicant states the following with regard to how the proposal will promote safety and quality:

> *"The research and studies conducted at NCBH are an important contribution to the effort to improve the diagnosis and treatment of injuries and illness in order to reduce cost for patients, families, and insurance carriers."*

Copies of NCBH's utilization management, risk management, infection control, and performance improvement plans are included in Exhibit 7. The applicant adequately demonstrates that the proposed project will promote safety and quality.

Promote Equitable Access

In Section III.2, page 44, the applicant states the following with regard to how the proposal will promote equitable access:

> *"This project will continue to serve the medically underserved population. NCBH contributes substantially to the care of medically underserved, including patients below the poverty level, racial and ethnic minorities, and Medicaid and Medicare patients. NCBH will also continue to treat patients from across North Carolina and southern Virginia and out of state, many of which cannot find treatment elsewhere in the state or region."*

The applicant provides copies of the NCBH charity care and patient financial policies and procedures in Exhibit 18. The applicant adequately demonstrates that medically underserved groups will have equitable access to the proposed services. See Criterion (13) for additional discussion relating to promoting equitable access which is hereby incorporated as if fully set forth herein.

Projected Volumes Incorporate GEN-3 Concepts

The applicant adequately demonstrates the need for the proposal. The applicant demonstrates that projected volumes for the proposed burn intensive care services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (5) for additional discussion relating to demonstration of how projected volumes incorporate the basic principles in meeting the needs of patients to be served which is hereby incorporated as if fully set forth herein. Consequently, the application is consistent with Policy GEN-3. In summary, the applicant is conforming to the need determination in the 2012 SMFP and is consistent with Policy GEN-3. Therefore, the application is conforming with this criterion.

(2) Repealed effective July 1, 1987.4

(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.

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The applicant, NCBH, proposes to add four new burn intensive care services beds to its existing Burn Center for a total of 12 burn intensive care services beds upon project completion. The applicant states that it will renovate space on 10 North Tower, which is the location of the existing burn intensive care unit (BICU). In Section II.1, page 13, the applicant describes the proposed project as follows:

> *"North Carolina Baptist Hospital (NCBH) proposes to renovate the 10th floor of North Tower and create a 12 bed intensive care unit* [for] *severely burned patients. NCBH proposes to renovate 1,770 square feet, which will allow the four incremental burn beds to be located in the same unit. … NCBH proposes to renovate the 10th floor of North Tower by displacing four acute care beds designate*[d] *for wound care patients located adjacent to the Burn ICU and relocating them to acute care rooms located at the end of the same floor. These rooms were previously used as temporary office space."*

Population to be Served

In Exhibit 8, the applicant provides projected patient origin for NCBH's Burn Center in the first two years of operation (FY2015 and FY2016), as shown in the table below.

County	Percent of Total
Guilford	8.9%
Forsyth	8.5%
Davidson	7.8%
Gaston	5.9%
Rowan	4.1%
Iredell	3.3%
Rockingham	3.3%
Surry	3.3%
Cabarrus	3.0%
Wilkes	3.0%
Mecklenburg	2.6%
Virginia	13.0%
All other states	7.4%
Other*	25.9%
TOTAL	**100.0%**

*The applicant lists the counties included in the *"Other"* category in Exhibit 8 of the application.

On page 52 of the application, the applicant states, *"The projected patient origin is expected to remain the same as the historical patient origin."* The applicant adequately identified the population proposed to be served.

Need to Add Four Burn Intensive Care Services Beds

In Section III.1(a) of the application, the applicant describes the factors supporting the need for the proposed project, including, the historical utilization and capacity of NCBH's existing burn intensive care services (page 37), the projected growth in the North Carolina population, particularly among at-risk groups (pages 38-39), and changes in referral patterns toward increased use of specialized burn centers for burn patients (page 36).

In Section IV.1, page 56, the applicant provides a table showing the historical and projected utilization for NCBH's BICU services through the first three years of operation (FY2014-FY2016) for the proposed project, which is summarized below:

Fiscal Year	Total	Patient	Average	Percent	Average

	BICU Beds	Days	Daily Census	Change in Patient Days	Occupancy Rate
2010 Actual	8	3,419	9	---	117.1%
2011 Actual	8	2,972	8	-13.1%	101.8%
2012 Projected	8	3,024	8	1.7%	103.6%
2013 Projected	8	3,077	8	1.8%	105.4%
2014 Year 1	12	3,131	9	1.8%	71.5%
2015 Year 2	12	3,186	9	1.8%	72.7%
2016 Year 3	12	3,242	9	1.8%	74.0%

As shown in the table above, NCBH projects to provide 3,242 patient days of care in the third operating year and, therefore, projects an average annual occupancy rate of 74 percent in the third operating year, which exceeds the 70 percent occupancy rate required by 10A NCAC 14C .3403(a).

In Section III.1(b), pages 40-42, the applicant describes the assumptions and methodology used to project the number of patient days to be provided during the first three years of operation as follows:

> *"Step 1: Define the patient population.*
>
> *Burn ICU patients were defined by having a primary ICD-9 diagnosis code between 940 – 949.99 and having spent at least one census day on the Burn ICU located on 10 North Tower in the date range July 1, 2006 through June 30, 2011. Table 1 depicts annual volumes, days, average length of stay (ALOS), as well as the average daily census (ADC) for Burn ICU patients from FY07 – FY11.*

Table 1: NCBH Historical Burn ICU Volumes					
NCBH Fiscal Years	***2007***	***2008***	***2009***	***2010***	***2011***
Volumes	*250*	*254*	*259*	*258*	*268*
Days	*3,362*	*3,573*	*3,645*	*3,419*	*2,972*
ALOS	*13.5*	*14.1*	*14.1*	*13.3*	*11.1*
ADC	*9*	*10*	*10*	*9*	*8*
Number of Allocated Beds	*8*	*8*	*8*	*8*	*8*
Occupancy	*115%*	*122%*	*125%*	*117%*	*102%*

> *As indicated above, the Burn ICU has experienced steady growth over the last 5 fiscal years, most notably between FY10 and FY11. In order to accommodate demand, the unit has successfully implemented a number of LOS reduction initiatives aimed at improving patient throughput and readiness for discharge. These initiatives have resulted in a 3.0 day LOS reduction on the Burn ICU from FY09 – FY11. Despite this effort, the current bed complement does not accommodate current demand or allow for future growth. With only 8 ICU beds, the Burn ICU consistently operates above 100% occupancy.*

Step 2: Calculate the compounded annual growth rate (CAGR) for Burn ICU volumes for the last 5 Fiscal Years (July 1, 2006 – June 30, 2011).

Table 2: NCBH Burn ICU CAGR						
NCBH Fiscal Years	***2007***	***2008***	***2009***	***2010***	***2011***	***5-Year CAGR***
Volumes	*250*	*254*	*259*	*258*	*268*	*1.75%*

Table 2 shows the annual volume of the Burn ICU from 2007 to 2011. During that time, NCBH experienced a 7.2% growth in Burn ICU admissions. The historical volumes result in a CAGR of 1.75% from 2007 to 2011.

Step 3: Apply the 5-year CAGR to project demand for the Burn ICU.

Based on the above need/demand methodology, Table 3 illustrates projected volumes for the Burn ICU. The LOS improvement achieved in FY11 is held constant during the interim and project years. This analysis results in a Burn ICU bed need of 14 by PY3 to accommodate demand based on an industry standard of 65% occupancy for intensive care units. NCBH is requesting approval to increase the capacity of the Burn ICU by 4 incremental beds, which results in a total bed complement of 12.

Annual projections moving forward from NCBH's last full fiscal year (FY 2011) are shown in Table 3."

Table 3: NCBH Burn ICU Volume Projections						
				Project Years		
		Interim Years		**PY 1**	**PY 2**	**PY 3**
NCBH Fiscal Years	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**
Volumes	268	273	277	282	287	292
Days	2,972	3,024	3,077	3,131	3,186	3,242
ALOS	11.1	11.1	11.1	11.1	11.1	11.1
ADC	8	8	8	9	9	9
Occupancy	102%	104%	105%	71%	73%	74%

As indicated in Table 2 above, admissions to the applicant's burn intensive care unit (BICU) increased from 250 patients in FY2007 to 268 patients in FY2011, or by 7.2 percent over the four-year period [268/250 = 1.072]. Also, based on the applicant's internal data, NCBH's BICU has operated above 100 percent of capacity in each of the last five operating years, even as the average length of stay for burn patients decreased from 14.1 days to 11.1 days from FY2009 to FY2011. In this application, the applicant projects its BICU utilization will increase from 268 admissions in FY2011 to 282 admissions in the first year of the project (FY2014), or by 5.2 percent over the three-year period. Exhibit 9 of the application contains

letters from 13 physicians and surgeons, including the NCBH medical directors for intensive care services, surgical services, emergency medicine, trauma surgery, and the burn ICU, expressing support for the proposed project. Based on the historical utilization of the applicant's existing burn intensive care services, the applicant's utilization projections are reasonable. Therefore, the applicant adequately demonstrated the need to add four burn intensive care services beds to its existing BICU.

In summary, the applicant adequately demonstrated the need the population projected to be served has for the proposed project. Therefore, the application is conforming to this criterion.

(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

(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.

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In Section III.3, pages 45-46, the applicant describes the alternatives considered, including maintaining the status quo, postponing the project, and relocating part of the burn intensive care unit to another location.

- The applicant states it rejected the status quo as unacceptable because the BICU currently operates at over 100 percent of capacity and the number of admissions is projected to continue to grow.
- The applicant considered the alternative of relocating a portion of the BICU to another location in the hospital, but rejected it due to the lack of availability of appropriate locations within the hospital.
- The applicant considered the alternative of postponing the project, but rejected it for the same reasons that maintaining the status quo was unacceptable.

The applicant adequately demonstrated that the proposal is its least costly or most effective alternative to meet the need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant(s) adequately demonstrate that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **North Carolina Baptist Hospital shall materially comply with all representations made in the certificate of need application.**

2. **North Carolina Baptist Hospital shall add four burn intensive care services beds for a total of 12 burn intensive care services beds upon completion of the project.**

3. **North Carolina Baptist Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**

4. **North Carolina Baptist Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section, in writing prior to issuance of the certificate of need.**

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

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In Section VIII.1, the applicant projects its capital cost for the project to be $1,365,770. In Section VIII.3, the applicant states the capital cost will be financed with accumulated reserves. In Section IX.1, the applicant projects no start-up expenses or initial operating expenses. In Exhibit 21 of the application, the applicant provides a letter from the Associate Vice President for Financial Planning for NCBH, which states

> *"North Carolina Baptist Hospital agrees to make available from its accumulated reserves a total of $1,365,770 for the capital costs incurred in the development of the aforementioned project. As Associate Vice President for Financial Planning for North Carolina Baptist Hospital, I can attest to the availability of funds for this purpose. These funds will be made available from the accumulated reserves of North Carolina Baptist Hospital. Please reference our audited financial statements, particularly our balance sheet, for evidence that funds are available for this purpose."*

Exhibit 22 of the application contains audited financial statements for North Carolina Baptist Hospital and Affiliates (NCBH) for the year ended June 30, 2011, which document that NCBH had $20.6 million in *"cash and cash equivalents"* as of June 30, 2011. The applicant

adequately demonstrated the availability of funds for the projected capital costs described in the application.

In pro forma financial statements (Form B), the applicant projects revenue will exceed operating costs (expenses) in each of the first three operating years. Operating costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application and Criterion (3) for utilization assumptions, which are hereby incorporated as if fully set forth herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues, and the application is conforming with this criterion.

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

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NCBH operates one of only two burn intensive care units in North Carolina. The 2012 State Medical Facilities Plan (2012 SMFP) includes a statewide Burn Intensive Care Services Bed Need Determination for eight additional burn intensive care services beds. The applicant proposes to develop four burn intensive care services beds. The applicant does not propose to develop more burn intensive care services beds than are determined to be needed in the service area. With the exception of the four burn intensive care services beds for which there is a need determination in the 2012 SMFP, the applicant does not propose any new services or capacity. Based on the applicant's internal data, NCBH's existing burn intensive care services beds operated in excess of 100 percent of capacity in each of past five years (FY2007-FY2011). Also, based on data reported in the *2012 Hospital License Renewal Application*, University of North Carolina Hospital at Chapel Hill's existing burn intensive care services beds operated in excess of 100 percent of capacity in FY2011. The applicant adequately demonstrates the need for its proposal. In addition, the applicant adequately demonstrates that the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

(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.

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In Sections VII.1 and VII.2, pages 72-76, the applicant projects the staffing in its burn intensive care unit will increase from 32.5 full-time equivalent (FTE) employees currently to 39.6 FTE employees in the second project year (FY2015).

Incremental BICU Staff Required	**FTEs**
Registered Nurse	4.7

Aides/Orderlies	1.0
Clerical	0.3
Social Worker	0.2
Physical Therapist	0.5
Occupational Therapist	0.2
Respiratory Therapist	0.2
Total	**7.1**

In Sections VII.1 and VII.2, pages 72-76, the applicant provides current and proposed staffing tables for the BICU at NCBH, which shows the administrative, clinical, and support personnel that will be available to support the proposed burn intensive care services beds. In Section VII.3, page 79, the applicant describes its recruitment and retention processes which will be used to recruit the additional BICU staff. In Section VII.8, page 80, the applicant identifies Thomas Sibert, M.D. as the Medical Director for NCBH. Exhibit 13 identifies James H. Holmes, M.D. as the Medical Director of Wake Forest Baptist Medical Center Burn Center. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

(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.

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In Section II.2, pages 14-15, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at NCBH. In Section V.2 of the application, the applicant states that it has transfer agreement with many facilities statewide. Exhibit 17 contains a list of facilities with which NCBH has transfer agreement and a copy of a sample transfer agreement. In Exhibit 9, the applicant provides letters from physicians and hospital administrators representing NCBH and other hospitals that support the proposed project. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

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

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The

availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

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

NA

(11) Repealed effective July 1, 1987.

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

NA

(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;

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In Section VI.13, page 69, the applicant provides the payer mix during FY2011 for the existing burn intensive care unit (BICU) at NCBH, as shown in the table below.

NCBH BICU Payer Category	**BICU Patient Days as % of Total**
Self Pay/Indigent/Charity	19.0%
Medicare/Medicare Managed Care	28.0%
Medicaid	23.1%
Commercial Insurance	1.1%

Managed Care	19.0%
Other	9.7%
Total	**100.0%**

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY2008-2009, respectively, for the North Carolina counties representing at least five percent of total patient days at UNCH-CH's burn intensive care unit in FY2011. The data in the table was obtained on August 9, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

County	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Davidson	17%	6.9%	18.4%
Forsyth	16%	5.7%	19.5%
Gaston	20%	8.6%	19.0%
Guilford	15%	5.9%	19.5%
Statewide	**17%**	**6.7%**	**19.7%**

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by the applicants.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and 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;

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Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 68, the applicant states:

"NCBH has not had any obligation to provide uncompensated care during the last three years. As stated in Section VI.6, NCBH provides, without obligation, a considerable amount of bad debt and charity care to residents of the service area."

In Section VI.10, page 68, the applicant states that there have not been any civil rights access complaints filed against NCBH in the past five years. 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

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In Section VI.15, page 70, the applicant provides the projected payer mix for the second operating year (FY2015) for the BICU at NCBH, as shown in the table below.

NCBH BICU Payer Category	**BICU Patient Days as % of Total**
Self Pay/Indigent/Charity	14.6%
Medicare/Medicare Managed Care	32.4%
Medicaid	27.2%
Commercial Insurance	1.0%
Managed Care	17.4%
Other	7.3%
Total	**100.0%**

In Section IV.15, page 70, the applicant states, *"For projection purposes, the payor mix for each service component is assumed to remain unchanged relative to the most recent fiscal year."* The applicant demonstrated that it will provide adequate access to medically underserved populations. Therefore, the application is conforming with 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.

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In Section VI.9, page 67, the applicant describes the range of means by which a person will access their services. 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.

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In Section V.1 of the application, the applicant states,

> *"As an acute care facility that has been providing services for more than 85 years, NCBH has established relationships with many clinical training programs in the Southeast and continues to provide teaching opportunities for these schools. With the acquisition of four incremental Burn ICU beds, NCBH will be able to continue to provide training support to the numerous clinical programs utilizing educational opportunities at the hospital by providing more space to accommodate students and new opportunities for learning experience."*

The information provided is reasonable and credible and supports a finding of conformity 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.

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See Section V.7, page 62, in which the applicant discusses the impact of the proposed project as it relates to fostering competition, and the impact on quality, access, and cost-effectiveness of services. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to burn intensive care services. This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to add four burn intensive care services beds and that it is a cost-effective alternative;
- The applicant has and will continue to provide quality services; and
- The applicant has and will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

(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.

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NCBH is certified by CMS for Medicare and Medicaid participation, accredited by the Joint Commission and licensed by the NC Department of Health and Human Services. According to files in the Acute and Home Care Licensure and Certification Section in the Division of Health Service Regulation, no incidents have occurred at NCBH within the eighteen months immediately preceding the date of the decision for which any sanctions or penalties related to quality of care were imposed by the State. 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.

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NCBH proposes to add four burn intensive care services beds to its existing burn intensive care unit. Therefore, the Criteria and Standards for Burn Intensive Care Services, promulgated in 10A NCAC 14C .3400, are applicable to this review. The application is conforming to all applicable Criteria and Standards for Burn Intensive Care Services. The specific criteria are discussed below.

SECTION .3400 - CRITERIA AND STANDARDS FOR BURN INTENSIVE CARE SERVICES

10A NCAC 14C .3402 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to develop a new burn intensive care unit or to add beds to an existing or approved burn intensive care unit shall use the Acute Care Facility/Medical Equipment application form.

-C- The applicant used the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to develop a new burn intensive care unit or to add beds to an existing or approved burn intensive care unit shall also provide the following additional information:

(1) the number of beds in the burn intensive care unit currently operated in the applicant's facility and the total to be operated following completion of the proposed project;

-C- In Section II.8, page 22, the applicant states it currently operates 8 burn intensive care services beds and, following the addition of the four proposed beds, will operate 12 burn intensive care services beds following completion of the proposed project.

(2) documentation of the applicant's experience in treating severely burned patients at its facility during the last year, including:

(A) the number of severely burned patients treated through emergency room services;

-C- In Section II.8, page 22, the applicant states, *"During CY 2011, NCBH treated 611 burn patients through the emergency department."*

(B) the number of severely burned patients referred to the applicant's facility from other facilities;

-C- In Section II.8, page 22, the applicant states 191 severely burned patients were referred to NCBH from other facilities in CY2011.

(C) the number of inpatient days of care provided to severely burned patients; and

-C- In Section II.8, page 24, the applicant states it provided 2,981 inpatient days of care on the burn intensive care unit (BICU) from January 1, 2011 to December 31, 2011.

(D) the number of severely burned patients the applicant referred to other facilities for burn treatment;

-C- In Section II.8, pages 24-25, the applicant states three severely burned patients were referred to another facility in CY2011.

(3) the number of severely burned patients from the proposed burn intensive care service area that are projected to require burn intensive care services, by the patient's county of residence, in each of the first 12 quarters of operation following completion of the project. The applicant shall state the methodology and assumptions used to make the projections;

-C- In Exhibit 8, the applicant provides a table showing the number of severely burned patients from the proposed burn intensive care service area that are projected to require burn intensive care services, by the patient's county of residence, in each of the first 12 quarters of operation following completion of the project. The applicant's methodology and assumptions used to make the projections are described in Section III.1, pages 40-42, and Section III.5, page 51.

(4) the projected utilization of the beds in the applicant's burn intensive care unit for each of the first twelve calendar quarters following completion of the proposed project, including the methodology and assumptions used for these projections;

-C- In Section II.8, page 25, the applicant provides the projected utilization of its burn intensive care unit for each of the first 12 quarters of operation following completion of the project. The applicant's methodology and assumptions used to make the projections are described in Section III.1, pp. 40-42.

(5) evidence that existing and approved burn intensive care units in the state are unable to accommodate the applicant's projected need for additional burn intensive care services;

-C- NCBH and University of North Carolina Hospitals at Chapel Hill (UNCH-CH) operate the only two existing burn intensive care units in the state. In Section III.1, page 40, the applicant states:

"Table 1 depicts annual volumes, days, average length of stay (ALOS), as well as the average daily census (ADC) for Burn ICU patients from FY07 – FY11.

Table 1: NCBH Historical Burn ICU Volumes					
NCBH Fiscal Years	***2007***	***2008***	***2009***	***2010***	***2011***
Volumes	*250*	*254*	*259*	*258*	*268*
Days	*3,362*	*3,573*	*3,645*	*3,419*	*2,972*
ALOS	*13.5*	*14.1*	*14.1*	*13.3*	*11.1*
ADC	*9*	*10*	*10*	*9*	*8*
Number of Allocated Beds	*8*	*8*	*8*	*8*	*8*
Occupancy	*115%*	*122%*	*125%*	*117%*	*102%*

As indicated above, the Burn ICU has experienced steady growth over the last 5 fiscal years, most notably between FY10 and FY11. In order to accommodate demand, the unit has successfully implemented a number of LOS reduction initiatives aimed at improving patient throughput and readiness for discharge. These initiatives have resulted in a 3.0 day LOS reduction on the Burn ICU from FY09 – FY11. Despite this effort, the current bed complement does not accommodate current demand or allow for future growth. With only 8 ICU beds, the Burn ICU consistently operates above 100% occupancy.

In Section II.8, page 25, the applicant states, *"Based on data reported in the FFY 2012 License Renewal Application, UNC's* [Burn Center] *occupancy rate is 107%, which far exceeds the recommended occupancy rate of 70% for burn units with more than 20 beds. Absent additional capacity, UNC would be unable to provide more burn intensive care services in a safe and efficient manner."* The application is conforming with this rule.

(6) letters from physicians or other evidence that document the referral sources of patients to the burn intensive care unit;

-C- Exhibit 9 contains letters from physicians that document the referral sources of patients to the burn intensive care unit.

(7) evidence of the applicant's capability to communicate with and access emergency transportation resources including, but not limited to air ambulance services;

-C- In Section II.8, page 26, the applicant provides documentation of its capability to communicate with and access emergency transportation resources.

(8) evidence of the applicant's capability to provide burn treatment services in the burn intensive care service unit on a 24 hour per day, 7 day per week basis;

-C- In Section II.8, page 27, and Exhibit 2, the applicant provides documentation of its capability to provide burn treatment services in the burn intensive care service unit on a 24 hour per day, 7 day per week basis.

(9) description of inservice training or continuing education programs specific to burn intensive care services that shall be provided to unit staff; and

-C- In Section II.8, page 27, and Exhibit 16, the applicant provides a description of inservice training and continuing education programs specific to burn intensive care services that are provided to NCBH's BICU staff.

(10) copies of written policies and procedures for the operation of the burn intensive care unit that shall be in effect at the time the unit becomes operational, for at least the following:

(A) arrangements for treatment of a patient when patient load exceeds optimal operational capacity;

-C- Exhibit 10 contains a copy of NCBH's policies and procedures on patient admissions, discharge, and follow-up care, as well as physician responsibilities for the care of burn patients.

(B) patient admission and discharge policies that are developed with input from the medical staff and the nursing service;

-C- Exhibit 10 contains a copy of NCBH's policies and procedures on patient admissions, discharge, and follow-up care.

(C) infection control and prevention, including handling of contaminated items, decontamination, transportation of patients outside of the unit, housekeeping and cleaning schedule, solid and liquid waste systems, staff and visitor traffic control, and aseptic isolation;

-C- Exhibit 10 contains a copy of NCBH's policies and procedures on burn wound care, including infection control and prevention. Exhibit 7 contains a copy of NCBH's infection control policies and procedures.

(D) the inclusion of the unit in the facility's external and internal disaster plans;

-C- The applicant provided a copy of NCBH's disaster preparedness policies and procedures.

(E) performance of special procedures; and

-C- Exhibit 10 contains a copy of NCBH's policies and procedures on special procedures (*"Special Care"*) on the BICU.

(F) acquisition and storage of homograft and heterograft skin.

-C- The applicant provided a copy of NCBH's policies and procedures on handling and storage of allograft (homograft and heterograft) human tissue.

(c) The applicant shall provide documentation, including a detailed floor plan of the proposed unit drawn to scale, to demonstrate that the proposed unit shall:

(1) be organized as a physically and functionally distinct entity with controlled access;

-C- Exhibit 11 contains a copy of floor plan for NCBH's BICU which shows that the BICU is organized as a distinct unit with controlled access.

(2) provide an effective means of isolation for patients suffering from communicable or infectious disease, for patients requiring protective isolation, and for disoriented or emotionally disturbed patients who require the services of the unit until placement elsewhere becomes possible;

-C- In Section II.8, page 28, the applicant states, *"Please see Exhibit 11 for line drawings demonstrating that the Burn ICU unit has controlled access, provides an effective means of isolation, allows for observation by nursing to patients from at least one vantage point and contains 12 licensed Burn ICU beds."*

(3) provide a means for observation by unit staff of all patients from at least one vantage point; and

-C- In Section II.8, page 28, the applicant states, *"Please see Exhibit 11 for line drawings demonstrating that the Burn ICU unit has controlled access, provides an effective means of isolation, allows for observation by nursing to patients from at least one vantage point and contains 12 licensed Burn ICU beds."*

(4) contain no fewer than 6 licensed acute care beds.

-C- NCBH's BICU currently operates 8 licensed acute care beds.

10A NCAC 14C .3403 PERFORMANCE STANDARDS

(a) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall demonstrate that:

(1) the existing burn intensive care units in the state had an overall average occupancy rate of at least 80 percent for the last year, which shall be calculated by dividing the total number of bed days utilized in the last year by severely burned patients in all facilities in the state that have burn intensive care units, by the total number of burn intensive care unit beds in all facilities in the state that have burn intensive care units multiplied by 365 days;

-C- In Section II.8, page 28, the applicant provides a table showing that the two existing burn intensive care units in the state, University of North Carolina Hospitals at Chapel Hill and NCBH, operated at an overall average occupancy rate of more than 80 percent in FY2011.

(2) the average occupancy rate of the applicant's existing unit for the last year was at least 70% in units with 20 or more beds, 65% in units with 10 to 19 beds, and 60% in units with 1 to 9 beds;

-C- The BICU at NCBH currently operates 8 beds. In Section II.8, page 29, the applicant provides a table showing utilization of the existing burn intensive care unit at NCBH operated at an average occupancy rate of more than 60 percent in all of FY2011, and continued to operate at an average occupancy rate of more than 60 percent in the first 9 months of FY2012.

(3) the applicant's unit shall be utilized at an annual occupancy rate of at least 70% in units with 20 or more beds, 65% in units with 10 to 19 beds, and 60% in units with 1 to 9 beds, no later than 2 years following completion of the proposed project; and

-C- The BICU at NCBH would operate 12 beds upon completion of the proposed project. In Section II.8, page 29, the applicant provides a table showing the projected utilization of the burn

intensive care unit at NCBH will exceed the required annual occupancy rate of 65 percent in the second operating year.

(4) each existing or approved burn intensive care unit shall be projected to be utilized at an annual occupancy rate of at least 70% in units with 20 or more beds, 65% in units with 10 to 19 beds, and 60% in units with 1 to 9 beds, no later than 2 years following completion of the applicant's proposed project.

-C- The BICU at NCBH would operate 12 beds upon completion of the proposed project. In Section II.8, page 29, the applicant provides a table showing the projected utilization of the BICU at NCBH will exceed the required annual occupancy rate of 65 percent in the second operating year. University of North Carolina Hospitals at Chapel Hill (UNCH-CH), which currently operates a 21-bed burn ICU, is the only other existing or approved burn intensive care unit. The applicant projects that UNCH-CH's burn intensive care unit will be utilized at an annual occupancy rate of more than 70 percent no later than 2 years following completion of the applicant's proposed project, as shown in the table below:

UNCH-CH Burn ICU Utilization	FY2011	FY2012	FY2013	FY2014	FY2015 PY 1	FY2016 PY 2	FY2017 PY 3
Discharges	903	1,002	1,025	1,048	1,071	1,087	1,100
Days	8,357	8,857	8,558	8,691	8,821	8,953	9,061
ALOS	9.3	8.8	8.4	8.3	8.2	8.2	8.2
ADC	23	24	23	24	24	25	25
# Burn ICU Beds*	21	21	21	21	25	25	25
Occupancy	109%	116%	112%	113%	97%	98%	99%

*Note: UNCH-CH has also applied to add four burn intensive care service beds (Project I.D. # J-8836-12), and the applicant assumes that UNCH-CH is approved to add four burn intensive care services beds for a total of 25 BICU beds by FY2015.

The applicant states, "[Above] *are the projections of utilization for the University of North Carolina at Chapel Hill's burn unit, which demonstrates that the unit will be utilized at an annual occupancy rate of approximately 95-98% during the first two years following completion of NCBH's proposed project. These occupancy rates exceed the required 70% as noted* [above]." The application is conforming with this rule.

(b) The calculation of occupancy rates in this Rule shall be based only on severely burned patients.

-C- In Section II.8, page 29, the applicant states, "*Severely burned patients are defined as Burn ICU patients with a primary ICD-9 diagnosis code between 940 – 949.99 and having spent at least one census day on the Burn ICU located on 10 North Tower.*"

(c) The applicant shall document all assumptions and data supporting the methodology used for all occupancy rates projected in this Rule.

-C- The applicant's methodology and assumptions used to make the projections are described in Section III.1, pp. 40-42, and Section III.5, page 51.

10A NCAC 14C .3404 SUPPORT SERVICES

(a) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall demonstrate that the following services, equipment and supplies shall be available to the burn intensive care unit 24 hours per day, 7 days per week:

(1) monitoring devices which allow nurses at a nursing station to monitor patients around-the-clock;
(2) ventilator capability at each bed in the unit;
(3) a tub, tank or table for the cleaning of burn wounds located in an area of the unit separate from the general patient care area;
(4) temperature control equipment or capability which allows for independent temperature control for each patient area;
(5) renal dialysis;
(6) an operating room;
(7) a clinical laboratory which is capable of performing tests and reporting the results on a timely basis, including blood chemistries, blood gas analyses, Ph levels, electrolyte determinations, and serum and urine osmolalities;
(8) microbiology services;
(9) blood bank services;
(10) diagnostic radiologic services;
(11) a direct intercommunication/alarm system between the nurses' station and the patient's bedside, with connections to treatment, work, lounge, or other areas from which additional personnel would be summoned;
(12) oxygen and compressed air and the means of administration;
(13) mechanical ventilatory assistance equipment;
(14) cardiac defibrillator with synchronization capability;
(15) respiratory and cardiac monitoring equipment;
(16) thoracentesis and closed thoracostomy sets;
(17) tracheostomy sets;
(18) tourniquets;
(19) vascular cutdown sets;
(20) infusion pumps;
(21) laryngoscopes and endotracheal tubes;
(22) tracheobronchial and gastric suction equipment;
(23) portable x-ray equipment; and
(24) a patient weighing device for bed patients.

-C- In Section II.8, page 31, and Exhibit 12, the applicant provides documentation that all of the services, equipment and supplies required by this Rule are available at NCBH's BICU 24 hours per day, 7 days per week.

(b) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall also demonstrate that the following services shall be available:

(1) aftercare services to burn unit patients for post hospitalization including social services, vocational counseling and physical rehabilitation; and

-C- In Section II.8, page 31, the applicant provides documentation that aftercare services to burn unit patients for post hospitalization including social services, vocational counseling and physical rehabilitation are available to NCBH's BICU patients.

(2) a community outreach and prevention education program, which shall include, but not be limited to, coordination with emergency medical service authorities in training in the assessment, care, triage and transfer of severely burned patients.

-C- In Section II.8, page 31, and Exhibit 16, the applicant provides documentation regarding the community outreach efforts of the NCBH Burn ICU.

10A NCAC 14C .3405 STAFFING AND STAFF TRAINING

(a) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall demonstrate that the following staff shall be available to provide the proposed services:

(1) a designated physician in charge of the unit with board certification in general or plastic surgery and at least one year of experience in a burn unit;

-C- In Section II.8, page 32, and Exhibit 13, the applicant provides documentation of a designated physician in charge of the Burn ICU at NCBH that meets the requirements of this Rule.

(2) in-house physician coverage by either a staff physician or a member of the house staff assigned to the unit 24 hours per day, 7 days per week;

-C- In Section II.8, page 32, the applicant provides documentation of in-house physician coverage by staff physicians assigned to the unit 24 hours per day, 7 days per week.

(3) a registered nurse administratively responsible for the nursing service in the unit who has experience working with burn patients and at least two years of intensive care experience or experience which the applicant determines to be equivalent to the intensive care experience;

-C- In Section II.8, page 32, and Exhibit 14, the applicant provides documentation of a registered nurse administratively responsible for the nursing services of the Burn ICU at NCBH that meets the requirements of this Rule.

(4) a burn specialist 24 hours per day, 7 days per week;

-C- In Section II.8, page 32, the applicant provides documentation of a burn specialist that will be available 24 hours per day, 7 days per week, at the Burn ICU at NCBH.

(5) a burn care technician 24 hours per day, 7 days per week;

-C- In Section II.8, page 32, the applicant states that burn care technicians are available 24 hours per day, 7 days per week, at the Burn ICU at NCBH.

(6) designated support staff available to the unit, including:
- *(A) anesthetist,*
- *(B) chaplain,*
- *(C) dietician,*
- *(D) inhalation therapist,*
- *(E) microbiologist,*
- *(F) occupational therapist,*
- *(G) pharmacist,*
- *(H) physical therapist, and*
- *(I) social worker;*

-C- In Section II.8, page 33, the applicant provides documentation of the availability of the support staff required by this Rule at the Burn ICU at NCBH.

(7) other non-surgical support services staff available for consultation, including:
- *(A) anesthesiology,*
- *(B) cardiology,*
- *(C) gastroenterology,*
- *(D) hematology,*
- *(E) infectious disease,*
- *(F) internal medicine,*
- *(G) nephrology,*
- *(H) neurology,*
- *(I) nutrition,*
- *(J) ophthalmology,*
- *(K) pathology,*
- *(L) pediatrics,*
- *(M) psychiatry,*
- *(N) pulmonary,*
- *(O) radiology, and*
- *(P) special education; and*

-C- In Section II.8, page 33, the applicant provides documentation of the availability of the other non-surgical support services staff available for consultation as required by this Rule at the Burn ICU at NCBH.

(8) surgical support specialists available for consultation, including:
- *(A) cardiothoracic,*
- *(B) neurologic,*
- *(C) OB-GYN,*
- *(D) ophthalmic,*
- *(E) oral and maxillofacial,*
- *(F) orthopaedic,*

(G) otorhinolaryngologic,
(H) pediatric,
(I) plastic (if not the director of the burn unit),
(J) urologic, and
(K) vascular.

-C- In Section II.8, page 34, the applicant provides documentation of the availability of the other surgical support services staff available for consultation as required by this Rule at the Burn ICU at NCBH.

(b) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall demonstrate that an organized staff education and training program shall be provided which is integral to the burn intensive care service unit and which ensures improvements in technique and the proper training of new personnel.

-C- In Section II.8, page 34, the applicant describes its staff education and training program for burn intensive care services staff.