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: J-8836-12 / University of North Carolina Hospitals at Chapel Hill / Add four burn intensive care services beds for a total 25 burn intensive care services beds / Orange 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, University of North Carolina Hospitals at Chapel Hill **[UNCH-CH]** proposes to add four new burn intensive care services beds to its existing Jaycee Burn Center for a total of 25 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 50, the applicant states the following regarding how the proposal maximizes healthcare value:

> *"Equitable access and maximizing healthcare value are achieved with this project because the additional beds will provide a greater opportunity to accommodate patient transfers and admissions. Expanding the bed capacity from 21 to 25 beds will enable the Burn Center to maximize value through economies of scale as certain existing staff, building systems and infrastructure, such as hydrotherapy rooms, can be utilized to support a larger number of beds."*

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

Promote Safety and Quality

In Section III.2, page 49, the applicant states the following with regard to how the proposal will promote safety and quality:

> *"The promotion of safety and quality is of major importance to UNC Hospitals. The development of additional burn intensive care beds will provide additional private patient rooms, enhance infection control and isolation features, and promote patient safety. Environment of care is an important consideration in the provision of quality care."*

A copy of the *"NC Jaycee Burn Center Quality Improvement Program"* is included in Exhibit 11. The applicant adequately demonstrates that the proposed project will promote safety and quality.

Promote Equitable Access

In Section III.2, page 50, the applicant states the following with regard to how the proposal will promote equitable access:

> *"Access to the proposed services will utilize the policies that UNC Hospitals has in place to allow the continued and enhanced provision of care to those in need. Please see application Sections V and VI for further discussion."*

The applicant provides copies of the admission, discharge, and financial assistance policies and procedures in Exhibit 29. 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. Criterion (13) 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.

Additionally, Policy GEN-4 of the 2012 SMFP is applicable to this review. Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities 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, the Certificate of Need Section 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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

In Section III.2, page 51, the applicant states:

> *"UNC Hospitals will develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds the energy*

> *efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. … The facility renovation plans and specifications for the project shall be researched and developed by the project architect, with input from facility engineering and administration, to include specific design features to ensure improved energy efficiency and water conservation."*

The applicant adequately demonstrates that it will assure improved energy efficiency and water conservation in the proposed renovation of the burn intensive care unit. Therefore, the application is consistent with Policy GEN-4.

In summary, the application is conforming to the need determination in the 2012 SMFP, and is consistent with Policy GEN-3 and Policy GEN-4. Therefore, the application is conforming to 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.

C

The applicant, UNCH-CH, proposes to add four new burn intensive care services beds to its existing Jaycee Burn Center for a total of 25 burn intensive care services beds upon project completion. The applicant states that it will renovate existing support spaces on the 5th Floor burn intensive care unit (BICU), including occupational/physical therapy space, break room, conference room, nurse manager and physician offices, consultation room, and registry offices, to accommodate the four new private rooms. The existing support functions which will be vacated from the BICU will be relocated to the 4th Floor. In Section II.1, pages 15-17, the applicant describes the proposed project as follows:

> *"UNC Hospitals is proposing to develop four additional burn intensive care beds in renovated space to increase the overall licensed capacity of the NC Jaycee Burn Center to 25 beds. The scope of services will continue to include pediatric and adult patients. … Renovation of 4,274 square feet is proposed to accommodate the four additional burn intensive care beds plus provide the necessary circulation and support space. … Schematic plans in Exhibit 5 depict the area of renovation and show the configuration of the four additional private beds. The benefit of this plan is that the present nurses' stations can accommodate these additional beds and maintain direct view of all existing and proposed patient rooms. … The cost of relocating existing support spaces to the 4th Floor support space has been included in the capital*

cost for the project. .. No major medical equipment will be acquired for the project."

Population to be Served

In Section III.5, the applicant provides projected patient origin for UNC Hospital's Jaycee Burn Center in the first two years of operation (FY2015 and FY2016), as shown in the table below.

County	Percent of Total
Wake	13.41%
Cumberland	6.10%
Alamance	5.43%
Durham	5.21%
Johnston	4.55%
Robeson	3.55%
Orange	3.44%
Mecklenburg	3.22%
Harnett	2.88%
Onslow	2.88%
New Hanover	2.44%
Lee	2.22%
Nash	2.00%
Brunswick	2.00%
Craven	2.00%
Other*	38.67%
TOTAL	**100.0%**

*The applicant lists the counties included in the *"Other"* category on page 57 of the application.

On page 58 of the application, the applicant states, *"Since patient origin has historically remained consistent with respect to utilization trends, the same patient origin mix is projected forward* [from FY2011]. *No material change in the patient origin is expected for future burn intensive care admissions."* 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 UNC Hospital'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 40).

In Section IV.1, pages 61-63, the applicant provides tables showing the historical and projected utilization for UNC Hospital's BICU services through the first three years of operation (FY2015-FY2017) for the proposed project, which is summarized below:

Fiscal Year	Total BICU Beds	Patient Days	Average Daily Census	Percent Change in Patient Days	Average Occupancy Rate
2009 Actual	21	5,818	15.9	---	75.9%
2010 Actual	21	6,242	17.1	7.3%	81.4%
2011 Actual	21	8,357	22.9	33.9%	109.0%
2012 Projected*	21	8,857	24.3	6.0%	115.6%
2013 Projected	21	8,558	23.4	-3.4%	111.7%
2014 Projected	21	8,691	23.8	1.6%	113.4%
2015 Year 1	25	8,821	24.2	1.5%	96.7%
2016 Year 2	25	8,953	24.5	1.5%	98.1%
2017 Year 3	25	9,061	24.8	1.2%	99.3%

*The applicant states FY2012 is projected based on 9 months actual utilization.

As shown in the table above, UNC Hospital projects to provide 9,061 patient days of care in the third operating year and, therefore, projects an average annual occupancy rate of 99.3 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 43-46, 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:

> *"The methodology for projecting future utilization is based on historical utilization data and conservative assumptions. The methodology and assumptions are as follows:*
>
> *1) Previous years' utilization statistics and current year's annual utilization (9 months actual and 3 months projected) are the basis of future years' projections. The last three months of FY 2012 are based on the average of the previous 9 months. … In recent years the numbers of total annual discharges from the BICU beds has increased at a strong rate; the average length of stay is decreasing.*
>
> *2) Growth in future years' total annual discharges from the BICU beds is conservatively based on the following annual increases:*
>
> | | | |
> |---|---|---|
> | *FY13* | *21 beds* | *2.31%* |
> | *FY14* | *21 beds* | *2.24%* |
> | *FY15 (Yr 1)* | *25 beds* | *2.19%* |
> | *FY16 (Yr 2)* | *25 beds* | *1.49%* |
> | *FY17 (Yr 3)* | *25 beds* | *1.20%* |

3) *Average length of stay (ALOS) for the BICU beds in future years is based on the following assumptions:*

FY13	*21 beds*	*8.35 days*
FY14	*21 beds*	*8.29 days*
FY15 (Yr 1)	*25 beds*	*8.24 days*
FY16 (Yr 2)	*25 beds*	*8.24 days*
FY17 (Yr 3)	*25 beds*	*8.24 days*

The decrease in annual [sic] *length of stay (ALOS) is an ongoing trend that relates to improvements in treatment outcomes, prevention, effective treatment of infections and the availability of a great depth of outpatient clinics and aftercare programs at UNC Hospitals. The ALOS is expected to remain at approximately 8.24 days for Years 1, 2 and 3 following project completion….*

4) *Patient Days of Care for the BICU in future years are based on the annual discharges multiplied times the average length of stay for the respective years….”*

As indicated in the table above, the utilization of the applicant’s BICU increased from 5,818 patient days in FY2009 to 8,357 patient days in FY2011, or by approximately 44 percent over the two-year period [8,357/5,818 = 1.44]. Also, based on 9 months of actual utilization data, the applicant projects it will provide 8,857 patient days of care in the BICU in FY2012, which would represent a 6 percent increase in patient days from FY2011 [8,857/8,357 = 1.06]. In this application, the applicant projects BICU utilization will increase from 8,857 patient days in FY2012 to 9,061 patient days in FY2017, or by only 2 percent over the five-year period. Exhibit 14 of the application contains letters from 60 physicians and surgeons 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.

C

In Section III.3, page 52, the applicant describes the alternatives considered, including maintaining the status quo, adding fewer beds, and relocating the entire burn intensive care unit to another location.

- The applicant states it rejected the status quo alternative due to several disadvantages, including the fact that the high occupancy rates on the BICU can result in delays for admissions, thereby causing prolonged lengths of stay and increased costs.
- The applicant considered the alternative of adding a smaller number of additional beds to the BICU, but rejected it due to the high utilization of the existing unit, and the fact that the renovations necessary to accommodate a smaller number of beds would be just as costly as the renovations to add four beds.
- The applicant considered the alternative of relocating the BICU and expanding the unit in another location, but rejected it due to the lack of availability of appropriate locations within the hospital given the importance of proximity to essential therapy and support services, the cost of displacing other licensed beds within the hospital, and the long delays that would result from needing to phase the renovations and relocations over several years.

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 adequately demonstrates 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. **University of North Carolina Hospitals at Chapel Hill shall materially comply with all representations made in the certificate of need application.**

2. **University of North Carolina Hospitals at Chapel Hill shall add four burn intensive care services beds for a total of 25 burn intensive care services beds upon completion of the project.**

3. **University of North Carolina Hospitals at Chapel Hill 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. University of North Carolina Hospitals at Chapel Hill 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.

C

In Section VIII.2, the applicant projects its capital cost for the project to be $2,773,100. In Section VIII.3, the applicant states the capital cost will be financed with cash and cash equivalents. In Section IX.1, the applicant projects no start-up expenses or initial operating expenses. In Exhibit 33 of the application, the applicant provides a letter from the Executive Vice President and Chief Financial Officer for UNC Hospitals, which states

> *"This letter is to confirm the availability of funding in excess of $2,773,100 specifically for use for the capital costs associated with the development of the above referenced project. Attached is a copy of our most recent audited financial statement for the fiscal years ending June 30, 2011. You can find disclosed in the 'Current Assets' section of the 'Statements of Net Assets' in the fiscal year 2011 audited financial statement, listed as line item 'Cash and Cash Equivalents' in the statement's Exhibit A-1, funds in excess of this amount which are available for this project.*"

Exhibit 34 of the application contains audited financial statements for University of North Carolina Hospitals at Chapel Hill (UNCH-CH) for the year ended June 30, 2011, which document that UNCH-CH had $119 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.

C

UNCH-CH 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. The applicant's existing burn intensive care services beds operated in excess of 100 percent of capacity in FY2011. Also, based on data reported in the *2012 Hospital License Renewal Application*, North Carolina Baptist Hospital's existing burn intensive care services beds operated at 79 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.

C

In Section VII.3, page 88, the applicant projects the incremental staffing required in the second operating year for the four additional burn intensive care services beds to be added to the existing BICU at UNCH-CH, as shown in the table below.

Incremental BICU Staff Required	**FTEs**
Clinical Nurse I	1.91
Clinical Nurse II	3.59
Clinical Nurse III	0.36
Clinical Nurse IV	0.21
LPN	0.09
Clinical Support Tech I	0.14
Clinical Support Tech II	0.23
Nursing Assistant I	1.54
Nursing Assistant II	0.04
Health Unit Coordinator	0.30
Physical Therapist II	0.29
Respiratory Therapist	0.94
Total	**9.63**

In Sections VII.1, pages 86-87, the applicant provides current and proposed staffing tables for the BICU at UNCH-CH, which shows the administrative, clinical, and support personnel that will be available to support the proposed burn intensive care services beds. In Section VII.6, pages 90-91, the applicant describes its recruitment and retention processes which will be used to recruit the additional BICU staff identified in Section VII.3. In Section VII.8, page 92, the applicant identifies Bruce A. Cairns, M.D. as the Medical Director for the BICU

at UNCH-CH. 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.

C

In Section II.2, page 19, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at UNCH-CH. In Section V.2 of the application, the applicant states that it has transfer agreements with many facilities statewide. Exhibit 7 contains a sample transfer agreement. The applicant provides letters from physicians supporting the proposed project in Exhibit 14. 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;

C

In Section VI.13, page 82, the applicant provides the payer mix during FY2011 for the existing BICU at UNCH-CH, as shown in the table below.

UNCH-CH BICU Payer Category	**BICU Patient Days as % of Total**
Self Pay/Indigent/Charity	18.8%
Medicare/Medicare Managed Care	16.4%
Medicaid	30.8%
Commercial Insurance	0.6%
Managed Care	20.1%
Other	13.3%
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)
Alamance	16%	6.2%	21.0%
Cumberland	18%	7.4%	20.3%
Durham	16%	5.7%	20.1%
Johnston	17%	6.7%	20.0%
Wake	10%	3.3%	18.4%
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;

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 82, the applicant states:

"UNC Hospitals has long since satisfied its 'free care' obligation under the Hill-Burton Act. Charity care provided by UNC Hospitals for the year ending June 30, 2011 was $133,844,195 (13.23% of net revenue). UNC Hospitals provides care to all persons based only on their need for care without regard to minority status or handicap/disability."

In Section VI.10, page 81, the applicant states that there have not been any civil rights access complaints filed against UNC Hospitals 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

C

In Section VI.14, page 83, the applicant provides the projected payer mix for the second operating year (FY2016) for the BICU at UNCH-CH, as shown in the table below.

UNCH-CH BICU Payer Category	**BICU Patient Days as % of Total**
Self Pay/Indigent/Charity	18.8%
Medicare/Medicare Managed Care	16.4%
Medicaid	30.8%
Commercial Insurance	0.6%
Managed Care	20.1%
Other	13.3%
Total	**100.0%**

In Section VI.14, page 83, the applicant states, *"The projected payor mix for Year 2 is expected to remain consistent with the FY 2011 payor mix percentages."* 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.

C

In Section VI.9, page 78, 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.

C

In Section V.1 of the application, the applicant states UNC Hospitals is an academic medical center with many health professional training programs, and relationships with many other programs. Section V.1(a), page 66, includes a list of institutions with which the applicant has these arrangements. Exhibit 27 contains a copy of a sample agreement between UNC Hospitals and other health professional training programs. 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.

C

See Section V.7, page 74, 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.

C

UNC Hospitals 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 UNC Hospitals 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.

C

UNCH-CH 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 24, the applicant states it currently operates 21 burn intensive care services beds and, following the addition of the four proposed beds, will operate 25 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 24, the applicant states one severely burned patient was treated through the emergency room during the last year.

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

-C- In Section II.8, page 24, the applicant states 657 severely burned patients were referred from other facilities (*"another hospital"*).

(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 8,357 inpatient days of care on the burn intensive care unit (BICU) from July 1, 2010 to June 30, 2011. Also, in Section IV.1, page 61, the applicant reports that it provided 6,770 inpatient days of care on the BICU during the first 9 months of FY2012 (July 2011 – March 2012).

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

-C- In Section II.8, page 24, the applicant states one severely burned patient was referred to another facility during the past year.

(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 18, 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 43-45, and Section III.5, page 58.

(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 IV.1, page 63, 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. 43-45.

(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- UNCH-CH and Wake Forest Baptist Medical Center operate the only two existing burn intensive care units in the state. In Section II.8, page 25, the applicant provides historical utilization data for those two existing burn intensive care units, which show that both of the units have historically operated at high levels of occupancy, as evidence that they are unable to accommodate the applicant's projected need for additional burn intensive care services.

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

-C- Exhibit 14 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 26, 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- Exhibit 16 contains a description of inservice training and continuing education programs specific to burn intensive care services that are provided to UNCH-CH'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 17 contains a copy of UNCH-CH's policies and procedures on patient transfers from outside hospitals, and Exhibit 8 contains a copy of UNCH-CH's disaster plan policies and procedures.

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

-C- Exhibit 29 contains a copy of UNCH-CH's policies and procedures on patient admissions and discharges, which the applicant states are "*regularly reviewed and updated by the hospital administration with input and review by nursing services and medical directors.*"

(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 19 contains a copy of UNCH-CH's policies and procedures on infection control which addresses all of the areas required in this rule.

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

-C- Exhibit 8 contains a copy of UNCH-CH's policies and procedures on disaster planning, including the BICU.

(E) performance of special procedures; and

-C- Exhibit 20 contains a copy of UNCH-CH's policies and procedures on special procedures on the BICU.

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

-C- Exhibit 21 contains a copy of UNCH-CH's policies and procedures on handling and storage of allograft (homograft and heterograft) human tissue on the BICU.

(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 5 contains a copy of the floor plan for UNCH-CH'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 that all of the patient rooms have isolation capabilities.

(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 29, the applicant states, "[The BICU] *configuration provides direct observation of all patient rooms from the nurses' stations. In addition, all of the patient rooms are equipped with video equipment that allows nursing staff to have enhanced patient observation. The proposed project will add four beds and the facility design will continue to provide direct and closed circuit television observation capabilities."*

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

-C- UNCH-CH's BICU currently operates 21 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 29, the applicant provides a table showing the two existing burn intensive care units in the state, UNCH-CH and North Carolina Baptist Hospital, 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 UNCH-CH currently operates 21 beds. In Section II.8, page 29, the applicant provides a table showing utilization of the existing burn intensive care unit at UNCH-CH operated at an average occupancy rate of more than 70 percent in FY2011.

(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 UNCH-CH would operate 25 beds upon completion of the proposed project. In Section II.8, page 30, the applicant provides a table showing the projected utilization of the burn

intensive care unit at UNCH-CH will exceed the required annual occupancy rate of 70 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 UNCH-CH would operate 25 beds upon completion of the proposed project. In Section II.8, page 30, the applicant provides a table showing the projected utilization of the NC Jaycee Burn Center at UNCH-CH will exceed the required annual occupancy rate of 70 percent in the second operating year. North Carolina Baptist Hospital (NCBH), which currently operates an 8-bed burn ICU, is the only other existing or approved burn intensive care unit. The applicant projects that NCBH's burn intensive care unit will be utilized at an annual occupancy rate of more than 60 percent no later than 2 years following completion of the applicant's proposed project, as shown in the table below:

NCBH Burn ICU Utilization	FY2010	FY2011	FY2012	FY2013	FY2014 PY 1	FY2015 PY 2	FY2016 PY 3
Discharges	258	268	273	277	282	287	292
Days	3419	2972	3024	3077	3131	3186	3242
ALOS	13.25	11	11	11	11	11	11
ADC	9	8	8	8	9	9	9
# Burn ICU Beds*	8	8	8	8	12	12	12
Occupancy	117%	102%	104%	105%	71%	73%	74%

*Note: NCBH has also applied to add four burn intensive care service beds (Project I.D. # G-8842-12), and the applicant assumes that NCBH is approved to add four burn intensive care services beds for a total of 12 BICU beds by FY2014.

The applicant states, *"NCBH's Burn ICU volumes have grown historically at 1.75% each year. The 5-year CAGR is a reasonable predictor of future growth, in that it accounts for any fluctuations in volume over a period of time. NCBH's PY 2 is July 1, 2015 to June 30, 2016. As seen in the table above, the occupancy is projected to be 73 percent which exceeds the 10A NCAC .3403(a)(4) performance standards."* 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 31, the applicant states, *"The UNC Hospital NC Jaycee Burn Center will exceed the performance standards based on the days of care for severely burned patients as seen in Section IV."*

(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. 43-45.

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 32, and Exhibit 22, the applicant provides documentation that all of the services, equipment and supplies required by this Rule are available at UNCH-CH'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 32, and Exhibit 23, 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 UNCH-CH'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 32, and Exhibit 24, the applicant provides documentation regarding the community outreach efforts of the NC Jaycee Burn Center at UNCH-CH, including the *"Sparky the Firedog"* burn prevention program.

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 33, and Exhibit 3, the applicant provides documentation of a designated physician in charge of the NC Jaycee Burn Center at UNCH-CH 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 33, and Exhibit 25, 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 33, and Exhibit 2, the applicant provides documentation of a registered nurse administratively responsible for the nursing services of the NC Jaycee Burn Center at UNCH-CH 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 33, and Section VII.3, the applicant provides documentation of a burn specialist that will be available 24 hours per day, 7 days per week, at the NC Jaycee Burn Center at UNCH-CH.

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

-C- In Section II.8, page 33, and Section VII.3, the applicant provides documentation of a burn care technician that will be available 24 hours per day, 7 days per week, at the NC Jaycee Burn Center at UNCH-CH.

(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 34, and Exhibit 25, the applicant provides documentation of the availability of the support staff required by this Rule at the NC Jaycee Burn Center at UNCH-CH.

(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 34, and Exhibit 25, 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 NC Jaycee Burn Center at UNCH-CH.

(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, and Exhibit 25, the applicant provides documentation of the availability of the other surgical support services staff available for consultation as required by this Rule at the NC Jaycee Burn Center at UNCH-CH.

(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 states, *"As seen in Exhibit 16, the Burn Center already has an organized staff education and training program which is integral to the burn intensive care service unit and which ensures improvements in technique and the proper training of new personnel."* Exhibit 16 contains a listing of staff education and training programs for the UNCH-CH burn intensive care services staff.