ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: August 29, 2012
FINDINGS DATE: August 29, 2012
PROJECT ANALYST: Fatimah Wilson
SECTION CHIEF: Craig Smith

PROJECT I.D. NUMBER: J-8812-12 / University of North Carolina Hospitals at Chapel Hill / Develop 27 acute care beds in Chapel Hill for a total of 756 acute care beds upon completion of this project and Project I.D. #J-8501-10 / 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

University of North Carolina Hospitals at Chapel Hill (UNC Hospitals) is currently licensed for and operating a total of 806 licensed beds of which 700 are acute care beds. (Project I.D. #J-8501-10 was approved for 36 additional acute care beds; 7 of the approved beds have been licensed with 29 beds remaining to be licensed). The applicant now proposes to add 27 new acute care beds in existing space for a total of 756 general acute care beds. The 2012 State Medical Facilities Plan (2012 SMFP) includes an Acute Care Bed Need Determination for 27 additional acute care beds in the Orange County Service Area. The 2012 SMFP states:

> *"Any qualified applicant may apply for a certificate of need to acquire the needed acute care beds. A person is a qualified applicant if he or she proposes to operate the additional acute care beds in a hospital that will provide:*
>
> *(1) a 24-hour emergency services department,*

(2) inpatient medical services to both surgical and non-surgical patients, and

(3) if proposing a new licensed hospital, medical and surgical services on a daily basis within at least five of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid services (CMS), as follows: … [as listed in the 2012 SFMP]."

The applicant proposes to develop all of the 27 acute care beds available for the Orange County Service Area in Orange County. The applicant does not propose to develop more acute care beds than are determined to be needed in the Orange County Service Area. UNC Hospitals currently operates a 24-hour emergency services department. In Section II.8, pages 23-24, the applicant provides the number of inpatient days of care by major diagnostic category (MDC) provided at UNC Hospitals during FY 2011. UNC Hospitals provided services in all 25 MDCs listed in the 2012 SMFP. Therefore, the applicant adequately demonstrates that it will provide medical and surgical services in at least five MDCs recognized by CMS. UNC Hospitals adequately demonstrates that it provides inpatient medical services to both surgical and non-surgical patients. Thus, UNC Hospitals is a qualified applicant and the proposal is consistent with the need determination in the 2012 SMFP for acute care beds in Orange County.

Policy GEN-3: Basic Principles is also applicable to this review. This policy states:

"A CON 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 (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing health care value for resources expended. A CON 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 CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area."

Regarding the promotion of safety and quality, in Section III, page 53, the applicant states,

"The promotion of safety and quality is of major importance to UNC Hospitals. The development of more modern inpatient rooms will increase patient safety. Environment of care is an important consideration in the provision of quality care. This proposed project will provide newly constructed facilities based on the latest industry standards, which can only serve safety and quality. "

Regarding plans for providing access to services for patients with limited financial resources and availability of capacity to provide these services, in Section III, page 54, the applicant states,

> *"Access to the services proposed to be provided in the proposed project will utilize the existing policies that UNC Hospitals has in place to allow the continued and enhanced provision of care to those in need."*

In Section VI.4, page 87, the applicant states,

> *"No citizen of North Carolina is refused non-elective treatment for services at UNC Hospitals because of his/her inability to pay."*

In Section VI.2, page 86, the applicant states,

> "*…No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status or lack of medical insurance."*

Regarding how the project will promote equitable access and maximize healthcare value for resources expended, in Section III, page 53, the applicant states,

> *"One option considered as an alternative to the proposed renovations was the development of a new multi-story bed tower on the main hospital campus on the last bid of land available for hospital expansion. The cost of a new multi-story bed tower on the main hospital campus was estimated to be too costly at this time. Due to the recent changes in the economy, it was deemed that exploring ways to add the 27 new beds on the main campus at this time would provide the maximum value for our resources and the added benefit of providing enhanced access. "*

The applicant adequately demonstrates the need to develop 27 additional acute care beds, to include a 24-bed BMTU. The applicant also demonstrated that projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. Projected utilization is based on reasonable, credible, and supported assumptions. See Criterion (3) for a description of the methodologies used to project utilization. The discussion in Criterion (3) regarding projected utilization is incorporated as if fully set forth herein. Thus, the application is conforming to Policy GEN-3.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities is also applicable to this review. This policy 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."

Regarding energy efficiency and sustainability for health service facilities, in Section III, page 54-55, 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 NC State Building Codes. The plan shall not adversely affect patient or resident health, safety or infection control.

…The facility renovation plans and specification for the project shall be researched and developed by the project architect, with input from plan engineering and administration, to include specific design features to ensure improved energy efficiency and water conservation. UNC Hospitals will develop and implement an Energy Efficiency and Sustainability Plan that is specific to the project and will address the following systems and features:

(1) Lighting Systems—Lighting systems will be renovated, added and upgrades as needed within the scope of the areas of renovations for the project to provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the NC State Building Codes. The changes to the lighting systems shall not adversely affect patient or resident health, safety or infection control.

(2) Water Systems—Water systems, hand wash facilities, and toilets will be modified, added and upgraded as needed within the scope of the areas of renovation for the project to provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the NC State Building Codes. The changes shall not adversely affect patient or resident health, safety or infection control.

(3) Heating, Ventilation and Air-Conditioning (HVAC) Systems—HVAC systems will be renovated, added and upgraded as needed within the scope of the areas of renovation for the project to provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the NC State Building Codes. The changes shall not adversely affect patient or resident health, safety or infection control.

(4) Minor Equipment such as ice achiness (machines) *will be evaluated prior to purchase and implementation based on energy efficient and water conservation. The minor equipment shall not adversely affect patient or resident health, safety or infection control.*

(5) Other potential energy conservation measures for the project will be researched and evaluated by the project engineer and architect as well as UNCH administration."

In summary, UNC Hospitals is conforming to the 2012 SMFP Need Determination and SMFP Policy GEN-3 and Policy GEN-4. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

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

C

University of North Carolina Hospitals at Chapel Hill (UNC Hospitals) is currently licensed for and operating a total of 806 licensed beds of which 700 are acute care beds. (Project I.D. #J-8501-10 was approved for 36 additional acute care beds; 7 of the approved beds have been licensed with 29 beds remaining to be licensed). The applicant proposes to add 27 new acute care beds in existing space for a total of 756 general acute care beds. In Section II.1(a), page 13, the applicant states,

"Several relocations of existing programs will be required to allow for the development of the proposed 27 beds. Part of the final result will be a 24-bed BMT unit on the 1st Floor of Neurosciences Hospital (NSH). This unit will be comprised of 16 existing BMTU beds relocated from the 4th Floor of the Cancer Hospital plus 8 of the new 27 bed allocation, for a new unit total of 24 BMTU beds. The remaining 19 new acute care beds will be housed in two locations. 16 of these new beds will be developed in the bed unit that is vacated by the existing 16 bed BMTU when BMTU relocates to the 1st Floor of NSH (and add 8 of the new beds to become a 24 bed unit). The remaining 3 new beds will be developed by allowing beds to remain open that were previously slated to close due to their being located in a semi-private room for a smaller-sized inpatient room."

The applicant does not propose to develop any ICU beds, Level II-IV neonatal bassinets, or sub beds previously slated to close due to their being located in a semi-private room or a smaller-sized -acute beds (i.e. psych, rehabilitation, skilled nursing, etc.)

In Section II.1(a), pages 13-15, the applicant describes the relocations of existing programs required to allow for the development of the additional 27 acute care,

*"**Relocate Existing Neurology Clinic from the Ground Floor NSH***
…This clinic is being relocated off-campus to the 2nd Floor of the Hedrick Office Building. Moving the Neurology Clinic off-campus to the Hedrick Building will allow the Psychiatry Clinic to move off of the 1st Floor of the NSH, as the Psychiatry Clinic currently occupies a portion of the NSH 1st Floor space that is proposed to be renovated to accommodate the relocated and expanded BMTU. …

Relocate Existing Psychiatry Clinic from the 1st Floor NSH
This clinic will be relocated to the Ground Floor of the NSH (vacated by the Neurology Clinic described above) to free up space on the 1st Floor NSH, which will eventually be renovated to accommodate the relocated and expanded BMTU. …

Relocate Part of the Existing Eating Disorders Program within 1st Floor NSH
This program is currently in two disparate locations on the 1st Floor NSH. The part of the program on the north-side of the 1st Floor NSH (1,923) does not need to relocate, but the 785 SF program space on the south – side will move adjacent to the north – side space. …This allows the south – side space to become vacated for the BMTU, and allows for both portions of the Eating Disorders program to be co-located. The space on the south – side portion of the program moves into is space that will be vacated when Psychiatry offices are moved off of the 1st Floor of the NSH.
Relocate other Existing Offices (Clinical Care Management and Psychiatry faculty, resident and administrative staff)
Clinical Care Management (CCM) offices are located on the 3rd Floor of NSH and will be relocated off-campus to the Eastowne Office Buildings. …Their vacated space on the

3rd Floor NSH will be used to house some of the offices relocated from the 1st Floor NSH as described below.

The Psychiatry faculty, residents and administrative support offices currently occupy 12,035 SF of space on the 1st Floor of the NSH, which needs to be vacated to allow for the relocation and expansion of the BMTU to the 1st Floor NSH.

... There is one other tenant on the 1st Floor NSH, the Department of Psychiatry's Crisis Unit, which will remain in its location and will not be altered or impacted.

FINAL OUTCOME

4th Floor Cancer Hospital – Vacated unit becomes the Proposed 16 Bed Med/Surg Unit when the existing 16 BMTU relocates
Once the BMTU relocates and expands on the 1st Floor of NSH, the existing 16 bed BMTU space will become a 16 bed Med/Surg inpatient acute care unit. …

1st Floor NSH – Vacated space becomes expanded / relocated 24 bed BMTU after existing programs are relocated and space is renovated
Once vacated, the required space on the 1st Floor NSH will be renovated for use as a 24 bed BMTU, to be composed of 16 existing/relocated inpatient bone marrow beds plus 8 new inpatient bone marrow beds.

Remaining 3 new Med/Surg Acute Care Beds
These beds will be developed by not closing the following existing inpatient beds on the existing 4 Anderson North unit: patient room 4706 second headwall, patient room 4707 second headwall and patient room 4716 second headwall. These rooms will remain semi-private rooms. These rooms were to become private rooms a part of the previously approved CON Project I.D. #J-8501-10 to add 36 licensed acute care beds. In this case, these three beds will now NOT be converted to private rooms."

Population to be Served

In Sections III.4(a) and III.5(c), the applicant provides current and projected patient origin for UNC Hospitals. The applicant states that they project no material change in patient origin in the foreseeable future. UNC Hospitals' current and projected patient origin for the first two years of the proposed project is illustrated below:

UNC Hospitals Current and Projected Patient Origin

County	Current (FY 11)	Projected (Year 1 and 2)

Orange	24.60%	24.60%
Wake	13.27%	13.27%
Durham	10.24%	10.24%
Alamance	9.30%	9.30%
Chatham	7.00%	7.00%
Lee	3.95%	3.95%
Cumberland	3.40%	3.40%
Harnett	2.05%	2.05%
Johnston	1.85%	1.85%
Guilford	1.80%	1.80%
Moore	1.34%	1.34%
Randolph	1.13%	1.13%
Robeson	1.07%	1.07%
All Other NC Counties*	17.31%	17.31%
NC Total	**98.31%**	**98.31%**
Other US Total	**1.78%**	**1.78%**
International Total	**0.01%**	**0.01%**
Total	**100.0%**	**100.0%**

*All Other includes counties with less than 1.0% (Anson, Beaufort, Bertie, Bladen, Brunswick, Buncombe, Burke, Cabarrus, Caldwell, Carteret, Caswell, Catawba, Cleveland, Columbus, Craven, Dare, Davidson, Davie, Duplin, Edgecomb, Forsyth, Franklin, Gaston, Gates, Graham, Granville, Greene, Halifax, Haywood, Henderson, Hertford, Hoke, Hyde, Iredell, Jackson, Jones, Lenoir, Lincoln, McDowell, Macon, Madison, Martin, Mecklenburg, Mitchell, Montgomery, Nash, New Hanover, North Hampton, Onslow, Pamplico, Pasquotank, Pender, Perquimans, Person, Pitt, Richmond, Rockingham, Rowan, Rutherford, Sampson, Scotland, Stanly, Stokes, Surry, Swain, Transylvania, Tyrell, Union, Vance, Warren, Washington, Watauga, Wayne, Wilkes, Wilson, Yadkin, Yancey), which equates to 17.31% of the category.

The applicant adequately identified the population it proposes to serve.

Need for the Proposed Project

In Section III.1(a), pages 44-51, the applicant describes the need for the proposed 27 additional acute care beds.

> *"UNC Hospitals continues to see growth in the number of patients it serves and high occupancies continue to be an issue. …The need for the proposed additional 27 beds is primarily based upon the inadequacy of the existing number of acute care beds to meet current patient needs and demands.*

> *…Over the past several years, the beds available to accommodate a specific patient's needs are often full. In response to this ongoing high occupancy, UNC Hospitals has submitted several CON applications to address patient needs, which are in different phases of development.*
>
> *In spite of these measures, UNC Hospitals continues to experience high occupancies and occasionally must refuse to accept or delay transfers of patients from other facilities due to the lack of an appropriate bed. Between March 2011 and February 2012, at least 1,705 patient transfers were not able to be accommodated due to a bed not being available in the appropriate level of care.*
>
> *…If an appropriate bed is not available for admissions for patients needing care, admissions must be deferred.*
>
> *Between 3/2011 and 2/2012, UNC Hospitals received at least 10,362 transfer requests and was able to accommodate 7,825 admissions, only 75.5% of the requests. At least 311 [78% of all lost transfers] were due to the unavailability of the level of bed request for that particular patient."*

The applicant demonstrated need for the 27 additional acute care beds on the basis of high occupancies and inadequacies of the existing number of acute care beds to meet current patient needs and demands.

In Section III.1(a), pages 45-51, the applicant describes the components of the project used to demonstrate need:

1) Growth Trends and Rates;

2) National Bone Marrow Transplant Volumes;

3) SMFP Need Determination for the Orange County Service Area;

4) BMTU; and

5) Medical / Surgical Beds;

<u>Growth Trends and Rates</u>

In Section III.1(a), page 45, the applicant states,

> *"Demographic data for Health Service Area IV and the Orange County acute care service area show that the population growth will increase demand for health care services, including inpatient acute care services. Between 2011 and 2016 the*

population of Health Service Area IV is projected to increase by more than 10% or 216,094 persons.

Projected Population Growth

County	***7/1/2011***	***7/1/2012***	***7/1/2013***	***7/1/2014***	***7/1/2015***	***7/1/2016***	***7/1/2017***
Chatham	*65,304*	*66,742*	*68,177*	*69,615*	*71,053*	*72,489*	*73,927*
Durham	*274,379*	*279,836*	*285,289*	*290,745*	*296,200*	*301,654*	*307,109*
Franklin	*62,224*	*63,880*	*65,051*	*66,486*	*67,727*	*69,268*	*70,527*
Granville	*61,430*	*62,310*	*63,190*	*64,073*	*64,955*	*65,835*	*66,716*
Johnston	*175,194*	*180,240*	*185,282*	*190,328*	*195,372*	*200,414*	*205,459*
Lee	*58,838*	*59,617*	*60,399*	*61,178*	*61,957*	*62,737*	*63,519*
Orange	*136,438*	*138,550*	*140,660*	*142,772*	*144,885*	*146,996*	*149,109*
Person	*39,962*	*40,458*	*40,847*	*41,321*	*41,734*	*42,187*	*42,617*
Vance	*45,682*	*45,888*	*46,094*	*46,300*	*46,507*	*46,713*	*46,918*
Wake	*932,665*	*958,015*	*983,367*	*1,008,719*	*1,034,069*	*1,059,422*	*1,084,772*
Warren	*21,121*	*21,210*	*21,301*	*21,391*	*21,481*	*21,571*	*21,662*
HSA' IV	*1,873,237*	*1,916,746*	*1,959,657*	*2,002,928*	*2,045,940*	*2,089,286*	*2,132,335*
STATE	*9,735,890*	*9,886,725*	*10,035,382*	*10,184,132*	*10,331,630*	*10,479,127*	*10,625,441*
Source: NC Office of Budget and Management, September 2011							

As shown above, the population of HSA IV is projected to increase by more than 10% between 2011 and 2016 and by more than 7% for the State of North Carolina. It is the assumption of the applicant as stated in Section III.1(a), page 46 that the aging of the population will drive greater demand for bone marrow transplants and inpatient admissions overall.

National Bone Marrow Transplant Volumes

In Section III.1(a), page 46, the applicant provides the national bone marrow transplant volumes from 2000 to 2010.

National Bone Marrow Transplant Volumes

Year	***0-10 Years***	***11-17 Years***	***18-30 Years***	***31-40 Years***	***41-50 Years***	***51-64 Years***	***64 + Years***	***Total***
2000	*290*	*179*	*303*	*335*	*333*	*220*	*12*	*1,672*
2002	*317*	*219*	*344*	*355*	*362*	*377*	*34*	*2,008*
2004	*363*	*208*	*415*	*353*	*451*	*651*	*78*	*2,519*
2006	*508*	*244*	*533*	*382*	*530*	*869*	*151*	*3,217*
2008	*648*	*322*	*653*	*472*	*692*	*1,240*	*303*	*4,330*
2009	*676*	*354*	*641*	*514*	*755*	*1,485*	*395*	*4,820*
2010	*752*	*327*	*671*	*557*	*771*	*1,669*	*481*	*5,228*
Source: Health Resources and Services Administration, US Department of Health and Human Services, C.W. Bill Young Cell Transplantation Program								

As shown in the table above, bone marrow transplant volumes have increased by a Compound Annual Growth Rate (CAGR) of 13.5% from 2000 to 2010 for all ages combined, thus identifying a need to expand BMT services at UNC Hospitals.

SMFP Need Determination for the Orange County Service Area

The 2012 State Medical Facilities Plan determined that there exists a need for 27 additional acute care beds for the Orange County acute care service area. Several relocations of existing programs will be required to allow for the development of the proposed 27 beds. UNC Hospitals proposes to develop all of the 27 acute care beds available for the Orange County Service Area in Orange County. UNC Hospitals is the only licensed acute care hospital and the sole provider of inpatient care in the acute care service area.

SMFP Target Capacity

In Section III.1(a), page 49, the applicant projects that 219,695 total inpatient days of care will be provided during year 3 of operation of the 756 licensed acute care beds. This results in an average daily census of 602 [219,695 patient days / 365 days per year = 602]. Once the ADC is applied across 365 days per year, the result is an occupancy rate of 79.6%. [602 ADC / 756 = 79.6%]. The projected occupancy of acute care beds surpasses the required target capacity of 75.2% set forth in the rule.

BMTU

In Section III.1(a), page 49, the applicant states,

> *"The BMTU occupancy during FY 11 was 79%. This occupancy is high but also deceptive as patients routinely must wait for admission to the unit to be able to receive their bone marrow transplant. The addition of 8 BMTU beds is proposed to help address this need, by expanding the number of BMTU beds available to 24.*
>
> *…This increase should help alleviate some of the patient admission backlog."*

In Section III.1(a), page 50, the applicant states,

> *"Even with the proposed expansion of 8 additional BMTU beds, the occupancy projected for project Year 3 for BMTU's resulting 24 beds remains very high. This growth in BMTU volumes can easily be accommodated based on the volume of bone marrow transplant requests we receive. Significant growth is expected upon opening of the additional beds, which is based on past UNC Hospitals' experience of opening expanded types of specialized units."*

The applicant states in Section III.1(a), page 50 that UNC Hospital's BMTU is currently operating at 85%. In Section IV.1, page 67, the applicant provides the historical utilization for the BMTU as follows:

	Prior Full FY 7/1/09 – 6/30/10	Last Full FY 7/1/10 – 6/30/11	Interim FY 7/1/11 – 6/30/12
	FY10	FY11	FY12
BMTU			
# Beds	16	16	16
Discharges	306	342	347
Pt. Days	4.544	4.808	4,960
% Occupancy	78%	82%	85%

With the aging population and expected overall population increases, the need for inpatient admissions and beds is expected to grow in the future. The applicant demonstrated need for the additional acute care beds at UNC Hospitals based on high utilization and occupancy of the existing BMTU in recent years.

Medical / Surgical Beds

In Section III.1(a), page 50-51, the applicant states,

> *"…Overall occupancy of inpatient beds on the Manning Drive campus is quite high. The Manning Drive campus also has significant space constraints, in general, in UNC Hospitals' patient care areas."*

The applicant documents in Section III.1(a), page 50 that UNC Hospital's medical /surgical beds are currently operating at 81%. In Section IV.1, page 67, the applicant provides the historical utilization for the Med/Surg unit as follows:

	Prior Full FY 7/1/09 – 6/30/10	Last Full FY 7/1/10 – 6/30/11	Interim FY 7/1/11 – 6/30/12
	FY10	FY11	FY12
Med/Surg			
# Beds	428	443	452
Discharges	30,809	32,181	31,938
Pt. Days	123,562	127,902	134,424
% Occupancy	79%	79%	81%

With the aging population and expected overall population increases, the need for inpatient admissions and beds is expected to grow in the future. The applicant demonstrated need for the additional acute care beds at UNC Hospitals based on high utilization and occupancy of inpatient nursing units in recent years.

In Section IV, pages 66-67, the applicant provides the assumptions and methodology used to project utilization. Additionally, in Section IV, page 66, the applicant provides the following assumptions regarding projected growth of acute care days at UNC Hospitals,

> *"Utilization projections are based on historical actuals projected forward. ALOS and discharges are from the pro formas, recent financial statements and departmental administration. Seasonal variation is based on actual used for pro formas. Existing historical patterns were projected forward and are expected to remain consistent over time. …*
>
> *BMTU CAGR from FY 11 through FY 17 equates to approximately 10.4% annual growth. Individual projected annual volume increases are less than this annually with a growth peak when BMTU opens additional beds in FY 15.*
>
> *Med/Surg CAGR from FY 11 through FY 17 equates to approximately 2.8% annual growth. Individual projected annual volume increases are less than this annually with a growth peak when additional beds are opened in FY 15. Projected volumes also account for other bed additions as approved in previous CON applications."*
>
> On page 125 of the pro formas, the applicant provides the following assumptions regarding projected growth of acute care days at UNC Hospitals,
>
> *"Volumes/Utilization*
>
> 1. *Inpatient discharges increase .58% in FY 2013, 1.53% in FY2014 and .25% through FY 2017 depending on bed complement.*
> 2. *Average length of stay for inpatients is 6.13 from FY 2012 through FY 2017*
> 3. *Inpatient case mix constant from FY 2012 = FY 2017 to reflect documentation improvements*
> 4. *Outpatient volume increases 2% in FY 2012 through FY 2017*
> 5. *Bed complement, 832 (2012), 835 (2013) and 862 thereafter"*

	Last Full FY	*1st Full FY*	*2nd Full FY*	*3rd Full FY*
	7/1/10 – 6/30/11	*7/14/14 – 6/30/15*	*7/1/15 – 6/30/16*	*7/1/16 – 6/30-17*
	FY11	*FY15*	*FY16*	*FY17*
All Patient Days	*238,394*	*257,083*	*257,726*	*258,370*
All Acute Pt. Days	*199,719*	*218,408*	*219,051*	*219,695*

As shown in the table above, the applicant provides the total inpatient days of care during the third year of operation (219,695) used to project acute care bed utilization.

In Section IV.1, page 67, the applicant provides historical and projected acute care bed utilization at UNC Hospitals, as shown below.

	Historical Utilization			Project Development		PY 1	PY 2	PY3
	Prior 7/1/09 to 6/30/10 FY 2010	**Last Full 7/1/10 to 6/30/11 FY 2011**	**Interim 7/1/11 to 6/30/12 FY 2012**	**Interim 7/1/12 to 6/30/13 FY 2013**	**Interim 7/1/13 to 6/30/14 FY 2014**	**1st Full 7/1/14 to 6/30/15 FY 2015**	**1st Full 7/1/15 to 6/30/16 FY 2016**	**1st Full 7/1/16 to 6/30/17 FY 2017**
BMTU								
# Beds	16	16	16	16	16	24	24	24
Discharges	306	342	347	349	370	526	530	535
Pt. Days	4,544	4,808	4,960	5,198	5,495	7,785	7,871	7,878
% Occupancy	78%	82%	85%	89%	94%	89%	90%	90%
Med/Surg								
# Beds	428*	443*	452*	440*	470*	506	506	506
Discharges	30,809	32,181	31,938	33,233	33,812	35,685	35,247	35,952
Pt. Days	123,562	127,902	134,424	132,932	139,239	145,953	144,159	147,043
% Occupancy	79%	79%	81%	83%	81%	81%	81%	83%
						19 new beds open		

*Note: These bed changes are part of previously approved CON applications currently under development and scheduled to be on-line at these times.

University of North Carolina Hospitals at Chapel Hill (UNC Hospitals) is currently licensed for and operating a total of 806 licensed beds of which 700 are acute care beds. (Project I.D. #J-8501-10 was approved for 36 additional acute care beds; 7 of the approved beds have been licensed with 29 beds remaining to be licensed). In Section I.9, page 2, the applicant provides a break down of UNC Hospital's bed inventory which shows that 700 beds are general acute care beds, 30 of the beds are inpatient rehabilitation beds and 76 are psychiatric beds, thus, for utilization / occupancy projection purposes, the applicant assumes a total of 700 acute care beds, excluding inpatient rehabilitation and psychiatric beds (806 – 76 – 30 = 700). In Section II.8, page 30, the applicant states,

> *"During Year 3 of operation of the beds, 219,695 total inpatient days of care are to be provided in 756 licensed acute care beds (not including 76 inpatient psychiatric beds and 30 inpatient rehabilitation beds). This reflects an average daily census of 602. [219,695 patient days divided by 365 days = 602] Applying this average daily census of 602 across 365 days per year, results in 79.6%. [602 ADC divided by 756 = 79.6%] This projection exceeds the required 75.2% set forth in this rule for replacement and 78% target occupancy rate in the need methodology. The inpatient day projections are based on historical trends applied forward. See application Sections III and IV for further discussion of projection."*

Based on 756 licensed acute care beds upon project completion, the applicant projects an average daily census ADC of 602 (219,695 patient days / 365 = 602), which is equivalent to an 79.6% (602 / 756 = 0.7963) average occupancy rate for the licensed beds. An occupancy rate of 79.6% exceeds the 75.2% target occupancy rate for hospitals with an ADC >400, required by 10A NCAC 14C .3803(a). Indeed, based on information provided by the applicant on page 67, the historical occupancy rate at UNC Hospitals has consistently exceeded the required target occupancy rate.

The applicant provides supporting documentation in Section III.1(a), pages 44-51, Section IV, pages 66-67, and the pro formas. The applicant's projected utilization for the acute care beds is based on reasonable and supported assumptions regarding historical growth in acute care admissions and patient days. Therefore, the applicant adequately demonstrates the need for 27 additional acute care beds.

In summary, the applicant adequately identified the population proposed to be served and adequately demonstrated the need 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.

C

Several programs will be relocating as a result of the proposed project. The Neurology Clinic will be relocating off-campus from the ground floor of NSH to the 2nd Floor of the Hedrick Office Building. The Clinical Care Management (CCM) offices will be relocating from the 3rd Floor of NSH to Eastowne Office Buildings. The project analyst notes that the relocations are within the same service area and are still located in Chapel Hill. No negative impact to patient services has been indicated by the applicant as a result of relocating these outpatient services to an off-campus site.

(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 55, the applicant discusses the alternatives to the proposed project that were considered prior to submission of this application and the basis for selection of the proposed project. The applicant 1) considered maintaining the status quo, however, this alternative was not deemed to be an effective alternative because it would mean that UNC

Hospitals would continue to operate with inefficiencies and inability to place patients in beds as required, 2) build a new bed tower on the Manning Drive campus, however, this alternative was not deemed to be an effective alternative because it would be quite complicated to construct a new bed tower due to limited space available on the Manning Drive campus to construct a new bed tower and would require more significant capital cost. Alternative three, was deemed to be the most effective alternative which is to develop the beds and associated renovations as proposed in this CON application. Furthermore, the application is conforming with all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20), 10A NCAC 14C. 2900 and .3800. The applicant adequately demonstrated that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is conforming with 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 be licensed for no more than 756 acute care beds, 30 inpatient rehabilitation beds and 76 psychiatric beds upon completion of this 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 and that would otherwise require a certificate of need.**

4. **University of North Carolina Hospitals at Chapel Hill shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representations in the written statement as described in paragraph one of Policy GEN-4.**

5. **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, page 104, the applicant projects that the total capital cost of the proposed project will be $16,178,760, including $12,086,500 for renovation of existing space, $586,760 for

equipment, $1,300,000 for consultant fees, and $1,576,500 for contingency. In Section IX, page 108, the applicant states there are no start-up or initial operating expenses associated with the proposed project. In Section VIII.3, page 105, the applicant states that accumulated reserves will be used to fund the proposed capital cost. Exhibit 34 contains a letter from the Chief Financial Officer at UNC Hospitals indicating the availability of funds for this project, which states,

> *"This letter is to confirm the availability of funding in excess of $16,178,760 specifically for use for the capital cost associated with the development of the above referenced project."*

Exhibit 35 contains a copy of UNC Hospitals' audited financial statements, which show as of June 30, 2011, UNC Hospitals had total assets of $1,627,765,197; $119,165,388 in cash and cash equivalents; and net assets (total assets less total liabilities) of $1,126,731,376. The applicant adequately demonstrated the availability of funds for the capital needs of the project.

The applicant provided Pro forma financial statements for the entire hospital and acute care services for the first three years of the project. For acute care services, the applicant projects that total revenue will exceed total expenses in each of the first three operating years. The applicant also projects an excess of revenue over expenses for the entire facility for each of the first three operating years. Projected costs and revenues are based on reasonable and credible assumptions, including projected utilization. See the Pro forma financial statements in the application and Criterion (3) for utilization assumptions.

In summary, the applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project, and adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to 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

UNC Hospitals operates the only acute care hospital in Orange County and proposes to develop, pursuant to a need determination in the 2012 State Medical Facilities Plan (SMFP), 27 new acute care beds in existing space. The 2012 SMFP includes an Acute Care Bed Need Determination for 27 additional acute care beds in the Orange County Service Area. The applicant proposes to develop all of the 27 acute care beds available for Orange County at its Chapel Hill campus. Eight of the new acute care beds will be added to the existing 16-bed BMTU for a total of 24-beds. The remaining 19-beds will be designated Med/Surg beds. UNCH is one of three providers of BMT Services in the State of North Carolina, the other two being Duke Medical Center and Wake Forest University Baptist Medical Center. UNC Hospitals BMTU cares for individuals undergoing allogeneic and autologous bone marrow transplants. UNC Hospitals continues to experience high occupancies and occasionally must refuse to accept or delay

transfers of patients from other facilities due to the lack of an appropriate bed. Currently, UNC Hospitals' BMTU is operating 16 beds at 85% occupancy and the Med/Surg Unit is operating 452 beds at 81% occupancy. UNC Hospitals adequately demonstrates it is more cost effective to develop the beds and associated renovations as proposed in this CON application because it will provide much needed bed capacity at an appropriate cost. The applicant adequately demonstrates the need to develop 27 additional acute care beds, to include a 24-bed BMTU. Projected utilization is based on reasonable, credible, and supported assumptions. Therefore, the applicant adequately demonstrated that the proposed project is not an unnecessary duplication of existing or approved health service capabilities or facilities, and is conforming with 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.1, page 96, the applicant provides the proposed staffing for the additional 27 acute care beds.

UNC Hospitals Proposed Staffing On Acute Care Inpatient Units

Table VII.1 2nd Full Fiscal Year 7/1/15-6/30-16 FY 16					
UNC Job Title	***UNCH Position Class Code***	***Total # of FTE Positions Employed***	***Average Annual Salary per FTE Position***	***Total # of Contract Hours***	***Average Hourly Contract Rate***
BMT Unit-relocates and grows to 24 beds (add 8 beds)					
Clinical Nurse I /Tier I	*2017*	*4*	*$45,237*	-	-
Clinical Nurse II / Tier II	*2018*	*17.4*	*$65,869*	-	-
Clinical Nurse III / Tier III	*2019*	*13*	*$77,299*	-	-
Clinical Nurse IV / Tier IV	*2020*	*3*	*$83,014*	-	-
Clinical Support Technician	*3024*	*14*	*$33,651*	-	-
Nursing Assistant	*3010*	*7*	*$27,782*	-	-
Health Unit Coordinator	*4601*	*7*	*$33,607*	-	-
Patient Services Manager III-IP-U	*9209*	*1*	*$101,397*	-	-
4 Cancer Hosp BMT Unit becomes 16 bed Med Surg Unit					
Clinical Nurse I /Tier I	*2017*	*5*	*$45,237*	-	-
Clinical Nurse II / Tier II	*2018*	*36.45*	*$65,869*	-	-
Clinical Nurse III / Tier III	*2019*	*11*	*$77,299*	-	-
Clinical Nurse IV / Tier IV	*2020*	*3*	*$83,014*	-	-
Clinical Support Technician	*3024*	*4.4*	*$33,651*	-	-
Nursing Assistant	*3010*	*4*	*$27,782*	-	-
Health Unit Coordinator	*4601*	*4.2*	*$33,607*	-	-
Patient Services Manager III-IP-U	*9209*	*1*	*$101,397*	-	-
Med Surg unit Staff – existing but won't close 3 beds ~ additional staff for 3 beds					
Clinical Nurse I /Tier I	*2017*	*0.67*	*$45,237*	-	-
Clinical Nurse II / Tier II	*2018*	*3*	*$65,869*	-	-
Clinical Nurse III / Tier III	*2019*	*2*	*$77,299*	-	-
Clinical Nurse IV / Tier IV	*2020*	*0.3*	*$83,014*	-	-
Clinical Support Technician	*3024*	*3.68*	*$33,651*	-	-
Nursing Assistant	*3010*	*3.87*	*$27,782*	-	-
Health Unit Coordinator	*4601*	*2.35*	*$33,607*	-	-
Patient Services Manager III-IP-U	*9209*	*0.3*	*$101,397*	-	-
Additional Other Support Positions					
Clinical Dietician	*2600*	*1.8*	*$49,067*	-	-
Dietician Technician	*5004*	*1.8*	*$29,473*	-	-
Pharmacist, Clinical Specialist	*2850*	*1.8*	*$110,468*	-	-
Food Services Asst	*5000*	*1.8*	*$23,108*	-	-
Housekeeper	*5050*	*1.8*	*$23,379*	-	-
Total		*160.35*			

As shown in the above table, the applicant projected the proposed staffing for the second full fiscal year following completion of the project. In Section VII.3, page 97, the applicant states that since the categories of positions already exist, standard recruitment initiatives will remain in force. In Section V.3(c), page 83, the applicant identifies Dr. Tony Lindsey as the current Chief of Staff for UNC Hospitals. The applicant demonstrates the availability of adequate health

manpower and management personnel for the provision of 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

Exhibit 3 contains a letter signed by the Executive Vice President and Chief Operating Officer which lists the ancillary and support services currently available at UNC Hospitals. Exhibit 28 contains a copy of a transfer agreement with Albemarle Hospital. Exhibit 9 contains letters from physicians expressing support for the proposed project. The applicant adequately demonstrated that the necessary ancillary and support services will be available and that the services will be coordinated with the existing health care system. Therefore, the applicant 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

The applicant proposes to renovate 66,298 square feet of existing space. The applicant proposes no new construction for the development of the additional 27 acute care beds.

(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

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 CY 2009, respectively. The data in the table were obtained on August 22, 2012. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	Total # of Medicaid Eligible as % of Total Population	**Total # of Medicaid Eligibles Age 21 and older as % of Total Population**	**% Uninsured CY 2008-2008-2008-09 % Uninsured (Estimate by Sheps Center)**
Orange County	9.0%	3.5%	18.9%
Statewide	17.0%	5.1%	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. Of the

38 beds the applicant proposes to develop, 11 are designated as medical/surgical pediatric beds. The remainder will serve primarily adults.

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 was 48.6% for those age 20 and younger (Orange County percentage was 48.7% for those age 20 and younger) and 31.6% for those age 21 and older (Orange County percentage was 33.0% 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 payor 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.

In Section VI.2(a-f), page 86, the applicant states,

> *"As North Carolina's only state-owned comprehensive, full-service hospital based program, UNC Hospitals has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status or lack of medical insurance."*

In Sections VI.12 and VI.13, page 92, the applicant provides the current payor mix for the entire facility and acute care inpatient services for FY 2011 at UNC Hospitals, as shown below.

UNC Hospitals
All Inpatient Days as a % of Total Utilization

FY 11	***Days***	***% Total***
Self Pay/Indigent/Charity	*15,163*	*6.4%*
Medicare/Medicare Managed Care	*70,806*	*29.7%*
Medicaid	*72,239*	*30.3%*
Commercial Insurance	*2,405*	*1.0%*
Managed Care	*62,966*	*26.4%*
Other	*14,814*	*6.2%*
Total	***238,394***	***100.0%***

UNC Hospitals Inpatient BMT Unit
All Inpatient Days as a % of Total Utilization

FY 11	***Days***	***% Total***
Self Pay/Indigent/Charity	*24*	*0.5%*
Medicare/Medicare Managed Care	*806*	*16.8%*
Medicaid	*767*	*16.0%*
Commercial Insurance	*72*	*1.5%*
Managed Care	*2,670*	*55.5%*
Other	*469*	*9.8%*
Total	***4,808***	***100.0%***

UNC Hospitals Inpatient Med Surg Only
All Inpatient Days as a % of Total Utilization

FY 11	***Days***	***% Total***
Self Pay/Indigent/Charity	*9,629*	*7.5%*
Medicare/Medicare Managed Care	*50,363*	*39.4%*
Medicaid	*28,690*	*22.4%*
Commercial Insurance	*1,456*	*1.1%*
Managed Care	*31,763*	*24.8%*
Other	*6,002*	*4.7%*
Total	***127,902***	***100.0%***

The applicant demonstrates that medically underserved populations currently have adequate access services offered at PCMH. Therefore, the application is conforming to this criterion.

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

C

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 91, the applicant states,

"UNC Hospitals has long since satisfied its "free care" obligation under the Hill-Burton Act."

In Section VI.10, page 91, the applicant states there have been no civil rights 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, pages 93, the applicant projects the payor mix for acute services to be provided at UNC Hospitals during Project Year 2, as illustrated in the following table:

UNC Hospitals
All Inpatient Days as a % of Total Utilization

FY 16 YR 2	***Days***	***% Total***
Self Pay/Indigent/Charity	*16,393*	*6.4%*
Medicare/Medicare Managed Care	*76,548*	*29.7%*
Medicaid	*78,097*	*30.3%*
Commercial Insurance	*2,600*	*1.0%*
Managed Care	*68,072*	*26.4%*
Other	*16,015*	*6.2%*
Total	***238,394***	***100.0%***

UNC Hospitals Inpatient BMT Unit
All Inpatient Days as a % of Total Utilization

FY 16 YR 2	***Days***	***% Total***
Self Pay/Indigent/Charity	*39*	*0.5%*
Medicare/Medicare Managed Care	*1,320*	*16.8%*
Medicaid	*1,256*	*16.0%*
Commercial Insurance	*118*	*1.5%*
Managed Care	*4,370*	*55.5%*
Other	*769*	*9.8%*
Total	***7,861***	***100.0%***

UNC Hospitals Inpatient Med Surg Only
All Inpatient Days as a % of Total Utilization

FY 16 YR 2	***Days***	***% Total***
Self Pay/Indigent/Charity	*10,853*	*7.5%*
Medicare/Medicare Managed Care	*56,764*	*39.4%*

Medicaid	*32,336*	*22.4%*
Commercial Insurance	*1,641*	*1.1%*
Managed Care	*35,800*	*24.8%*
Other	*6,765*	*4.7%*
Total	***144,159***	***100.0%***

In Section VI.2, page 86, the applicant states UNC Hospitals does not discriminate based on race, color, creed, age, sex, national origin, religion, disability status, sexual preference, or sources of payment for care. 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(a), page 89, the applicant documents the range of means by which patients would have access to the services to be provided at UNC Hospitals. The information provided is reasonable and credible and supports a finding of conformity with 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, page 69, and referenced exhibits, UNC Hospitals provides a list of institutions with which it maintains working agreements to facilitate the clinical needs of health professional training programs. The applicant states,

> *"The clinical components of the project currently serve, and will continue to serve, as resources for undergraduate, graduate and post graduate medical and other health science education programs for the University of North Carolina Chapel Hill."*

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 Sections II, III, V, VI and VII. In particular, see Section V.7, pages 84-85, in which UNC Hospitals discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. Approval of 27 additional acute care beds in the Orange County will allow the distribution of beds in the county to be more closely aligned with the population. 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 acute care services in Orange County. This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to add 27 acute care beds to the existing facility for a total of 756 acute care beds with a 24-bed BMTU and a 16-bed Med Surg Unit and that it is a cost-effective alternative;

- The applicant proposes to provide quality services; and states:

  > *"The promotion of safety and quality is of major importance to UNC Hospitals. The development of more modern inpatient rooms will increase patient safety. Environment of care is an important consideration in the provision of quality care. This proposed project will provide newly constructed facilities based on the latest industry standards, which can only serve safety and quality. "*

- The applicants propose to provide adequate access to medically underserved populations.

  > *"Access to the services proposed to be provided in the proposed project will utilize the existing policies that UNC Hospitals has in place to allow the continued and enhanced provision of care to those in need.*
  >
  > *No citizen of North Carolina is refused non-elective treatment for services at UNC Hospitals because of his/her inability to pay.*
  >
  > *No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status or lack of medical insurance."*

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 accredited by the Joint Commission and certified by CMS for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred at UNC Hospitals within the eighteen months immediately preceding the date of this 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

The application submitted by University of North Carolina Hospitals at Chapel Hill (UNC Hospitals) is conforming with all applicable Criteria and Standards for Acute Care Beds as promulgated in 10A NCAC 14C .3800 and Criteria and Standards for Bone Marrow Transplantation Services as promulgated in 10A NCAC 14C .2900. The specific criteria are discussed below.

Criteria and Standards for Acute Care Beds 10A NCAC 14C .3800 Information Required of Applicant

.3802(a) This rule states, *"An applicant that proposes to develop new acute care beds shall complete the Acute Care Facility/Medical Equipment application form."*

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

3802(b)(1) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: (1) the number of acute care beds proposed to be licensed and operated following completion of the proposed project."*

-C- In Section II.8, page 23, the applicant states that it proposes to add 27 new acute care beds for a total of 756 licensed and operational acute care beds upon completion of this project.

.3802(b)(2) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (2) documentation that the proposed services shall be provided in conformance with all applicable facility, programmatic, and service specific licensure, certification, and JCAHO accreditation standards."*

-C- In Section II.6, page 20, the applicant states,

> *"…UNC Hospitals' facilities are required to meet the following standards:*
>
> - *Conditions for participation in Medicare and Medicaid;*
> - *OSHA;*
> - *North Carolina Hospital Licensure standards;*
> - *National Fire Protection Association (NFPA);*
> - *The Joint Commission (formerly JCAHO);*
> - *North Carolina Board of Nursing;*
> - *Accreditation Council for Graduate Medical Education (ACGME); and*
> - *College of American Pathologists.*
>
> *UNC Hospitals' facilities currently meet and will continue to meet the above licensure, certification and accreditation standards, and as noted…the clinical areas are in compliance with OSHA requirements, The Joint Commission rules, North Carolina DFS regulations, National Fire Protection Association codes, and any other mechanical and electrical codes as promulgated in the building codes of the State of North Carolina."*

.3802(b)(3) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (3) documentation that the proposed services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies."*

-C- Exhibit 39 includes the location and design specifications for all of the new beds association with the proposed project. In Section II.8, page 23, the applicant states that

the facility design will be consistent with all national and state building, handicapped services, and life safety codes.

.3802(b)(4) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (4) if adding new acute care beds to an existing facility, documentation of the number of inpatient days of care provided in the last operating year in the existing licensed acute care beds by medical diagnostic category, as classified by the Centers for Medicare and Medicaid Services according to the list set forth in the applicable State Medical Facilities Plan."*

-C- In Section II.8, page 23, the applicant provides the number of inpatient days of care provided in the existing licensed acute care beds at UNC Hospitals during the last operating year (FY 2011) by medical diagnostic category, as classified by the Centers for Medicare and Medicaid Services according to the list set forth in the 2012 State Medical Facilities Plan.

.3802(b)(5) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (5) the projected number of inpatient days of care to be provided in the total number of licensed acute care beds in the facility, by county of residence, for each of the first three years following completion of the proposed project, including all assumptions, data and methodologies."*

-C- In Section II.8, pages 25-26, the applicant provides the projected number of inpatient days of care to be provided in the total number of licensed acute care beds in the facility, by county of residence, for each of the first three operating years following completion of the project, as follows:

All Acute Days	FY 15	FY 16	FY 17	All Acute Days	FY 15	FY 16	FY 17
County Name	Days	Days	Days	County Name	Days	Days	Days
Alamance	20,218	20,311	20,371	Lee	8,602	8,642	8,668
Alexander	49	49	49	Lenoir	510	512	513
Alleghany	36	36	36	Lincoln	90	91	91
Anson	133	133	134	McDowell	76	76	76
Ashe	45	45	45	Macon	42	42	42
Avery	45	45	46	Madison	23	23	23
Beaufort	241	243	243	Martin	93	93	94
Bertie	118	119	119	Mecklenburg	996	1,001	1,004
Bladen	466	468	470	Mitchell	27	27	27
Brunswick	1,081	1,086	1,090	Montgomery	476	478	479
Buncombe	330	331	332	Moore	2,920	2,933	2,942
Burke	135	136	136	Nash	1,494	1,501	1,506
Cabarrus	277	278	279	New Hanover	1,858	1,866	1,872
Caldwell	119	119	120	North Hampton	350	351	352
Camden	10	11	11	Onslow	1,999	2,009	2,014
Carteret	667	670	672	Orange	53,630	53,878	54,036
Caswell	1,088	1,094	1,097	Pamlico	80	80	80
Catawba	220	221	222	Pasquotank	104	104	105
Chatham	15,212	15,283	15,328	Pender	600	603	605
Cherokee	15	15	15	Perquimans	36	36	36
Chowan	56	56	56	Person	1,918	1,926	1,932
Clay	6	6	6	Pitt	725	728	730
Cleveland	168	168	169	Polk	10	10	10
Columbus	588	591	593	Randolph	2,463	2,475	2,482
Craven	975	980	982	Richmond	1,187	1,193	1,196
Cumberland	7,457	7,491	7,513	Robeson	2,323	2,333	2,340
Currituck	50	50	50	Rockingham	665	668	670
Dare	250	251	252	Rowan	239	241	241
Davidson	392	394	395	Rutherford	59	59	60
Davie	39	39	39	Sampson	1,981	1,991	1,996
Duplin	715	718	720	Scotland	826	830	833
Durham	22,321	22,424	22,490	Stanly	185	186	187
Edgecomb	588	591	592	Stokes	60	60	61
Forsyth	579	582	583	Surry	109	110	110
Franklin	1,195	1,200	1,204	Swain	24	24	24
Gaston	289	291	292	Transylvania	55	55	55
Gates	18	18	18	Tyrrell	17	17	17

All Acute Days	FY 15	FY 16	FY 17	All Acute Days	FY 15	FY 16	FY 17
County Name	**Days**	**Days**	**Days**	**County Name**	**Days**	**Days**	**Days**
Graham	19	19	19	Union	249	250	250
Granville	1,667	1,675	1,680	Vance	1,313	1,319	1,323
Greene	143	144	144	Wake	28,943	29,077	29,163
Guilford	3,920	3,938	3,950	Warren	450	452	453
Halifax	1,317	1,323	1,327	Washington	51	51	51
Harnett	4,466	4,486	4,500	Watauga	84	85	85
Haywood	97	98	98	Wayne	1,708	1,716	1,721
Henderson	150	151	151	Wilkes	71	71	71
Hertford	100	100	101	Wilson	1,017	1,021	1,024
Hoke	850	854	856	Yadkin	61	61	62
Hyde	26	26	26	Yancey	17	17	17
Iredell	180	180	181	**North Carolina Total**	**214,131**	**215,122**	**215,754**
Jackson	34	35	35	**Other US Total**	**3,887**	**3,905**	**3,917**
Johnston	4,030	4,049	4,061	**International Total**	**24**	**24**	**24**
Jones	124	125	125	**Total**	**218,042**	**219,051**	**219,695**

.3802(b)(6) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (6) documentation that the applicant shall be able to communicate with emergency transportation agencies 24 hours per day, seven days per week."*

-C- As an existing acute care facility, the applicant states,

> *"Since 1986, UNC Air Care has served the state of North Carolina providing 24-hour response by air and ground for patients of all ages and medical emergencies. …Communication with emergency transportation agencies and services is ongoing for UNC Hospitals' staff."*

.3802(b)(7) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (7) documentation that services in the emergency care department shall be provided 24 hours per day, seven days per week, including a description of the scope of services to be provided during each shift and the physician and professional staffing that will be responsible for provision of those services."*

-C- In Section II.8, pages 26, the applicant states,

> *"…UNC Hospitals' Emergency Room is operational 24 hours a day, 7 days a week. The Department of Emergency Medicine provides full time services in the Emergency Department, and is supplemented by other clinical services as required. …The Emergency Room is an integral part of the UNC Hospitals' Level I Trauma Center. …The existing center meets all Level 1 criteria with respect to the scope of services to be provided during each shift, and the*

physician professional staffing that are responsible for provision of those services."

In Exhibit 7, the applicant provides a copy of the rules pertaining to trauma center designation criteria.

.3802(b)(8) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (8) copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay."*

-C- Exhibit 8 contains a copy of UNC Hospitals' policy on Patient Rights and Responsibilities.

.3802(b)(9) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (9) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs."*

-C- The applicant states In Section II.8, page 27 that the written response contained in this application's Section VI.1 documents UNC Hospitals' current participation in, and commitment to continue to participate in and comply with conditions of participation in the Medicare and Medicaid programs. UNC Hospitals past and continued participation in these programs is also evident through its ongoing participation in The Joint Commission on Accreditation of Healthcare Organizations accreditation process. .

.3802(b)(10) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (10) documentation of the health care services provided by the applicant, and any facility in North Carolina owned or operated by the applicant's parent organization, in each of the last two operating years to Medicare patients, Medicaid patients, and patients who are not able to pay for their care."*

-C- The applicant provided the following chart to illustrate the inpatient Medicare/Medicaid patients served in FY11 at UNC Hospitals, Rex Hospital, Rex Rehab & Nursing Care Center and Chatham Hospital, all components of the UNC Health Care System:

UNC Hospitals		
Inpatient Acute Care Days of Care	***10/09-9/10***	***10/10-9/11***
Self Pay/Indigent/Charity	*12,377*	*13,299*
Medicare & Medicare Managed Care	*57,993*	*61,705*
Medicaid	*59,135*	*59,849*
Commercial Insurance	*1,956*	*2,144*
Managed Care	*49,873*	*52,581*
Other	*14,149*	*13,677*
TOTAL	***195,483***	***203,255***

Source: Licensure Renewal Application Forms

Rex Hospital		
Inpatient Acute Care Days of Care	***10/09-9/10***	***10/10-9/11***
Self Pay/Indigent/Charity	*5,193*	*3,047*
Medicare & Medicare Managed Care	*44,958*	*52,211*
Medicaid	*4,835*	*6,897*
Commercial Insurance	*344*	*461*
Managed Care	*33,044*	*39,941*
Other	*798*	*1,034*
TOTAL	***101,382***	***103,591***

Source: Licensure Renewal Application Forms

Rex Rehab & Nursing Care Center -Licensed as part of Rex Hospital		
Nursing Facility Days of Care	***10/09-9/10***	***10/10-9/11***
Medicare	*11,533*	*10,524*
Medicaid	*17,829*	*19,859*
Private Pay	*7,832*	*5,670*
Other	*2,579*	*2,637*
TOTAL	***39,773***	***38,690***

Source: Licensure Renewal Application Forms

Chatham Hospital		
Inpatient Acute Care Days of Care	***10/09-9/10***	***10/10-9/11***
Self Pay/Indigent/Charity	*184*	*178*
Medicare & Medicare Managed Care	*1,724*	*1,888*
Medicaid	*151*	*112*
Commercial Insurance	*50*	*41*
Managed Care	*168*	*205*
Other	-	-
TOTAL	***2,267***	***2,424***

Source: Licensure Renewal Application Forms

.3802(b)(11) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (11) documentation of strategies to be used and activities undertaken by the applicant to attract physicians and medical staff who will provide care to patients without regard to their ability to pay."*

-C- In Section II.8, page 28, the applicant states, *"Attached in Exhibit 9 are numerous letters of support for this project from these same physicians and medical staff who have clearly demonstrated that successful strategies are used and activities undertaken by them to provide care to patients without regard to their ability to pay."*

.3802(b)(12) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: … (12) documentation that the proposed new acute care beds shall be operated in a hospital that provides inpatient medical services to both surgical and non-surgical patients."*

-C- In Section II.8, pages 28-29, the applicant states, *"…UNC Hospitals provides, and will continue to provide, inpatient medical services to the following types of licensed general acute care services: burn, cardiac, cardiovascular surgery, medical ICU, surgical ICU, neonatal ICU, pediatric ICU, respiratory ICU, neurosurgery ICU, gynecology, medical acute care, surgical acute care, telemetry care, neonatal Level III, neonatal Level II, obstetric, oncology, orthopaedics, pediatric, bone marrow transplant, ophthalmology, otolaryngology, and clinical research unit, in addition to many subspecialty units or services within these classifications. Beyond acute care services, UNC Hospitals also provides, and will continue to provide, comprehensive in-patient rehabilitation care and inpatient psychiatric care. "*

.3802(c) This rule states *"An applicant proposing to develop new acute care beds in a new licensed hospital or on a new campus of an existing hospital shall also submit the following information:*

(1) the projected number of inpatient days of care to be provided in the licensed acute care beds in the new hospital or on the new campus, by major diagnostic category as recognized by the Centers for Medicare and Medicaid Services (CMS) according to the list set forth in the applicable State Medical Facilities Plan;

(2) documentation that medical and surgical services shall be provided in the proposed acute care beds on a daily basis within at least five of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services (CMS) according to the list set forth in the applicable State Medical Facilities Plan;

(3) copies of written policies and procedures for the provision of care within the new acute care hospital or on the new campus, including but not limited to the following:
(A) the admission and discharge of patients, including discharge planning;
(B) transfer of patients to another hospital;
(C) infection control; and
(D) safety procedures;
(4) documentation that the applicant owns or otherwise has control of the site on which the proposed acute care beds will be located; and

(5) documentation that the proposed site is suitable for development of the facility with regard to water, sewage disposal, site development and zoning requirements; and provide the required procedures for obtaining zoning changes and a special use permit if site is currently not properly zoned."

(6) correspondence from physicians and other referral sources that documents their willingness to refer or admit patients to the proposed new hospital or new campus."

-NA- The applicant proposes to add the new acute care beds to the existing hospital on the same campus.

.3803 PERFORMANCE STANDARDS

.3803(a) This rule states *"An applicant proposing to develop new acute care beds shall demonstrate that the projected average daily census (ADC) of the total number of licensed acute care beds proposed to be licensed within the service area, under common ownership with the applicant, divided by the total number of those licensed acute care beds is reasonably projected to be at least 66.7 percent when the projected ADC is less than 100 patients, 71.4 percent when the projected ADC is 100 to 200 patients, and 75.2 percent when the projected ADC is greater than 200 patients, in the third operating year following completion of the proposed project or in the year for which the need determination is identified in the State Medical Facilities Plan, whichever is later."*

-C- In Section II.8, page 30, the applicant states,

> *"During Year 3 of operation of the beds, 219,695 total inpatient days of care are to be provided in 756 licensed acute care beds (not including inpatient psychiatric beds and 30 inpatient rehabilitation beds). This reflects an average daily census of 602. [219,695 patient days divided by 365 days =602] Applying this average daily census of 602 across 365 days per year, results in 79.6%. [602 ADC divided by 756 = 79.6&] This projection exceeds the required 75.2% set forth in this rule for replacement and 78% target occupancy rate in the need methodology. The inpatient day projections are based on historical trends applied forward."*

.3803(b) This rule states *"An applicant proposing to develop new acute care beds shall provide all assumptions and data used to develop the projections required in this Rule and demonstrate that they support the projected inpatient utilization and average daily census."*

-C- The applicant's assumptions and data used to develop the projections required in this Rule are provided in Section III.1(a), pages 44-51, and Section IV, pages 66-67 and pro forma's page 125. The applicant's assumptions regarding projected inpatient utilization and average daily census are reasonable and credible and support a finding of conformity with this rule. See Criterion (3) for additional discussion.

.3804 SUPPORT SERVICES

.3804(a) This rule states *"An applicant proposing to develop new acute care beds shall document that each of the following items shall be available to the facility 24 hours per day, seven days per week:*

(1) laboratory services including microspecimen chemistry techniques and blood gas determinations;
(2) radiology services;
(3) blood bank services;
(4) pharmacy services;

(5) oxygen and air and suction capability;
(6) electronic physiological monitoring capability;
(7) mechanical ventilatory assistance equipment including airways, manual breathing bag and ventilator/respirator;
(8) endotracheal intubation capability;
(9) cardiac arrest management plan;
(10) patient weighing device for a patient confined to their bed; and
(11) isolation capability."

-C- Exhibit 3 contains a letter signed by Dr. Brian P. Goldstein, Executive VP and COO which states that UNC Hospitals will continue to make all of the above listed items available 24 hours per day, seven days per week.

.3804(b) This rule states *"If any item in Paragraph (a) of this Rule will not be available in the facility 24 hours per day, seven days per week, the applicant shall document the basis for determining the item is not needed in the facility."*

-C- In Section II.8, page 31, the applicant states, *"All items in Paragraph (a) of this Rule are available in the facility 24 hours per day, seven days per week."*

.3804(c) This rule states *"If any item in Paragraph (a) of this Rule will be contracted, the applicant shall provide correspondence from the proposed provider of its intent to contract with the applicant."*

-C- In Section II.8, page 31, the applicant states that none of the items listed in Paragraph (a) of this Rule will be contracted.

.3805 STAFFING AND STAFF TRAINING

.3805(a) This rule states *"An applicant proposing to develop new acute care beds shall demonstrate that the proposed staff for the new acute care beds shall comply with licensure requirements set forth in Title 10A NCAC 13B, Licensing of Hospitals."*

-C- In Section II.8, page 31, the applicant states that each area adding the proposed beds will be staffed, and sufficient staff training provided for all staff, in conformance with all applicable programmatic, and service specific licensure, certification, and The Joint Commission accreditation standards.

.3805(b) This rule states *"An applicant proposing to develop new acute care beds shall provide correspondence from the persons who expressed interest in serving as Chief Executive Officer and Chief Nursing Executive of the facility in which the new acute care beds will be located, documenting their willingness to serve in this capacity."*

-C- In Section II.8, page 31, the applicant states, *"See Exhibits 12, 13 and 14 respectively, for letters from Mr. Gary Park regarding service as the President, Dr. William Roper regarding service as the CEO, and Ms. Mary Tonges, RN, regarding service as the Chief Nursing Executive."*

.3805(c) This rule states *"An applicant proposing to develop new acute care beds in a new hospital or on a new campus of an existing hospital shall provide a job description and the educational and training requirements for the Chief Executive Officer, Chief Nursing Executive and each department head which is required by licensure rules to be employed in the facility in which the acute care beds will be located."*

-NA- The applicant does not propose to develop new acute care beds in a new hospital or on a new campus of an existing hospital.

.3805(d) This rule states *"An applicant proposing to develop new acute care beds shall document the availability of admitting physicians who shall admit and care for patients in each of the major diagnostic categories to be served by the applicant."*

-C- In Section II.8, page 32, the applicant states that UNC Hospitals currently has over 1,078 medical and dental staff with admitting privileges. Section II.8, pages 32-33 contains a list of UNC Hospitals' current medical staff by specialty.

.3805(e) This rule states *"An applicant proposing to develop new acute care beds shall provide documentation of the availability of support and clinical staff to provide care for patients in each of the major diagnostic categories to be served by the applicant."*

-C- In Section II.8, page 34, the applicant states, *"…Support and clinical staff is sufficient to provide care for patients in each of the major diagnostic categories the hospital serves. …Ongoing recruitment processes are in place for these services or departments, and UNC Hospitals does not anticipate difficulty in filling any vacant position."*

Criteria and Standards for Bone Marrow Transplantation Services 10A NCAC 14C .2900
Information Required of Applicant

.2902(a) This rule states *"An applicant proposing new or expanded autologous or allogeneic bone marrow transplantation services shall use the Acute Care Facility/Medical Equipment Application form."*

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

.2902(b) This rule states *"An applicant proposing new or expanded autologous or allogeneic bone marrow transplantation services shall also provide the following additional information:*

(1) the projected number of autologous and allogeneic transplant patients by disease type (e.g. Hodgkin's lymphoma Stage III) to be performed in each of the first 12 calendar quarters following completion of the proposed project, including the methodology and assumptions used for the projections.

-C- In Section II.8, page 35, the applicant provides the following projections,

KEY:

DISEASE

ALL = acute lymphoblastic leukemia
AML = acute myelogenous leukemia
CLL = chronic lymphocytic leukemia
CML = chronic myelogenous leukemia
NHL= non-Hodgkin's lymphoma
HD = Hodgkin's disease
MDS = myelodysplastic syndrome
MM = multiple myeloma

TYPE OF TRANSPLANT

Allo R = Related Donor transplant
Allo UR = Unrelated Donor transplant
Auto = Patients own cells

Following are the projections for the first 12 quarters of the project:

		FY 15				***FY 16***				***FY 16***			
Diagnosis	***Transplant Type***	***Q1***	***Q2***	***Q3***	***Q4***	***Q1***	***Q2***	***Q3***	***Q4***	***Q1***	***Q2***	***Q3***	***Q4***
ALL	*Allo-R*	*1*	*0*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*
ALL	*Allo-UR*	*2*	*2*	*2*	*2*	*3*	*2*	*2*	*2*	*2*	*3*	*3*	*2*
AML	*Allo-UR*	*4*	*4*	*4*	*4*	*5*	*4*	*5*	*4*	*5*	*5*	*4*	*5*
AML	*Allo-UR*	*6*	*5*	*5*	*5*	*6*	*6*	*7*	*6*	*6*	*7*	*6*	*7*
CLL	*Allo-R*	*0*	*1*	*1*	*0*	*1*	*0*	*1*	*0*	*0*	*1*	*0*	*1*
CML	*Allo-R*	*1*	*0*	*0*	*1*	*0*	*1*	*0*	*1*	*1*	*0*	*1*	*0*
CML	*Allo-UR*	*1*	*2*	*2*	*1*	*2*	*2*	*2*	*1*	*2*	*2*	*2*	*2*
NHL	*Auto*	*8*	*7*	*7*	*8*	*8*	*8*	*8*	*9*	*9*	*9*	*9*	*9*
NHL	*Allo-R*	*0*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*
NHL	*Allo-UR*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*0*	*1*	*1*	*0*
HD	*Auto*	*2*	*3*	*2*	*3*	*2*	*3*	*3*	*3*	*3*	*3*	*3*	*3*
HD	*Allo-R*	*1*	*0*	*1*	*0*	*0*	*1*	*1*	*0*	*1*	*0*	*0*	*1*
MDS	*Allo-R*	*1*	*2*	*2*	*1*	*2*	*2*	*2*	*1*	*2*	*2*	*2*	*2*
MDS	*Allo-UR*	*1*	*2*	*2*	*1*	*2*	*1*	*2*	*2*	*2*	*2*	*2*	*2*
MM	*Auto*	*22*	*22*	*22*	*23*	*24*	*25*	*24*	*25*	*27*	*27*	*26*	*27*
SOLID TUMOR	*Auto*	*5*	*5*	*6*	*5*	*6*	*6*	*5*	*6*	*6*	*7*	*7*	*6*
ANEMIAS	*Allo-R*	*0*	*1*	*0*	*1*	*1*	*0*	*0*	*1*	*0*	*1*	*1*	*0*
ANEMIAS	*Allo-UR*	*2*	*1*	*1*	*1*	*0*	*1*	*1*	*0*	*2*	*1*	*1*	*2*
		58	*58*	*60*	*58*	*65*	*64*	*66*	*63*	*70*	*72*	*70*	*71*
					234				***258***				***283***

In Section II.8, page 35, the applicant states,

> "*The projections are based on the current actual mix of patients by disease and type of transplant. 10% annual growth in bone marrow transplants was projected consistent with other utilization projections contained in Section IV. This projected growth is conservative considering the past several years the bone marrow transplant volume has experienced more than 17% annual growth. Note: bone marrow transplant volumes do not correlate directly to all patients utilizing the bone marrow transplant unit. There are several other types of oncology patients that are routinely requiring to be housed in the unit, such as acute leukemics and non-acute leukemics with complications.*"

(2) a copy of the applicant's proposed policy and guidelines for participation in peer-reviewed clinical trials or research protocols.

-C- Exhibit 15 contains the existing Clinical Research Policy containing these guidelines.

.2902(c) This rule states *"An applicant that proposes new autologous or allogeneic bone marrow transplantation services shall provide documentation that the applicant will participate in approved clinical trials or research protocols and also participate in a National Cancer Institute approved cooperative research group."*

-C- The applicant states that this rule is not applicable according to pre-application discussions on a prior BMTU application since this project does mot propose the addition of a new autologous or allogeneic bone marrow transplant program.

.2902(d) This rule states *"An applicant that proposes expanded autologous or allogeneic bone marrow transplantation services shall provide documentation that the applicant is participating in approved clinical trials or research protocols, and is participating in a National Cancer Institute approved cooperative research group."*

-C- In Section II.8, page 36, the applicant provides the following mix experienced for Calendar Year 2011,

Protocol	*Type of Transplant*	*# of Transplants*
IRB approved research protocol clinical trial	*Allogeneic – related*	*6*
IRB approved research protocol clinical trial	*Allogeneic – unrelated*	*6*
IRB approved research protocol clinical trial	*Autologous*	*18*
Non-research protocol	*Allogeneic – related*	*16*
Non-research protocol	*Allogeneic – unrelated*	*25*
Non-research protocol	*Autologous*	*76*

.2902(e) This rule states *"An applicant that proposes to provide new or expanded autologous or allogeneic bone marrow transplantation services for clinical purposes shall:*

(1) provide documentation of existing referral networks and other referral sources for patients to be treated with bone marrow transplantation, and

-C- In Section II.8, page 36, the applicant provides the physician referral sources experienced within the BMT transplant program for CY 2011,

Referral Source	***Type of Transplant***	***# of Transplantation***
External physician	*Allogeneic – related*	*18*
External physician	*Allogeneic – unrelated*	*14*
External physician	*Autologous*	*64*
Internal physician	*Allogeneic – related*	*4*
Internal physician	*Allogeneic – unrelated*	*17*
Internal physician	*Autologous*	*30*

This is considered a typical mix of referral sources. It is expected that this general mix of types of referral sources will continue in the future.

(2) Identify the sources of reimbursement for the procedures and demonstrate the availability of these sources for treatment of the specific diseases proposed to be treated with bone marrow transplantation.

In Section II.8, page 36, the applicant provides the mix of reimbursement sources experienced for BMT transplants for CY 2011,

Reimbursement Source	***Type of Transplant***	***# of Transplantation***
Aetna	*Allogeneic – related*	*1*
BCBS (all types)	*Allogeneic – related*	*11*
BCBS (all types)	*Allogeneic – unrelated*	*13*
BCBS (all types)	*Autologous*	*31*
Cigna	*Allogeneic – related*	*1*
Cigna	*Autologous*	*8*
HEALTH CHOICE	*Allogeneic – unrelated*	*1*
HUMANA	*Autologous*	*2*
INCLUSIVE HEALTH	*Allogeneic – unrelated*	*1*
INCLUSIVE HEALTH	*Autologous*	*1*
MAILHANDLERS	*Allogeneic – unrelated*	*1*
Medcost	*Allogeneic – unrelated*	*1*
Medcost	*Autologous*	*1*
Medicaid	*Allogeneic – related*	*5*
Medicaid	*Allogeneic – unrelated*	*9*
Medicaid	*Autologous*	*18*
Medicare	*Allogeneic – related*	*3*
Medicare	*Autologous*	*18*
Tricare	*Allogeneic – related*	*1*
Tricare	*Allogeneic – unrelated*	*1*
Tricare	*Autologous*	*8*
UNITED HEALTHCARE	*Autologous*	*4*
WELLPATH	*Autologous*	*3*
WELLS FARGO	*Allogeneic – unrelated*	*1*

This is considered a typical mix of sources. It is expected that this general mix of types of referral sources will continue in the future.

.2902(f) This rule states *"An applicant that proposes to provide new or expanded autologous or allogeneic bone marrow transplantation services for research purposes shall demonstrate how capital costs and service operations for the research will be funded and shall provide documentation of the commitment of the funding agency.*

In Section II.8, page 37, the applicant states,

"This question is not applicable, as the expansion of the bone marrow service is not being proposed for research purposes."

.2903 PERFORMANCE STANDARDS

.2903(a) This rule states "*An applicant that proposes to provide new or expanded autologous or allogeneic bone marrow transplantation services shall demonstrate that:*

(1) all existing facilities within the applicant's bone marrow transplantation service area which have been offering bone marrow transplantation services for at least two years shall have performed at least 20 transplants during the most recent 12 month period;

-NA- In Section II.8, page 38, the applicant states,

*"This question is not applicable to the review of this project for UNC Hospitals. Pursuant to N.C. General Statute **§** 13 1E-1 83(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 services 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."*

See Rule 2902 above and Section IV for historical utilization.

(2) all existing and approved facilities within the applicant's bone marrow transplantation service area will provide at least 20 transplants during the second year of operation following completion of the project; and

-NA- In Section II.8, page 39, the applicant states,

"This question is not applicable to the review of this project for UNC Hospitals. Pursuant to N.C. General Statute § 13 lE- 183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health services 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."

See Rule 2902 above and Section IV for projected utilization.

(3) the projected utilization for the new or expanded bone marrow transplantation program shall perform at least 20 transplants during the second year of operation following completion of the project.

-C- In Section II.8, page 39, the applicant states,

"The response to rule 10A NCAC .2902(b)(1) above includes the number and mix of transplant patients from 1/2011 through 12/2011, as well as the projected type and mix of transplant patients for the first three years of operation of the project. …It is projected that during Project Year 2, FY 16, 258 transplants will be performed."

.2903(b) This rule states "*An applicant that proposes to provide new or expanded autologous or allogeneic bone marrow transplantation services shall describe all of the assumptions and methodologies used to calculate the projections requested in Subparagraphs (a)(2) and (3) of this Rule."*

-C- In Section II.8, page 39, the applicant states,

"As addressed in response to 10A NCAC .2902(b)(1), the projections are based on the current actual mix of patients by disease and type of transplant. Growth was projected consistent with other BMT utilization projections contained in Section IV. 10% annual growth in bone marrow transplants was projected consistent with other utilization projections above. This projected growth is conservative considering the past several years the bone marrow transplant volume has experienced more than 17% annual growth."

.2903(c) This rule states "*An applicant that proposes the use of bone marrow transplantation services for clinical use shall demonstrate that all equipment, supplies and pharmaceuticals proposed for the service have been certified for clinical use by the U.S. Food and Drug Administration or will be operated under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services' regulations."*

-C- In Section II.8, page 39, the applicant states,

"…After undergoing scientific review, approved studies are forwarded to the UNC School of Medicine Committee on the Protection of the Rights of Human Subjects (Institutional Review Board or IRB) for final review and approval. This IRB is accredited by the Office for the Protection of the Rights of Research Subjects (OPRR), which is a division of the US Department of Health and Human Services, and is charged with reviewing both scientific integrity and patient safety."

.2904 SUPPORT SERVICES

.2904(a) This rule states "*An applicant that proposes to provide new or expanded autologous or allogeneic bone marrow transplantation services shall demonstrate that the following will be available in the facility upon initiation of bone marrow transplantation services:*

1) accommodations which offer 24 hour critical support and which are appropriate for patients whose immune systems are depressed from the effects of the treatment;
2) air handling systems which are appropriate for patients whose immune systems are depressed from the effects of the treatment;
3) if processing autologous bone marrow transplantation services, cryopreservation equipment for the storage of bone marrow;
4) laboratory services which are available to the bone marrow transplant patient on a twenty-four hour basis;
5) radiology services, including CT scanning and nuclear medicine, which are available to the bone marrow transplant patient on a twenty-four hour basis;
6) total body radiotherapy for patients whose treatment protocols require total body irradiation;
7) irradiated red cells, platelets and other blood products available on a twenty-four hour basis;
8) access to blood bank services which are accredited by the American Association of Blood Banks;
9) operating and recovery room resources;
10) microbiology and virology laboratories;
11) a multi-disc,p1!naiy plan for providing rehabilitative services;
12) basic and clinical laboratory research;
13) an active, formal research program related to the proposed bone marrow transplantation program; and

-C- In Section II.8, page 40, the applicant states that Exhibit 16 contains a letter from Dr. Thomas C. Shea, Medical Director of the Bone Marrow and Blood Stem Cell Transplant Program, confirming the current and continued availability of the above service.

.2904(b) This rule states "*An applicant that proposes to provide new or expanded allogeneic bone marrow transplantation services shall also demonstrate that the following will be available in the facility upon initiation of allogeneic bone marrow transplantation services:*

(1) if proposing allogeneic bone marrow transplantation services, laboratory facilities for histocompatibility testing which are certified by the American Society for Histocompatibility and Immunogenetics; and

-C- In Section II.8, page 40, the applicant states that Exhibit 17 contains a copy of the current certification from the American Society for Histocompatibility and Immunogenetics for UNC Hospitals' McLendon Clinical Laboratories.

(2) if proposing allogeneic bone marrow transplantation services, an established on-site program to promote bone marrow donation.

-C- In Section II.8, page 40, the applicant states,

> *"The bone marrow transplant program at UNC actively promotes bone marrow and stem cell transplant donation throughout the year as an on-going service to the public. Specific promotion occurs annually throughout the month of April ('Donor Awareness Month') with extensive literature, posters, and flyers provided to the public regarding marrow donation."*

.2904(c) This rule states *"A proposal to provide new or expanded bone marrow transplantation services shall provide evidence that, prior to the operation of the service, the applicant will develop a clinical oversight committee for bone marrow transplant services.:*

1) *developing screening criteria for appropriate bone marrow transplantation utilization;*
2) *reviewing clinical protocols;*
3) *reviewing appropriateness and quality of clinical procedures;*
4) *developing educational programs; and*
5) *overseeing the data collection, evaluation, and reporting activities of the bone marrow transplantation service."*

-C- In Section II.8, page 41, the applicant states that Exhibit 18 contains a copy of the BMT Quality Management Plan, which addresses each of these activities.

.2905 STAFFING AND STAFF TRAINING

.2905(a) This rule states *"An applicant shall demonstrate that it can meet each of the following staffing requirements:*

(1) a bone marrow transplant clinical coordinator;

-C- In Section II.8, page 41, the applicant states that Exhibit 19 contains a copy of the BMT Program Staff Policy. Section III.7 of this policy addresses the position of the Transplant Nurse Coordinator (TNC).

(2) a physician licensed to practice medicine in North Carolina who will be designated as the director of the program and who has documented experience within the past year in:

- *A) pretransplant evaluation;*
- *B) bone marrow processing;*
- *C) the provision of medical care services to hospitalized bone marrow transplant patients; and*
- *D) post-transplant care;*

-C- In Section II.8, page 42, the applicant states that Exhibit 19 contains a copy of the BMT Program Staff Policy. This policy defines the staff qualifications that staff must have in order to receive the necessary training in cognitive and procedure skills, and maintain these skills. Specifically, Section 1.0 of this policy addresses the overall Program Director, who is responsible for the clinical coordination of the program. Additionally,

Exhibit 2 contains a copy of the curriculum vitae of Dr. Thomas C. Shea who currently serves as the Director of the BMT Program.

(3) availability of physicians in the following specialties to the bone marrow transplantation program on a 24 hour basis:
- *A) hematology or oncology;*
- *B) gastroenterology;*
- *C) nephrology;*
- *D) infectious diseases;*
- *E) pulmonary diseases; and*
- *F) pediatrics (if pediatric patients will be treated);*

-C- In Section II.8, page 42, the applicant states that access to the above specialties, are available to the bone marrow and stem cell transplant program on a 24 hour basis. The applicant provided a list of physicians by specialty and Exhibits 22, 2, and 20 contain documentation of the physician's training.

(4) laboratory staff who are trained in the processing of bone marrow;

-C- In Section II.8, page 42, the applicant states that Exhibit 23 contains a copy of the curriculum vitae of Yara Park, MD, who is specially trained in the processing of bone marrow, peripheral blood stem cells and cord blood.

(5) a state certified social worker with a master's degree in social work who is available for inpatient and outpatient ongoing support of both the patient and family; and

-C- In Section II.8, page 42, the applicant states that Exhibit 24 contains a copy of the curriculum vitae of Kathryn Tesh Roundtree, MSW, LCSW, who is the inpatient social worker assigned to the BMT Program as well as Katherine Kingsbury, MSW, LCSW who is the outpatient social worker assigned to the BMT Program.

(6) a board-certified or equivalently qualified psychiatrist who is available for inpatient and outpatient ongoing support of both the patient and family.

-C- In Section II.8, page 42, the applicant states that Exhibit 25 contains documentation of the training of Donald Rosenstein, MD, who provides psychiatric services for the BMT Program.

.2905(b) This rule states "*An applicant shall demonstrate that a program of staff education and training which is integral to the bone marrow transplantation service and which ensures improvements in technique and the proper training of new personnel will be provided.*

-C- In Section II.8, page 42, the applicant states that Exhibit 26 contains documentation of the BMT Nursing Staff Training policy which describes in detail the staff education and training applicable for all Registered Nurses and Nursing Assistants who care from adult and pediatric patients receiving a stem cell transplant.