ATTACHMENT - REQUIRED STATES AGENCY FINDINGS

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

Decision Date: March 29, 2016
Findings Date: April 1, 2016

Project Analyst: Bernetta Thorne-Williams
Team Leader: Lisa Pittman

Project ID #: F-11110-15
Facility: Novant Health Huntersville Medical Center
FID #: 990440
County: Mecklenburg
Applicant(s): The Presbyterian Hospital
Project: Relocate 48 acute care beds and one operating room from Novant Health Presbyterian Medical Center to Novant Health Huntersville Medical Center for a total of 139 acute care beds and seven operating rooms including on dedicated C-Section operating room upon project completion

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 States Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

The Presbyterian Hospital d/b/a Novant Health Huntersville Medical Center (NHHMC) proposes to relocate 48 acute care beds and one operating room (OR) from Novant Health Presbyterian Medical Center (NHPMC), located at 200 Hawthorne Lane in Charlotte to NHHMC located at 10030 Gilead Road in Huntersville for a total of 139 licensed acute care beds, seven ORs (including one dedicated C-Section OR), upon project completion. Both acute care facilities are located in Mecklenburg County. On page 3, the applicant states:

"The applicant will use the 48 beds to add 44 additional acute medical surgical beds, 2 additional ICU beds, and 2 additional Neonatal Intensive Care Unit Level III beds. In addition, NHHMC seeks ... approval to relocate one existing ... operating room from NHPMC to NHHMC."

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2015 States Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to the review of this application.

Policies

The following three policies are applicable to this review; Policy AC-1: Use of Licensed Bed Capacity Data for Planning Purposes, Policy AC-5: Replacement of Acute Care Bed Capacity, and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy AC-1: Use of Licensed Bed Capacity Data for Planning Purposes states:

"For planning purposes, the number of licensed beds shall be determined by the Division of Health Service Regulation in accordance with standards found in 10A NCAC 13B - Section .6200 and Section .3102 (d).

Licensed bed capacity of each hospital is used for planning purposes. It is the hospital's responsibility to notify the Division of Health Service Regulation promptly when any of the space allocated to its licensed bed capacity is converted to another use, including purposes not directly related to health care."

On page 10, the applicant states the proposed project is for the relocation of 48 acute care beds from NHPMC to NHHMC. The applicant provides the proposed redistribution and use of those 48 beds on page 10 of the application.

Therefore the application is conforming to Policy AC-1.

Policy AC-5: Replacement of Acute Care Bed Capacity states:

"Proposals for either partial or total replacement of acute care beds (i.e., construction of new space for existing acute care beds) shall be evaluated against the utilization of the total number of acute care beds in the applicant's hospital in relation to utilization targets found below. For hospitals ***not*** *designated by the Centers for Medicare & Medicaid Services as Critical Access Hospitals, in determining utilization of acute care beds, only acute care bed "days of care" shall*

be counted. For hospitals designated by the Centers for Medicare & Medicaid Services as Critical Access Hospitals, in determining utilization of acute care beds, only acute care bed "days of care" ***and*** *swing bed days (i.e., nursing facility days of care) shall be counted in determining utilization of acute care beds. Any hospital proposing replacement of acute care beds must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application. Additionally, if the hospital is a Critical Access Hospital and swing bed days are proposed to be counted in determining utilization of acute care beds, the hospital shall also propose to remain a Critical Access Hospital and must demonstrate the need for maintaining the swing bed capacity proposed within the application. If the Critical Access Hospital does not propose to remain a Critical Access Hospital, only acute care bed "days of care" shall be counted in determining utilization of acute care beds and the hospital must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application."*

Facility Average Daily Census	***Target Occupancy of Licensed Acute Care Beds***
1-99	*66.7%*
100-200	*71.4%*
Greater than 200	*75.2%*

NHHMC is currently licensed for 91 acute care beds. The applicant proposes to relocate 48 acute care beds from NHPMC to NHHMC for a total of 139 licensed acute care beds, upon project completion. The applicant illustrates the current utilization and the projected utilization in Project Year 3 (PY) for NHHMC, in the table below.

NHHMC Utilization

Acute Care	**August 2014- July 2015**	**PY 3 FY 22**
Days of Care	24,090	34,357
ADC	66.0	94.5
# of Licensed Beds	91	139
Occupancy Rate	72.5%	67.7%

Source: Exhibit 3, Table 1 and page 89
ADC = Average Daily Census

As illustrated in the table above, the applicant's projection exceeds the occupancy rate of 66.7% found in this policy. Also see discussion concerning utilization of the acute care beds found in Section III.1(a) and (b), pages 60-97, Section IV, page 117 and Exhibit 3.

Therefore the application is conforming to Policy AC-5.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

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

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

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

The proposed capital expenditure for this project is greater than $5 million. The applicant states the proposed project will conform to or exceed the energy efficiency and water conservation standards incorporated in the latest edition of the North Carolina State Building Codes in Section XI.7, page 179. Additionally, on page 179, the applicant describes the methods that will be used to maintain energy efficiency and conserve water. See Exhibit 15 for a copy of Novant Health's Sustainable Energy Management Plan which further identifies NH's energy conservation strategies.

The applicant adequately demonstrates the proposal includes a plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4, subject to Condition 4 in Criterion (4).

Conclusion

In summary, the applicant adequately demonstrates that the proposal to relocate 48 acute care beds and one OR from NHPMC to NHHMC is consistent with Policies AC-1, AC-5 and GEN-4. Therefore, the application is conforming to this criterion, subject to Condition 4 in Criterion (4).

(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

The applicant proposes to relocate 48 acute care beds from NHPMC to NHHMC of which 44 will be general acute medical/surgical beds, two will be ICU beds and two will be Neonatal Intensive Care Unit (NICU) Level III beds for a total of 139 licensed acute care beds and six shared ORs (excluding the one dedicated C-Section OR) at NHHMC, upon project completion.

In Section II.1(a), pages 10-11, the applicant describes the proposed project, as follows:

"NHHMC is seeking to expand its acute care beds capacity by 48 beds … [and] *add one more operating room …*

These 44 beds will allow the addition of two more nursing units with acute inpatient beds. …

Currently, NHHMC has five shared operating rooms located on the first floor … and one dedicated C-Section operating room on the third floor… NHHMC is seeking … one more shared operating room, for a total of six shared inpatient/outpatient operating rooms and one C-Section [operating] *room… In addition, pre-op and post-op recovery and support spaces will be expanded to support the projected growth of surgical and endoscopy services in the … surgical suite.*

[The] *pharmacy space will need to be expanded …*
…

By renovation of about 10,000 [square feet] *in the existing … facility and the construction of approximately 60,000 new square feet … to expand the Central Energy Plant Capacity for the hospital …* [and] *upsize the mechanical and electrical infrastructure … At the completion of the project the square footage … will have expanded from* [approximately] *269,800 SF … to* [approximately] *330,400 SF …"*

Population to be Served

On page 48, the 2015 SMFP defines the service area for acute care services by county (or multicounty service area for counties without a hospital). NHHMC is located in

Mecklenburg County. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section III.4(a), page 104, the applicant identifies the patient origin for the entire acute care facility as well as for the acute inpatient population served at NHHMC during FY2015. The following table illustrates historical patient origin for services at NHHMC including the proposed service components (inpatient acute care, inpatient and outpatient surgical, ICU and NICU services), as reported by the applicant in Section III.4(a) and (b), pages 104-106.

NHHMC Patient Origin Aug. 2014 – July 2015

County	Entire Facility	Acute Inpatient Services	Inpatient Surgical Services	Outpatient Surgical Services	ICU Services	NICU Level III
Mecklenburg	66.9%	65.8%	59.9%	59.2%	67.1%	75.9%
Iredell	10.2%	10.3%	11.7%	13.8%	10.3%	3.4%
Lincoln	7.5%	8.8%	9.0%	8.5%	8.5%	2.3%
Gaston	4.7%	5.3%	5.1%	4.7%	5.8%	5.7%
Cabarrus	3.7%	4.0%	5.2%	4.9%	2.1%	9.2%
All Others*	7.0%	5.8%	9.1%	8.9%	6.3%	3.5%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

*All Other includes patients from other counties and states not listed above.

As illustrated above, Mecklenburg, Iredell and Lincoln counties represent 85% of the acute care inpatient origin at NHHMC, 80.6% of inpatient surgical, 81.5% of outpatient surgical patient origin and 86% of ICU patient origin. The three counties with the highest patient origin for NICU services are Mecklenburg, Gaston and Cabarrus counties totaling 90.8%. It should be noted that Mecklenburg, Iredell and Lincoln counties represented 84.6% of the patient origin for the entire acute care facility.

In Section III.5(c), pages 107-109, the applicant projects patient origin for all proposed service components will remain the same as the historical patient origin in FY 2015, as illustrated in the tables below.

Acute Care Inpatient Services				
County	**% Patient Origin**	**PY 1 FY 20**	**PY 2 FY 21**	**PY 3 FY 22**
Mecklenburg	65.8%	20,473	21,510	22,599
Iredell	10.3%	3,196	3,358	3,528
Lincoln	8.8%	2,747	2,886	3,032
Gaston	5.3%	1,659	1,743	1,831
Cabarrus	4.0%	1,250	1,313	1,380
All Others*	5.8%	1,800	1,891	1,987
Total	100.0%	31,125	32,701	34,357

Inpatient Surgical Services				
County	**% Patient Origin**	**PY 1 FY 20**	**PY 2 FY 21**	**PY 3 FY 22**
Mecklenburg	59.9%	976	1,025	1,077
Iredell	11.7%	191	200	210
Lincoln	9.0%	147	154	162
Gaston	5.1%	83	87	91
Cabarrus	5.2%	85	89	94
All Others*	9.1%	147	155	163
Total	100.0%	1,628	1,711	1,797
Outpatient Surgical Services				
County	**% Patient Origin**	**PY 1 FY 20**	**PY 2 FY 21**	**PY 3 FY 22**
Mecklenburg	59.2%	2,072	2,107	2,141
Iredell	13.8%	484	492	501
Lincoln	8.5%	296	301	306
Gaston	4.7%	165	167	170
Cabarrus	4.9%	172	175	178
All Others*	8.9%	310	315	320
Total	100.0%	3,500	3,558	3,616

ICU Services				
County	**% Patient Origin**	**PY 1 FY 20**	**PY 2 FY 21**	**PY 3 FY 22**
Mecklenburg	67.1%	434	455	479
Iredell	10.3%	66	70	73
Lincoln	8.5%	55	58	61
Gaston	5.8%	37	39	41
Cabarrus	2.1%	13	14	15
All Others*	6.3%	41	43	45
Total	100.0%	646	679	713
NICU Services				
County	**% Patient Origin**	**PY 1 FY 20**	**PY 2 FY 21**	**PY 3 FY 22**
Mecklenburg	75.9%	91	92	94
Iredell	2.3%	3	3	3
Lincoln	9.2%	11	11	11
Gaston	3.4%	4	4	4
Cabarrus	5.7%	7	7	7
All Others*	3.4%	4	4	4
Total	100.0%	120	122	123

*All Other includes patients from other counties and states not listed above.

As illustrated above, the applicant projects that its patient origin will remain the same for the first three years of operation following completion of the proposed project. See Exhibit 3 for additional information concerning patient origin.

The applicant adequately identifies the population NHHMC proposes to serve.

Analysis of Need

In Section III.1(a), page 61, the applicant states the need to relocate 48 acute care beds from NHPMC to NHHMC is based on the on the following factors:

- Increase in acute inpatient utilization
- Increase in emergency department utilization
- Medical staff growth and physician recruitment
- Increase in market share
- Population growth
- Growth and development in the service area

The applicant discusses the above factors on pages 61-87 of the application, as summarized below.

Increase in acute inpatient utilization

On page 62, the applicant provides historical inpatient utilization for NHHMC from August 2011 through July 2015 which shows an increase of 5.1% in cases and a 4.6% increase in days of care. This growth was supported by the addition of 15 licensed acute care beds in September 2012 and an additional ten licensed acute care beds in May 2015. The applicant reports an Average Annual Growth Rate (AAGR) for this four year period of 6.3%.

NHHMC Growth in Cases

Year	FFY	Annual Growth
2011	5,556	
2012	5,597	0.7%
2013	6,117	9.3%
2014	6,458	5.6%
2015	6,725	4.1%
2011-2015 AAGR		4.9%
2012-2015 AAGR		6.3%

The applicant further states on page 62, that even with the additional acute care beds added in May 2015, NHHMC experienced an average daily census (ADC) that exceeded 85% for 23 days from May 2015 through midnight on September 28, 2015. Additionally, the applicant states that NHHMC exceeded 90% ADC for 11 days during that same timeframe.

Furthermore, on page 63, the applicant states NHHMC is the only acute care hospital in northern Mecklenburg County and since January 2015 experienced 120 days where the occupancy exceeded 100%.

Increase in emergency department utilization

On page 63, the applicant states that the emergency department (ED) visits have remained fairly constant during the last five years fluctuating between 32,047 and 33,335. However, the admission rate for those visiting the ED increased from 9.9% in FY 2010 to 17.4% in FFY 2014. This is an increase of 2,535 admissions [5,707 (FY 2014 admissions) – 3,172 (FY 2010 admissions) = 2,535] which is a Compound Annual Growth Rate (CAGR) of 15.82% for that four year timeframe. This is on average 15.6 patients per day. The applicant reports on pages 63-64, that the increase in ED patients requiring admittance to the hospital has created a bed-hold issue in the ED. The

applicant reports that from January to September 2015, 161 patients were held in the ED overnight due to the unavailability of an inpatient acute care bed (this number excludes those patients awaiting transfer to an inpatient psychiatric facility). The applicant also reports having to redirect ambulance services to other acute care facilities 26 times in CY 2015.

Medical staff growth and physician recruitment

On pages 64-65, the applicant provides a table which illustrates the growth of medical staff by specialty. The applicant states that when NHHMC opened in 2004 it had roughly 148 active medical staff in 23 specialties and today the hospital operates with 398 physicians in 46 specialties. The applicant states that the continued increase in physicians, surgeons, specialties and services has increased utilization at NHHMC.

Increase in market share

On pages 65-66, the applicant reports an increase in the market share of 11 of the 14 ZIP codes included in NHHMC service area, as illustrated in the table below.

ZIP Codes/County	City	Market Share		
		2013	2014	2015
28027 - Cabarrus	Concord	2.3%	2.8%	3.5%
28031 - Mecklenburg	Cornelius	40.6%	39.3%	41.6%
28036 - Mecklenburg	Davidson	30.4%	24.9%	31.3%
28037 - Lincoln	Denver	27.7%	27.0%	28.2%
28078 - Mecklenburg	Huntersville	44.1%	43.0%	43.3%
28080 - Lincoln	Iron Station	11.1%	9.4%	7.7%
28115 - Iredell	Mooresville	8.5%	9.1%	7.9%
28117 - Iredell	Mooresville	13.4%	13.6%	15.9%
28120 - Gaston	Mount Holly	4.6%	3.8%	5.1%
28214 - Mecklenburg	Charlotte	5.5%	7.12%	7.06%
28216 - Mecklenburg	Charlotte	11.0%	11.5%	11.9%
28262 - Mecklenburg	Charlotte	5.1%	5.6%	6.0%
28269 - Mecklenburg	Charlotte	13.2%	14.2%	11.6%
Total All Service Area		14.56%	14.64%	15.02%

Population growth

On pages 67-70, the applicant discusses the projected population growth in NHHMC's service area. The applicant states that NHHMC's service area is projected to grow 1.9% per year from 2015-2020. The applicant states on page 67 that the ZIP code where

NHHMC is located (ZIP code 28078) is projected to grow 3.1% annually during the same timeframe. On page 67, the applicant provides projected growth in population.

Growth and development in the service area

On pages 71-78, the applicant discusses how growth and development in the service area has increased the need for additional acute care beds at NHHMC. On page 71, the applicant states that Huntersville (where NHHMC is located) is the 46th fastest growing suburb in the United States, as such, new businesses and families are moving to the area. The applicant discusses the growth and development of Cornelius, Davidson, Lake Norman, Denver and Mountain Island Lake in subsequent pages. The applicant provides a table on page 75 which illustrates the population growth in the Lake Norman Region (Huntersville, Cornelius and Davidson), as compared to North Carolina and Mecklenburg County, as summarized below.

Location	1990	2006	2010	20 Year Growth
NC States	6,628,637	8,856,505	9,535,483	44%
Charlotte MSA*	1,024,643	1,462,636	1,720,586	68%
Mecklenburg County	511,433	827,445	919,628	80%
Charlotte (City)	395,934	630,478	731,424	85%
Lake Norman Region	9,641	68,005	80,156	731%

*Cabarrus, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Union counties in North Carolina and Chester, Lancaster and York counties in South Carolina.

As illustrated above, the 20-year growth rate for the Lake Norman Region (1990 to 2010) was 731% for a CAGR of 11.7%. The area is projected to continue to grow.

ICU Bed Utilization

The applicant proposes to relocate 48 acute care beds from NHPMC to NHHMC with two of those beds being designated as Intensive Care Unit (ICU) beds. NHHMC currently operates six ICU beds. The applicant provides the historical utilization for NHHMC ICU beds on pages 78-79, as illustrated below.

ICU Utilization

	Federal Fiscal Years	
	FFY 14	**FFY 15 Estimated**
Total Admits	494	511
Total Days	1,520	1,578
ALOS	3.1	3.1
ADC	4.16	4.32
# of Beds	6	6
Utilization	69.4%	72.1%

*Prior to application submission

The applicant estimates that the ICU bed utilization at NHHMC was over 70% in FFY 2015 with an average length of stay (ALOS) of 3.1 days.

Level III NICU Bed Utilization

The applicant also proposes to use two of the 48 relocated acute care beds as Level III Neonatal Intensive Care Unit (NICU) beds for a total of four NICU beds at NHHMC upon project completion. The applicant discusses NHHMC growth in obstetrical services and historical utilization on pages 79-81. The applicant reports an increase in obstetrical services in the past 24 months, as illustrated in the table below.

Obstetrical Utilization

	CY 2013	**CY 2014**	**CY 2015**	**CAGR**
Admits	1,011	1,176	1,320	14.3%
Days of care	2,655	3,028	8,110	8.2%
ALOS	2.63	2.57	2.36	-5.7%

As illustrated above, the applicant's obstetric admissions experienced a Compound Annual Growth Rate (CAGR) of over 14% from 2013 to 2015.

On page 81, the applicant provides the historical utilization for the existing NICU beds at NHHMC:

NICU Utilization

	CY 2013	**CY 2014**	**Estimated CY 2015**	**Last 12 Months**
Total Days	844	908	677	781
ADC	2.3	2.5	1.9	2.1
# of Beds	2	2	2	2
Utilization	115.6%	124.4%	92.8%	107.0%

As illustrated above, NHHMC's average daily census (ADC) over the past 12 months was 2.1 or 107.0% utilization which exceeds the 75% utilization as required by 10A NCAC 14C .1403(a)(1).

The applicant reports on page 80, that 11% of births in Mecklenburg County require NICU services and that in 2013 9.5% of the births at NHHMC required Level III NICU care. That percentage dropped in 2014 and 2015 due to the increase in total births from 2013-2015 which then resulted in some babies in need of Level III NICU care being transferred to NHPMC. NICU cases represented 8.6% and 6.0% of the total births at NHHM in CY 2014 and 2015, respectively. NHHMC uses an 8.6% growth rate to project future NICU cases.

OR Utilization

The applicant proposes to relocate one operating room from NHPMC to NHHMC. The relocation would not increase the OR inventory in Mecklenburg County. The applicant states that NHHMC opened in October 2004 with four shared ORs and one dedicated C-Section OR. In 2010 Novant Health Huntersville Outpatient Surgery (NHHOS) opened with two dedicated outpatient ORs on NHHMC's campus. On page 82, the applicant states that in 2012 the four shared operating rooms at NHHMC operated above the planning target of 80% which prompted the applicant to submit a CON application for a fifth operating room (See Project I.D. # F-10054-12). The fifth operating room opened in November 2014. The applicant reports that since that time inpatient surgical utilization has increased by 7.2%. On page 8, the applicant illustrates this growth from CY 2012 - 2015 for the shared ORs at NHHMC. On page 83, the applicant illustrates the combined surgical growth of NHHMC and NHHOS, as shown below.

Combined Surgical Cases

	FY 2014 Cases	FY 2015 Cases	Annual Growth
Inpatient	895	959	7.2%
Outpatient	4,096	4,053	-1.1%

As illustrated, the inpatient surgical volume at NHHMC has grown by 7.2%, however, the outpatient surgical volume has decreased by -1.0%. The applicant attributes this decrease in to the opening of Mallard Creek Orthopedic Surgery Center Demonstration Project above 2014. The applicant reports on page 83 that outpatient surgical procedures reflected a growth of 4.2% from January to July 2015, signaling a rebound in volume at NHHMC.

On page 84, the applicant illustrates an increase in NHHMC's inpatient surgical market share in Mecklenburg County from CY2013 through the first quarter of CY2015. The

table on page 84 also reflects an increase in the market share of surrounding counties: Cabarrus, Iredell and Lincoln. Hence, the applicant shows an increase in NHHMC market share in four of the five counties served.

Projected Utilization

In Section III.1(b), pages 87-101, the applicant provides the assumptions and methodology used to project acute care utilization and surgical volume at NHHMC, as follows:

Acute Care Projections

Step 1: Determine Base Volume for Use in Acute Care Projections

On page 87, the applicant provides NHHMC's acute care utilization from October 2013 - July 2015. The applicant reports that NHHMC's projections are based on acute care utilization from August 2014 - July 2015.

Step 2: Determine Growth Rate for Use in Acute Care Projections

On page 88, the applicant provides the four year average annual growth rate in acute care admissions of 5.1% and in the number of days, 4.8% (August 2010 – July 2015).

Step 3: Project Acute Care Cases and Days of Care at NHHMC

On page 88, the applicant used the 5.1% annual growth rate to project future acute care admissions at NHNMC, as illustrated in the table below.

Novant Health Huntersville Medical Center Projected Acute Care Admissions August 2015 – July 2022

Acute Care	*Aug 14-Jul 15*	*Projected Growth Rate*	*Aug 15-Jul 16*	*Aug 16-Jul 17*	*Aug 17-Jul 18*	*Aug 18-Jul 19*	*Aug 19-Jul 20*	*Aug 20-Jul 21*	*Aug 21-Jul 22*
Admissions	*6,754*	*5.1%*	*7,096*	*7,455*	*7,833*	*8,230*	*8,646*	*9,084*	*9,544*

The applicant projects an increase in admissions of 2,790 over seven years. On page 89, the applicant calculates the patient days based on a four year average length of stay (ALOS) of 3.6 days.

Step 4: Convert Projected Acute Care Days to Project Years and Determine Bed Need

The applicant states on page 89 that the proposed project is projected to be operational by July 1, 2019. The applicant converted August 2016-July 2020 days of care (Step 3) to Project Years 1-3, as illustrated in the table below.

Novant Health Huntersville Medical Center
Projected Acute Care Days of Care
July 1, 2019 – June 30, 2022

	PY 1 Jul 19-Jun20	***PY 2 Jul 20-Jun 21***	***PY 3 Ju1 21-Jun 22***
Projected Days of Care	*31,125*	*32,701*	*34,357*
ADC	*85.4*	*90.0*	*94.5*
Beds Needed at 66.7% Occupancy	*128*	*135*	*142*
Proposed Bed Capacity	*139*	*139*	*139*
Utilization	*61.4%*	*64.7%*	*68.0%*

As illustrated, the applicant projects a total of 34,357 days of care in PY 3. With 139 general acute care beds, this is an Average Daily Census (ADC) of 94 patients or 67.7% utilization. Projected utilization is based on reasonable, credible and adequately supported assumptions.

ICU Projections

The applicant provides its assumptions and methodology for projected ICU bed utilization in Section III.1(b), pages 90-91. The applicant currently operates six ICU beds and proposes to designate two of the 48 relocated beds from NHPMC as medical/surgical ICU beds. The applicant states that the projected need for two additional ICU beds is based on future acute care patient days multiplied by NHHMC ICU percent of total patient days. The assumptions used are as follows:

Step 1: Determine ICU Patient Days as a Percent of Total Patient Days

On page 90, the applicant illustrates that ICU days as a percent of total days varied from 5.3% to 6.4% during the last twelve months (August 2014 – July 2015). The average percentage for the past five years, FFY 2011 - FFY 2015, is 6.3%. The applicant opted to use a growth rate of 6.4% to project future ICU days of care based on the most recent data.

Step 2: Project Future ICU Patient Days

Using the percentage determined in Step 1 of 6.4%, the applicant projects the need for ICU beds at NHHMC in PY 1- 3, as illustrated in the table below.

NHHMC Projected ICU Bed Need

	Aug 14-Jul 15	PY 1 Jul 19-Jun 20	PY 2 Jul 20-Jun 21	PY 3 Ju1 21-Jun 22
Projected Acute Care Patient Days	24,090	31,125	32,701	34,357
Percent of Total Days	6.4%	6.4%	6.4%	6.4%
Projected Med/Surg - ICU Pt Days	1,550	2,003	2,104	2,211
ICU - ADC	4.2	5.5	5.8	6.1
# of ICU Beds	6	8	8	8
% Utilization	70.8%	68.6%	72.1%	75.7%

The applicant adequately demonstrates the need for two additional ICU beds.

NICU Projections

NHHMC currently operates two Level III NICU beds and proposes to add two beds for a total of four Level III NICU beds upon project completion. The applicant provides its three-step methodology and assumptions for the two additional Level III NICU beds at NHHMC, as follows:

Step 1: Determine Base Volume for Use in Obstetrical Projections

On pages 91-93, the applicant states that NHHMC's obstetrical department has experienced growth including the addition of a third office location in 2014 and a new OB/GYN physician and a certified nurse midwife in 2015. The applicant uses data from January to September 2015 to estimate CY 2015 total cases and then uses this data to project future utilization. Projected obstetrical cases were calculated using a growth rate of 1.28%. The applicant provides a table on page 92, which illustrates that NHHMC projects to have 1,399 OB cases in PY 1, 1,417 in PY 2, and 1,435 in PY 3.

Step 2: Calculate NICU Level III Projected Volume
The applicant reports on page 92 that the two Level III NICU beds at NHHMC have high utilization, often exceeding 100%. The applicant uses the CY 2014 percentage of total births of 8.6% at NHHMC to project future Level III NICU bed utilization. On page 92, the applicant illustrates the projected utilization for the Level III NICU beds, as shown below.

NHHMC Projected NICU Level III Cases

	PY 1 Jul 19-Jun20	PY 2 Jul 20-Jun 21	PY 3 Ju1 21-Jun 22
Total OB Cases/Births*	1,399	1,417	1,435
NICU %	8.6%	8.6%	8.6%
Total Projected Cases	120	122	123

*Cases = births for this analysis

Step 3: Calculate NICU Level III Projected Inpatient Days and Bed Need

The applicant states on page 93 that the ALOS for Level III NICU beds at NHHMC has fluctuated in the past three years. The applicant uses an ALOS of 9.52 days, which reflects the actual ALOS over the past twelve months, to project future Level III NICU patient days, as illustrated in the table below.

NHHMC Projected NICU Level III Patient Days

	PY 1 Jul 19-Jun 20	PY 2 Jul 20-Jun 21	PY 3 Ju1 21-Jun 22
Total Projected Cases	120	122	123
ALOS	9.52	9.52	9.52
Days	1,146	1,161	1,175
ADC	3.14	3.18	3.22
# of Beds	4	4	4
Projected Utilization	78.5%	79.5%	80.5%

As shown above, during PY 3, the occupancy rate is projected to be 80.5% which exceeds 75% as required by 10A NCAC 14C .1403(a)(2).

Operating Room Projections

The applicant currently operates six shared operating rooms and one dedicated C-Section OR. On pages 94-97, the applicant provides NHHMC's assumptions and methodology for projected OR utilization, as follows:

Step 1: Determine Base Volume for Use in Surgical Projections

The applicant uses historical surgical data from August 2014 - July 2015 as the baseline for OR projections. See Table 7 in Exhibit 3 for additional information.

Step 2: Project Inpatient Surgical Projections

Based on August 2014 - July 2015 data, the applicant projects future inpatient surgical volume will be 18.9% of total admissions at NHHMC. On page 94, the applicant provides a table, which illustrates the projected inpatient volume at NHHMC, which reflects an annual growth of approximately 5% for inpatient surgical admissions. The applicant projects 1,805 surgical cases in PY 3.

Step 3: Project Outpatient Surgical Services

The applicant states that outpatient surgical procedures have decreased since 2010 with the opening of NHHOS and Mallard Creek Surgery Center. However, the marketplace is projected to grow, including NHHMC. The applicant utilizes a weighted population growth rate of 1.7% to project outpatient surgery as shown on page 95. The 2015 outpatient growth rate is used to project NHHOS's surgery volume. Also see Table 12 in Exhibit 3 for additional information.

Step 4: Project Operating Room Need for Novant Health Huntersville Medical Center

On page 96, the applicant uses the projected inpatient and outpatient volumes in Steps 2 and 3 to project operating volume for NHHMC in PY 1-3, as summarized below.

NHHMC Projected OR Need

	PY 1 Jul 19-Jun 20	**PY 2 Jul 20-Jun 21**	**PY 3 Ju1 21-Jun 22**
Inpatient Cases	1,628	1,711	1,797
Outpatient Cases	3,500	3,558	3,616
Weighted OR Volume*	10,209	10,546	10,896
OR's Needed at 1872 hrs	5.45	5.63	8.82
# of ORs Needed	5.0	6.0	6.0

*2015 SMFP – standard number of hours per operating room per year (9 hours x 260 days x 0.8 = 1,872 hours per operating room per year)

Step 5: Project Operating Room Need for Novant Health Huntersville Medical Center Plus Novant Health Huntersville Outpatient Surgery

The applicant bases the need for an additional shared operating room on the continued population and economic growth in the NHHMC services area. On page 97, the applicant illustrates the need for the additional OR, as shown in the table below. NHHMC and NHHOS are located on the same campus and share overlapping surgical staff. Looking at the combined OR need for both facilities supports the need for the proposed six shared ORs at NHHMC and two dedicated ambulatory surgery ORs at NHHOS.

NHHMC & NHHOS Projected OR Need

	Aug 19 - Jul 20	Aug 20 - Jul 21	Aug 21 - Jul 22
NHHMC - Projected Inpatient Surgery	8,646	9,084	9,544
NHHMC - Projected Outpatient Surgery	3,505	3,562	3,621
NHHOS - Projected Outpatient Surgery	2,162	2,216	2,271
Data Converted to Project Year	**PY 1 Jul 19-Jun20**	**PY 2 Jul 20-Jun 21**	**PY 3 Ju1 21-Jun 22**
Inpatient Cases	1,628	1,711	1,797
Outpatient Cases	5,657	5,769	5,883
Weighted Volume	13,371	13,785	14,216
OR's Needed at 1,872 hours*	7.14	7.26	7.59
# of ORs Needed	7.0	7.0	8.0

*2015 SMFP – standard number of hours per operating room per year (9 hours x 260 days x 0.8 = 1,872 hours per operating room per year)

The applicant demonstrates a need for eight total ORs in PY 3 (excluding one dedicated C-Section OR). NHHMC would consist of a complement of six shared ORs, two dedicated ambulatory surgery rooms and one dedicated C-Section OR, on the NHHMC campus upon project completion. The applicant does not propose to increase the number of operating rooms in the service area, but rather to relocate one existing operating room from NHPMC to NHHMC.

The applicant adequately demonstrates the need for two additional ORs for a total of eight ORs (excluding the one dedicated C-Section OR) at NHHMC.

Summary

The applicant adequately demonstrates the need to relocate 48 additional acute care beds from NHPMC to NHHMC of which 44 beds will be used as general medical/surgical acute care beds, two will be ICU beds and two will be Level III NICU beds upon project completion.

Access

In Section VI.2, pages 129-134, the applicant states that NHHMC has traditionally provided services to all individuals regardless of race, creed, color or handicap conditions. On pages 142-143, the applicant provides the percentage of those who have had all or part of their services paid by Medicare/Medicaid and/or self-pay/indigent/charity in CY 2014 for the entire hospital and for the service components included in the proposed project, as summarized below:

	Medicare/ Medicaid	Self-pay/ Indigent/Charity
Entire Hospital	38.03%	8.71%
Inpatient Services	58.68%	3.99%
Surgical Services	33.53%	3.01%
ICU	71.88%	6.56%
NICU	36.63%	2.36%

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population has for the proposed project and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. 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

The applicant proposes to relocate 48 acute care beds from NHPMC to NHHMC. In Section III.7(a), pages 112-113, the applicant reports that NHPMC is currently licensed for 637 acute care beds. The applicant or its parent company Novant Health, Inc. is approved to relocate 50 acute care beds to Novant Health Mint Hill (Project # F-7648-06), and relocate 20 acute care beds to Novant Health Matthews Medical Center (Project I.D. # F-10213-13). These relocations will leave NHPMC with a bed inventory of 567. See Exhibit 3, Table 37 for a detailed discussion of the acute care bed relocations. On page 113, the applicant provides the projected utilization of acute care beds at NHPMC in FFY2019-2022, as illustrated in the table below.

NHPMC Projected Bed Utilization

	FFY 19	FFY 20	FFY 21	FFY 22
Projected DOC*	133,812	136,086	138,400	140,753
ADC	336.6	372.8	379.2	385.6
Beds Needed @ 75.2% Occupancy	488	496	504	513
Bed Capacity	567	567	567	567
Projected Surplus	79	71	63	54

*DOC = Days of Care

As illustrated above, even with the relocation of 48 acute care beds to NHHMC, NHPMC is projected to have a surplus of acute care beds during all three project years of the proposed project.

The applicant states on pages 114-115 that the population currently being served at NHPMC will not be negatively impacted by the proposed relocation of the acute care beds and one operating room. In Exhibit 3, Tables 21-23 the applicant provide the projected OR volume at NHPMC based on historical data. Tables 29-30 provide patient origin, by County, by ZIP code and the projected market share. Tables 37-38 provides the current and projected acute care bed inventory and the projected bed need for NHPMC, upon completion of the proposed project.

Therefore, the applicant adequately demonstrates that the needs of the population currently being served at NHPMC will continue to be adequately met following the relocation of 48 acute care beds and one OR from NHPMC to NHHMC.

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

CA

In Section III.3, pages 102-103, the applicant describes the five alternatives considered which include the following:

1) Maintain Status Quo – NHHMC considered maintaining the status quo; however, the applicant concluded that this option was not acceptable nor sustainable given the growth in the population in the service area served by NHHMC.

2) Construct an Additional Floor to House 14 Additional Acute Care Beds – The applicant considered constructing an additional floor adjacent to the existing Level III and OB support unit. However, this option would require the temporary relocation of the kitchen air handler located on the roof and would disrupt two patient floors. The applicant also concluded that 14 additional acute care beds would not be an effective alternative to meet the growing need for acute care beds at NHHMC.

3) Construct an Additional Floor to House 16 Additional Acute Care Beds – The applicant considered adding a floor adjacent to the existing Labor and Delivery service on the 3rd floor. However, the applicant concluded that 16 beds would not be an effective alternative to meet the growing need for additional acute care beds in northern Mecklenburg County.

4) Relocate More than 48 Additional Acute Care Beds – The applicant considered relocating more than 48 acute care beds from NHPMC. However, representatives from both acute care facilities and the NH Planning and Development Team concluded that based on historical utilization, population growth, available market share and growth with within the service area, additional beds were not warranted.

5) Develop the Project as Proposed – The applicant states on page 103, that construction of a four story addition to the existing inpatient tower is the least intrusive and most effective alternative to meet the need for additional acute care beds and one additional OR at NHHMC. The applicant states the proposal will meet the need for additional services in northern Mecklenburg County while maintaining sufficient bed capacity at NHPMC in downtown Charlotte.

The applicant adequately demonstrates that relocating 48 acute care beds and one OR from NHPMC to NHHMC is the most effective alternative to meet the need for additional acute care services at NHHMC.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative. In summary, the applicant demonstrates that its proposal is the least costly or most effective alternative to meet the need.

Therefore, the application is conforming to this criterion and is approved subject to the following conditions:

1. **The Presbyterian Hospital d/b/a Novant Health Huntersville Medical Center shall materially comply with all representations made in its certificate of need application.**

2. **The Presbyterian Hospital d/b/a Novant Health Huntersville Medical Center 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 which would otherwise require a certificate of need.**

3. **The Presbyterian Hospital d/b/a Novant Health Huntersville Medical Center shall relocate no more than 48 existing acute care beds and one existing operating room from Novant Health Presbyterian Medical Center to Novant Health Huntersville Medical Center for a total of no more than 139 acute care beds (127 general medical/surgical beds, eight intensive care beds and four intensive care level III neonatal beds) and seven operating rooms (one of which is a dedicated C-Section operating room), upon project completion.**

4. **The Presbyterian Hospital d/b/a Novant Health Huntersville Medical Center 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.**

5. **Prior to issuance of the certificate of need, The Presbyterian Hospital d/b/a Novant Health Huntersville Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

(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

The applicant proposes to renovate existing space and construct a four story expansion to the bed tower at NHHMC to accommodate 48 relocated beds and one relocated OR.

Capital and Working Capital Costs

In Section VIII.1, pages 160-162, the applicant states that the total capital cost of the project will be $45,661,870, as shown in the table below.

Project Capital Cost

Site Costs	$669,269
Construction / Labor Costs	$32,896,561
Fixed & Movable Equipment Purchase/Lease	$3,229,000
Information Technology	$2,096,920
Furniture	$650,000
Consultant Fee	$50,515
Architect & Engineering Fees	$2,100,000
Assortment of Fees	$50,000
Security/Nurse Call/Low Voltage System	$898,680
Interest During Construction	$1,342,633
Contingency	$1,678,292
Total Capital Cost	**$45,661,870**

In Section IX, page 169, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Availability of Funds

In Section VIII.3, page 162, the applicant states that the project will be funded through Novant Health, Inc.'s accumulated reserves. Exhibit 10 contains a December 6, 2015 letter signed by the Senior Vice President of Finance for Novant Health, Inc., which states:

> *"This letter will serve to confirm that Novant Health, Inc. will be funding from its Accumulated Reserves the capital cost of $45,661,870 for the proposed Novant Huntersville Medical Center expansion adding acute beds and a sixth operating room."*

Exhibit 10 of the application contains the audited financial statements for Novant Health, Inc. and Affiliates (NH) for the years ending December 31, 2013 and 2014. As of December 31, 2014, NH had $353,797,000 in cash and cash equivalents, 5,403,023,000 in total assets and $2,665,164,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

In the pro forma financial statement for the service components (Form C), the applicant projects that revenues will exceed operating expenses in each of the first three years for the service components proposed in the application, as illustrated in the table below.

NHHMC Projections

	PY 1 FY20	PY 2 FY21	PY 3 FY22
Acute Inpatient Services			
Gross Patient Revenue	$281,757,722	$307,865,370	$336,394,108
Deductions from Gross Patient Revenue	$185,535,104	$202,726,771	$221,512,707
Net Patient Revenue	$96,222,618	$105,138,598	$114, 881,401
Total Expenses	$62,544,909	$68,340,315	$74,673,157
Net Income	$33,677,709	$36,798,283	$40,208,243
Surgical Services			
Gross Patient Revenue	$190,735,360	$203,819,032	$217,764,911
Deductions from Gross Patient Revenue	$116,337,046	$124,317,296	$132,823,440
Net Patient Revenue	$74,398,314	$79,501,736	$84,941,472
Total Expenses	$48,359,064	$51,676,300	$55,212,139
Net Income	$26,039,250	$27,825,437	$29,729,333
ICU Services			
Gross Patient Revenue	$36,570,222	$39,950,822	$43,661,843
Deductions from Gross Patient Revenue	$27,179,483	$29,691,991	$32,450,072
Net Patient Revenue	$9,390,739	$10,258,831	$11,211,771
Total Expenses	$6,104,000	$6,668,262	$7,287,675
Net Income	$3,286,738	$3,590,569	$3,924,096
NICU Services			
Gross Patient Revenue	$3,204,122	$3,375,903	$3,553,276
Deductions from Gross Patient Revenue	$823,601	$867,757	$913,349
Net Patient Revenue	2,380,521	$2,508,146	$2,639,927
Total Expenses	$1,547,344	$1,630,301	$1,715,958
Net Income	$833,177	$877,846	923,969

Additionally, in Form B, the applicant projects that revenues will exceed operating expenses in each of the first three years for the entire hospital.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section 10 and the Pro Forma section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates 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

On page 48, the 2015 SMFP defines the service area for acute care services by county (or multicounty service area for counties without a hospital). NHHMC is located in Mecklenburg County. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to relocate 48 acute care beds and one existing OR from NHPMC to NHHMC. The proposed relocation would not increase the number of acute care beds or operating rooms in Mecklenburg County. According to the 2015 SMFP there are seven licensed acute care facilities with 2,088 acute care beds and 135 ORs in Mecklenburg County. Mecklenburg County has 21 additional ORs located in ambulatory surgery centers. The table below reflects the licensed acute care facilities, bed inventory and ORs in Mecklenburg County.

Mecklenburg County Licensed Acute Care Beds and Operating Rooms

Facility	Location	# of Licensed Acute Care Beds 2015 SMFP	# of Licensed Acute Care Beds 2016 SMFP	# of ORs 2015 SMFP
Carolinas Medical Center	Downtown	814	976	47
Carolinas Medical Center – Mercy/Pineville**	South	368	206	27
Carolinas Medical Center - University	East	94	94	9
Novant Health Charlotte Orthopedic*	South	64	-	12
Novant Health Huntersville	North	75	75	5
Novant Health Matthews	South	134	134	8
Novant Health Presbyterian	Downtown	539	603	24
Total		**2,088**	**2,088**	**135**

Source: 2015 SMFP and 2015 License Renewal Applications
*Novant Health Charlotte Orthopedic was added to Novant Presbyterian's license effective 3/22/14
**Carolinas Medical Center - Mercy is licensed under Carolinas Medical Center

The applicant adequately demonstrates that those residents residing closer to NHPMC will continue to have their acute care and surgical needs met. See pages 112-115.

Consequently, the applicant adequately demonstrates the need the population proposed to be served has for the 48 additional acute care beds and one additional OR at NHHMC. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

Therefore, the applicant adequately demonstrates the project will not result in the unnecessary duplication of existing or approved acute care or surgical services in the Mecklenburg County service area. Consequently, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1(b), pages 147-148, the applicant provides the current and projected staffing for NHHMC's acute care beds and operating rooms. NHHMC currently employs 176.40 full time equivalent (FTE) positions in its acute care beds and operating rooms and projects to increase the number of FTEs by 90.25 for a total of 266.65 FTEs during the second full fiscal year following completion of the proposed project, as illustrated in the table below.

Current and Proposed Staffing FTEs
Acute Care Beds and Operating Rooms
July 1, 2020 - June 30, 2021

Designation	Current FTEs	Projected FTEs
Inpatient Med/Surg		
Nurse Manager	1.00	1.00
CNA	27.50	55.00
Unit Receptionist	10.00	15.00
RN	44.20	80.00
Clinical Unit Manager	5.00	6.00
ICU		
RN	15.00	20.00
CNA	5.00	5.00
NICU		
RN	5.00	10.00
ORs		
Nursing Manager	1.00	1.00
RN/Clinical Coordinator	1.00	1.00
RN/OR	9.45	10.95
Admin Specialist	1.00	1.00
Surg. Tech	7.45	8.95
OR Assistant	2.00	3.00
RN/OR Clinical Shift Manger	1.00	1.00
Sterile Processing Supervisor	1.00	1.00
Sterile Processing Tech	6.00	7.00
Anesthesia		
CRNA	11.40	12.90
Anesthesia Tech	2.00	2.00
Anesthesia Manager	1.00	1.00
RN/Anesthesia	0.40	0.65
OR Pre/Post Recovery		
ACU RN	12.00	14.20
RN/Clinical Coordinator	2.00	2.00
LPN	1.00	2.00
CNA	2.00	3.00
Unit Specialist	1.00	1.00
Clinical Shift Manager	1.00	1.00
Total Projected FTEs	**176.40**	**266.65**

As illustrated the above, the applicant projects 157.00 FTE positions for general medical/surgical services, 25.00 FTEs for ICU services, 10.00 FTEs for NICU services, 34.90 FTEs for surgical services, 16.55 FTEs for anesthesia and 16.55 FTEs for pre – and

post-OR recovery in the second full fiscal year following completion of the proposed project. In Section VII.3 (a), page 152, the applicant states:

> *"The proposed new beds and operating room will not add any new positions (job titles) since the job positions already exist at NHHMC in the Medical-Surgical Acute Beds, ICU, and NICU nursing units and Surgical Services..."*

In Section VII.6 (a) and (b), pages 154-156, the applicant provides NHHMC's recruitment and staff retention plans. In Section VII.8 (a), page 157, the applicant states Dr. Lisa Gorsuch is the Chief Medical Officer for NHHMC. See Exhibit 17 for a copy of Dr. Gorsuch's letter of support. On pages 158-159, the applicant provides the number of NHHMC active medical staff by specialty.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

The applicant currently provides the service components proposed in this application. The necessary ancillary and support services are currently available. In Section II.2, pages 12-13, the applicant states:

> *"All the key ancillary and support services that are offered at NHHMC today-nursing, radiology, pharmacy, laboratory & pathology services, respiratory therapy, housekeeping, food services/dietary and nutrition, emergency services, speech, physical, and occupational therapy, surgical services, billing, finance, clinical equipment management, and strategic sourcing. The necessary hospital based clinical and non-clinical and support services will continue to be available 24 hours per day, 7 days per week to support the operation of the proposed 48 new acute care beds and the additional OR."*

Exhibits 5, 6, and 7 contain documentation of the availability of ancillary and support services at NHHMC. Exhibit 2 contains letters of support from physicians for the proposed project. The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to 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.

C

The applicant proposes to develop the proposed project in a combination of existing renovated space and newly constructed space located on NHHMC campus. The application proposes 60,605 square feet of new construction and renovation of 10,035 existing square feet. The applicant states the total square footage of NHHMC is 269,809 and the proposed square feet upon project completion is projected to be 330,414.

Exhibit 13 contains a letter from McCulloch England Associates Architects which estimates that construction costs and architectural/engineering fees will total $35,665,830.00, with $33,565,830.00 of that total being construction costs, which corresponds to the project capital cost projections provided by the applicant in Section VIII, page 161. In Section XI.7, page 179 and Exhibit 15, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

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

C

In Section VI.12 and VI.13, pages 142-143, the applicant provides the payor mix during CY 2014 for NHHMC and the proposed service components, as illustrated in the table below:

NHHMC CY 2014
Historical Payor Source
Number of Cases as a Percent of Total Utilization

	Entire Facility	**Inpatient Services**	**Surgical Services**	**ICU Services**	**NICU Services**
Self-Pay / Indigent / Charity	8.71%	3.99%	3.01%	6.56%	2.36%
Medicare/Medicare Managed Care	27.29%	50.07%	29.01%	66.47%	0.00%
Medicaid	10.74%	8.61%	4.52%	5.41%	36.63%
Commercial Insurance	0.94%	0.60%	0.72%	0.13%	2.26%
Managed Care	49.89%	35.34%	59.41%	19.95%	58.11%
Other	2.43%	1.39%	3.33%	1.48%	0.64%
Total	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**

In Section VI.2, page 129, the applicant states:

"It is the policy of all the Novant Health facilities and programs, including Novant Health Huntersville Medical Center, to provide necessary services to all individuals without regard to race, creed, color, or handicap. Novant Health facilities and programs do not discriminate …"

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	**% 65+**	**% Female**	**% Caucasian**	**% Persons in Poverty***	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance***
Mecklenburg	10%	52%	49%	15%	6%	19%
Iredell	15%	51%	77%	13%	9%	18%
Lincoln	16%	50%	85%	16%	11%	19%
Gaston	15%	52%	75%	17%	13%	18%
Cabarrus	13%	51%	69%	12%	7%	16%
Statewide	15%	51%	64%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.
*These statistics are not comparable to other geographic levels of these estimates.

However, a direct comparison to the applicant's 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, women or handicapped persons utilizing health services.

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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;

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 141, the applicant states:

> *"Novant Health's tertiary hospitals (Novant Health Forsyth Medical Center and Novant Health Presbyterian Medical Center) fulfilled their Hill-Burton obligations long ago. ... The quota was exceeded as of 1982. ... NHHMC and all Novant facilities in North Carolina continue to comply with the community service obligation and there is no denial, restriction, or limitation of access to minorities or handicapped persons."*

See Exhibit 9 for a copy of the applicant's policies and procedures regarding charity care, admissions and discharge.

In Section VI.10 (a), page 141, the applicant states that no civil rights equal access complaints have been filed against the hospital or any other Novant acute care facilities during the past five years. Therefore, 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(a) and VI.15(a), pages 143-145, the applicant provides the projected payor mix for the entire facility and for the proposed components, as illustrated in the table below:

NHHMC PY 2 FY 21
Projected Payor Source as a Percent of Total Utilization

	Entire Facility	Inpatient Services	Surgical Services	ICU Services	NICU Services
Self-Pay / Indigent / Charity	7.78%	2.98%	2.57%	5.44%	0.00%
Medicare/Medicare Managed Care	26.81%	50.79%	31.86%	64.31%	0.00%
Medicaid	10.87%	6.22%	4.82%	6.09%	27.75%
Commercial Insurance	1.03%	0.78%	0.37%	0.22%	0.00%
Managed Care	50.91%	37.25%	57.90%	23.18%	63.67%
Other	2.60%	1.98%	2.48%	0.76%	8.58%
Total	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**

As illustrated above, the applicant projects a slight change in its payor sources for PY 2 from its historical payor mix. The most significant changes include a lower percentage of inpatient services being paid by Medicaid and a higher percentage of

those services being paid by Managed Care. Additionally, the applicant projects a higher percentage of patients will have their surgical care services paid by Medicare/Medicare Managed Care while less of their ICU patients will have their services paid by this payor source. No NICU services are projected to be paid by Self-Pay/Indigent/Charity payor source.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9, pages 139-140, the applicant describes the range of means by which a person will have access to its services. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1(b), page 118, the applicant states, *"NHHMC ... has clinical education agreements in place with many healthcare training institutions."* See Exhibit 4 for a detailed list of those programs with which NHHMC has clinical training agreements. The information provided in Exhibit 4 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

The applicant proposes to relocate 48 acute care beds and one operating room from NHPMC to NHHMC. The proposed relocation will not result in a change in the number of licensed acute care beds or operating rooms in Mecklenburg County.

On page 44, the 2015 SMFP defines the service area for acute care services as a single county (or multicounty service area for counties without a hospital). NHHMC is located in Mecklenburg County. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the 2015 SMFP there are seven licensed acute care facilities with 2,088 acute care beds and 135 ORs in Mecklenburg County. Mecklenburg County has 21 additional ORs located in ambulatory surgery centers. The table below reflects the licensed acute care facilities, bed inventory and ORs in Mecklenburg County.

Mecklenburg County Licensed Acute Care Beds and Operating Rooms

Facility	Location	# of Licensed Acute Care Beds 2015 SMFP	# of Licensed Acute Care Beds 2016 SMFP	# of ORs 2015 SMFP
Carolinas Medical Center	Downtown	814	976	47
Carolinas Medical Center – Mercy/Pineville**	South	368	206	27
Carolinas Medical Center - University	East	94	94	9
Novant Health Charlotte Orthopedic*	South	64	-	12
Novant Health Huntersville	North	75	75	5
Novant Health Matthews	South	134	134	8
Novant Health Presbyterian	Downtown	539	603	24
Total		**2,088**	**2,088**	**135**

Source: 2015 SMFP and 2015 License Renewal Applications
*Novant Health Charlotte Orthopedic was added to Novant Presbyterian's license effective 3/22/14
**Carolinas Medical Center - Mercy is licensed under Carolinas Medical Center

The applicant operates the only acute care facility in northern Mecklenburg County. In Section III.1, page 60, the applicant defines its service area as 14 different ZIP codes in Mecklenburg, Iredell, Lincoln, Gaston and Cabarrus counties. On page 62, NHHMC reports having expanded its acute care bed capacity twice since opening the acute care facility in 2004 to keep up with the growing demand for inpatient acute care beds at the facility. In this application, the applicant proposes to relocate 48 acute care beds and one operating room from Novant Health Presbyterian Medical Center to Novant Health Huntersville Medical Center for a total of 139 licensed acute care beds and six

operating rooms (excluding one dedicated C-Section OR), upon project completion. See page 10.

In Section V.7, pages 123-127, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

> *"In June 2015, NHHMC was named one of the '100 Great Community Hospitals' by Becker's Hospital Review."*

On page 124, the applicant continues:

> *"Novant Health's continued commitment to increasing efficiencies has made Novant a leader in the field. Novant Health will bring this experience and disciplined approach to the operation of the proposed bed expansion and surgical services at NHHMC."*

The applicant concludes that Novant Health's attention to cost effectiveness, quality services, and access, including its charity care policies, helps to enhance competition in the service area by providing residents in northern Mecklenburg County and surrounding counties with quality care.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to relocate 48 acute care beds and one OR and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that NHHM has and will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant adequately demonstrates NHHMC has and will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13) are incorporated herein by reference.

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

In Section I.12, page 5, the applicant states that in addition to NHHMC, Novant Health currently owns and operates ten other hospitals in North Carolina and has been approved for another hospital in Mint Hill, in Charlotte (Mecklenburg County). According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the States on any facility owned and operated by Novant Health in North Carolina. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of the facilities, the applicant provided sufficient evidence that quality care has been provided in the past and adequately demonstrated that there is no pattern of substandard quality of care. Therefore, the application is conforming to this criterion.

(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 States 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 is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms, as promulgated in 10A NCAC 14C .2100, Criteria and Standards for Intensive Care Services, as promulgated in 10A NCAC 14C .1200 and the Criteria and Standards for Neonatal Services as promulgated in 10A NCAC 14C .1400. The specific criteria are discussed below.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

.2102 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall identify each of the following specialty areas that will be provided in the facility:

(1) gynecology;
(2) otolaryngology;
(3) plastic surgery;
(4) general surgery;
(5) ophthalmology;
(6) orthopedic;
(7) oral surgery; and
(8) other specialty area identified by the applicant.

-NA- NHHMC is an existing acute care hospital and does not propose to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

(b) An applicant proposing to increase the number of operating rooms in a service area, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall provide the following information:

(1) the number and type of operating rooms in each licensed facility which the applicant or a related entity owns a controlling interest in and is located in the service area (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(2) the number and type of operating rooms to be located in each licensed facility which the applicant or a related entity owns a controlling interest in and is located in the service area after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(3) The number of inpatient surgical cases, excluding trauma cases reported by Level I, II and III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-Section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each licensed facility listed in response to Subparagraphs (b)(1) and(b)(2) of this Rule:

(4) The number of inpatient surgical cases, excluding trauma cases reported by Level I, II and III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-Section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each licensed facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule;
(5) A detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;
(6) The hours of operation of the proposed operating rooms;
(7) If the applicant is an existing facility, the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in the facility during the preceding 12 months and a list of all services and items included in the reimbursement;
(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility and a list of all services and items in the reimbursement; and
(9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

-NA- NHHMC is an existing acute care hospital. The applicant proposes to relocate one existing OR from NHPMC to NHHMC.

(c) An applicant proposing to relocate existing or approved operating rooms within the same service area shall provide the following information:
(1) the number and type of existing and approved operating rooms in each facility in which the number of operating rooms will increase or decrease (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

-C - On pages 21-22, the applicant provides the number of existing ORs at NHHMC and NHPMC, as illustrated in the table below.

	NHHMC	**NHPMC**
Shared Inpatient/Outpatient ORs	5	33
Dedicated Ambulatory ORs	0	6
Dedicated Open Heart Surgery ORs	0	3
Dedicated C-Section ORs	1	3
Total ORs	**6**	**45**

(2) the number and type of operating rooms to be located in each affected facility after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

-C- On page 22, the applicant provides the following information to illustrate the number of ORs at each site following completion of the proposed project and the transfer of one OR from NHPMC to NHHMC.

	NHHMC	**NHPMC**
Shared Inpatient/Outpatient ORs	6	32
Dedicated Ambulatory ORs	0	6
Dedicated Open Heart Surgery ORs	0	3
Dedicated C-Section ORs	1	3
Total ORs	**7**	**44**

The applicant states on page 22, that the total number of ORs at NHPMC does not reflect the approved relocation of ORs from NHPMC to Novant Health Mint Hill Medical Center (see Project I.D. # F-7648-06 in which Novant Health proposed to relocate 50 existing acute care beds and five existing ORs from Presbyterian Orthopedic Hospital and 1 existing GI endoscopy procedure room from Presbyterian Hospital Matthews to establish a new hospital in Mint Hill). When the NH Mint Hill project is completed, the ORs at NHPMC will be adjusted to reflect the relocation of five ORs from NHPMC to NH Mint Hill.

(3) the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;

-C- On page 23, the applicant provides the number of inpatient surgical cases and outpatient surgical cases performed in the most recent 12 month period (August 2014 to July 2015) in the operating rooms in each facility listed in Subparagraphs (c)(1) and (c)(2) of this Rule:

	Inpatient Surgical Cases*	Outpatient Surgical Cases	Total Surgical Cases
NHHMC	1,277	3,229	4,506
NHPMC**	7,459	20,585	28,044
Total	**8,736**	**23,814**	**32,550**

*Excluding trauma cases, dedicated open heart and C-Section rooms.
**NHPMC includes surgical volumes from NHPMC, Novant Health Charlotte Orthopedic Hospital (NHCOH), Novant Health Charlotte Outpatient Surgery (NHCOS) and Novant Health Midtown Surgery Center (NHMSC).

(4) the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;

-C- On pages 23-24, the applicant provides the number of surgical cases projected to be performed in each of the first three operating years of the proposed project at NHHMC and NHPMC, as listed in (c)(1) and (c)(2) of this Rule:

Facility	PY1	PY2	PY3
Inpatient			
NHHMC	1,628	1,711	1,797
NHPMC	6,815	6,815	6,815
Total Inpatient Cases	8,443	8,526	8,612
Outpatient			
NHHMC	3,500	3,558	3,616
NHPMC	24,343	25,739	26,582
Total Outpatient Cases	27,843	29,297	30,198
Total Surgical Cases	**36,286**	**37,823**	**38,810**

The discussion regarding utilization in Criterion (3) is incorporated herein by reference.

(5) a detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

-C- The applicant provides the assumptions and methodology used in the development of its projections in Section II, Section III.1(b), Section IV and Exhibit 3. The assumptions used to project the number of surgical cases at

NHHMC are reasonable and supported. The discussion regarding utilization in Criterion (3) is incorporated herein by reference.

(6) the hours of operation of the facility to be expanded;

-C- In Section II, page 25, the applicant states the proposed hours of operation will be as follows:

- 7:30 a.m. - 3:00 p.m. (5 ORs): 5:00-7:00 p.m. (2 ORs); and 7:00-9:00p.m. (1 OR), Monday through Friday.
- 3:00-5:00 p.m. (5 ORs) Monday through Tuesday.
- 3:00-5:00 p.m. (4 ORs) Wednesday through Friday.

Additionally, the applicant states that the services at NHHMC will continue to be available 24 hours a day, 7 days per week, and 52 weeks per year.

(7) the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in each affected facility during the preceding 12 months and a list of all services and items included in the reimbursement;

-C- The applicant provides tables with the average reimbursement for the 20 most commonly performed surgical procedures at NHHMC and NHPMC in Section II, pages 26-29. The applicant states that reimbursement includes the hospital's surgery fee as well as other fees related to the entire patient stay for inpatients, but does not include professional fees, which are billed separately by physicians.

(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility to be expanded and a list of all services and items included in the reimbursement; and

-C- The tables in Section II, pages 30-31 contain the projected average reimbursement to be received per procedure for the surgical procedures projected to be performed at NHHMC.

9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

-C- In Section II, page 32, the applicant provides a list of providers of pre-operative services and procedures not included in the facility's charges.

(d) An applicant proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 States Medical Facilities Plan shall provide:

(1) the single surgical specialty area in which procedures will be performed in the proposed ambulatory surgical facility;

(2) a description of the ownership interests of physicians in the proposed ambulatory surgical facility;

(3) a commitment that the Medicare allowable amount for self-pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be at least seven percent of the total revenue collected for all surgical cases performed in the proposed facility;

(4) for each of the first three full fiscal years of operation, the projected number of self-pay surgical cases;

(5) for each of the first three full fiscal years of operation, the projected number of Medicaid surgical cases;

(6) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the self-pay surgical cases to be served in the proposed facility, i.e. provide the projected Medicare allowable amount per self-pay surgical case and multiply that amount by the projected number of self- pay surgical cases;

(7) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the Medicaid surgical cases to be served in the facility, i.e. provide the projected Medicare allowable amount per Medicaid surgical case and multiply that amount by the projected number of Medicaid surgical cases;

(8) for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of self-pay surgical cases;

(9) for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of Medicaid surgical cases;

(10) for each of the first three full fiscal years of operation, the projected total revenue to be collected for all surgical cases performed in the proposed facility;

(11) a commitment to report utilization and payment data for services provided in the proposed ambulatory surgical facility to the stateswide data processor, as required by G.S. 131E-214.2;

(12) a description of the system the proposed ambulatory surgical facility will use to measure and report patient outcomes for the purpose of monitoring the quality of care provided in the facility;

(13) descriptions of currently available patient outcome measures for the surgical specialty to be provided in the proposed facility, if any exist;

(14) if patient outcome measures are not currently available for the surgical specialty area, the applicant shall develop its own patient outcome measures to be used for monitoring and reporting the quality of care provided in the proposed facility, and shall provide in its application a description of the measures it developed;
(15) a description of the system the proposed ambulatory surgical facility will use to enhance communication and ease data collection, e.g. electronic medical records;
(16) a description of the proposed ambulatory surgical facility's open access policy for physicians, if one is proposed;
(17) a commitment to provide to the Agency annual reports at the end of each of the first five full years of operation regarding:
(A) patient payment data submitted to the statewide data processor as required by G.S. 131E-214.2;
(B) patient outcome results for each of the applicant's patient outcome measures;
(C) the extent to which the physicians owning the proposed facility maintained their hospital staff privileges and provided Emergency Department coverage, e.g. number of nights each physician is on call at a hospital; and
(D) the extent to which the facility is operating in compliance with the representations the applicant made in its application relative to the single specialty ambulatory surgical facility demonstration project in the 2010 States Medical Facilities Plan.

-NA- NHHMC does not propose to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 States Medical Facilities Plan.

.2103 PERFORMANCE STANDARDS

(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks per year.

-C- On page 34, the applicant states the OR services at NHHMC will continue to be available for use five days per week and 52 weeks per year. On-call teams are available to provide services outside the proposed regular hours of operations for the ORs.

(b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program

to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) demonstrate the need for the number of proposed operating rooms in the facility, which is proposed to be developed or expanded, in the third operating year of the project is based on the following formula: {[(Number of facility projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-Section rooms, times 3.0 hours) plus (Number of facilities projected outpatient cases times 1.5 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1,872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the States Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions of less than 0.2; and the difference is a negative number or a positive number less than 0.2, the need is zero; or

-C- The applicant adequately demonstrates the need to relocate one shared operating room from NHPMC to NHHMC, as illustrated in the table below.

Project YR 3

Project Year 3 Total Cases	5,413
Project Year 3 Total Weighted Hours	10,815
ORs Needed = Hours/1,872 Rounded	6.0
Current # of Shared ORs	5.0
ORs Proposed	1.0

(c) A proposal to increase the number of operating rooms (excluding dedicated C-Sections operating rooms) in a service area shall:

(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases report by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' times 1.5 hours)] divided by 1,872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, the need is zero;

-C- The Mecklenburg County OR service area has more than 10 operating rooms. The applicant provides a table which demonstrates the need for a sixth shared OR at NHHMC on page 35. Also see Exhibit 3, Table 7 for additional information.

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than

0.3, and if the difference is a negative number or a positive number less than 0.3, the need is zero; and

-NA- The Mecklenburg County OR service area has more than 10 operating rooms.

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions of less than 0.2; and if the difference is a negative number or a positive number less than 0.2, the need is zero.

-NA- The Mecklenburg County OR service area has more than 10 operating rooms.

(d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.

-NA- The applicant does not propose to develop an additional dedicated C-section operating room.

(e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and

(2) demonstrate the need in the third operating year of the project based on the following formula: [Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1,872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating

rooms in the service area. The need for the conversion is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.

-NA- NHHMC does not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

-C- In Section II.8, page 37, Section III.1, Section IV and Exhibit 3, the applicant provides a description of the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding utilization in Criterion (3) is incorporated herein by reference.

.2104 SUPPORT SERVICES

(a) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide copies of the written policies and procedures that will be used by the proposed facility for patient referral, transfer, and follow-up.

-NA- NHHMC is an existing acute care hospital. The applicant does not propose to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital.

(b) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide documentation showing the proximity of the proposed facility to the following services:

(1) emergency services;
(2) support services;
(3) ancillary services; and
(4) public transportation.

-NA- NHHMC is an existing acute care hospital. The applicant does not propose to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital.

.2105 STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in a facility, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall identify, justify and document the availability of the number of current and proposed staff to be utilized in the following areas:

(1) administration;
(2) pre-operative;
(3) post-operative;
(4) operating room; and
(5) other.

- C- In Section VII, pages 147-148, the applicant provides the existing and projected staff for NHHMC.

(b) The applicant shall identify the number of physicians who currently utilize the facility and estimate the number of physicians expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel.

-C- In Section II, page 38, the applicant states that NHHMC's current medical staff includes 104 surgeons, 53 anesthesiologists, 10 pathologists and 41 radiologists. Exhibit 5 contains physician letters of support. Exhibit 5, page 341 contains a letter from the Senior Vice President of Medical Affairs which identifies the criteria to be used by the facility.

(c) The applicant shall provide documentation that physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the service area in which the facility is, or will be, located or documentation of contacts the applicant made with hospitals in the service area in an effort to establish staff privileges.

-C- Exhibit 5 contains a letter from the Senior Vice President of Medical Affairs documenting that the physicians and surgeons with privileges to practice at NHHMC are active members in good standing at NHHMC.

(d) The applicant shall provide documentation that physicians owning the proposed single specialty demonstration facility will meet Emergency Department coverage responsibilities in at least one hospital within the service area, or documentation of contacts the applicant made with hospitals in the service area in an effort to commit its physicians to assume Emergency Department coverage responsibilities.

-NA- The applicant does not propose to establish a new single specialty demonstration facility.

.2106 FACILITY

(a) An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital shall demonstrate that reporting and accounting mechanisms exist and can be used to confirm that the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.

-NA- NHHMC is an existing acute care hospital and does not propose to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital.

(b) An applicant proposing a licensed ambulatory surgical facility or a new hospital shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years of completion of the facility.

-NA- NHHMC is an existing acute care hospital and does not propose to establish a new licensed ambulatory surgical facility or a new hospital.

(c) All applicants shall document that the physical environment of the facility to be developed or expanded conforms to the requirements of federal, state, and local regulatory bodies.

-C- Exhibit 5 contains a letter from the Vice President of Design and Construction Services documenting that the physical environment of the facility will continue to conform to the requirements of federal, state and local regulatory bodies.

(d) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility or a new hospital shall provide a provide a floor plan of the proposed facility identifying the following areas:

- *(1) receiving/registering area;*
- *(2) waiting area;*
- *(3) pre-operative area;*
- *(4) operating room by type;*
- *(5) recovery area; and*

(6) observation area.

-NA- NHHMC is an existing acute care hospital and does not propose to establish a new licensed ambulatory surgical facility, a new campus of an existing facility or a new hospital.

(e) An applicant proposing to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility shall demonstrate the capability of the existing ambulatory surgical program to provide the following for each additional specialty area:

(1) physicians;
(2) ancillary services;
(3) support services;
(4) medical equipment;
(5) surgical equipment;
(6) receiving/registering area;
(7) clinical support areas;
(8) medical records;
(9) waiting area;
(10) pre-operative area;
(11) operating rooms by type;
(12) recovery area; and
(13) observation area.

-NA- The applicant proposes to relocate an existing OR from NHPMC to NHHMC.

SECTION .1200 – CRITERIA AND STANDARDS FOR INTENSIVE CARE SERVICES

10A NCAC 14C .1202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes new or expanded intensive care services shall use the Acute Care Facility/Medical Equipment application form.

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

(b) An applicant proposing new or expanded intensive care services shall submit the following information:

(1) the number of intensive care beds currently operated by the applicant and the number of intensive care beds to be operated following completion of the proposed project;

-C- The applicant provides the following information in a table on page 41 of the application.

Bed Category	Current and Proposed ICU Beds
Medical/Surgical ICU Beds	6
Proposed Medical/Surgical ICU Beds	2
# of Medical/Surgical Beds Upon Project Completion	**8**

(2) documentation of the applicant's experience in treating patients at the facility during the past twelve months, including:
(A) the number of inpatient days of care provided to intensive care patients;

-C- On page 41, the applicant documents that NHHMC provided 1,555 inpatient days of care to intensive care patients from July 2014 through June 2015. See Exhibit 3, Table 4 for additional information on inpatient ICU days of care at NHHMC.

(B) the number of patients initially treated at the facility and referred to other facilities for intensive care services; and

-C- On page 42, the applicant states that 68 patients were treated at NHHMC and then referred to another facility for intensive care services in the past 12 months.

(C) the number of patients initially treated at other facilities and referred to the applicant's facility for intensive care services.

-C- On page 42, the applicant states eight patients were treated at other facilities and transferred to NHHMC for intensive care services.

(3) the projected number of patients to be served and inpatient days of care to be provided by county of residence by specialized type of intensive care for each of the first twelve calendar quarters following completion of the proposed project, including all assumptions and methodologies;

-C- The applicant provides the projected number of discharges and days of care by county of patient origin for NHHMC on page 42, and in Exhibit 3, Table 6. The total number of discharges and days is illustrated in the table below. The applicant states that ICU inpatient days of care equate to 6.5% of projected overall medical/surgical inpatient days of care. The applicant based this projection on the historical data reflected in the 2012-2015 LRAs. Mecklenburg

and Iredell county residents make up 66.8% and 12.6%, respectively, of the projected ICU patient days of care, with lesser percentages of patients from Lincoln, Gaston, Cabarrus and all others, respectively representing, 8.6%, 5.0%, 1.6% and 5.3%.

	FY 20				FY 21				FY 22			
	1Q1	**1Q2**	**1Q3**	**1Q4**	**2Q1**	**2Q2**	**2Q3**	**2Q4**	**3Q1**	**3Q2**	**3Q3**	**3Q4**
# ICU Patients	161	162	162	162	170	170	170	170	178	178	178	178
ICU Patient Days	500	501	501	501	526	526	526	526	552	553	553	553

(4) data from actual referral sources or correspondence from the proposed referral sources documenting their intent to refer patients to the applicant's facility;

-C- Exhibit 6 contains letters of support from referring physicians and other medical professionals.

(5) documentation which demonstrates the applicant's capability to communicate effectively with emergency transportation agencies;

-C- See Exhibit 6 for a letter from the ICU Nurse Manager documenting NHHMC's ability to communicate effectively with emergency transportation agencies.

(6) documentation of written policies and procedures regarding the provision of care within the intensive care unit, which includes the following:

(A) the admission and discharge of patients;
(B) infection control;
(C) safety procedures; and
(D) scope of services.

-C- Exhibit 21 contains documentation of written policies and procedures regarding the provision of care within the ICU which include each of the areas set forth in subparagraphs (A) through (D) above.

(7) documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity, separate from the rest of the facility, with controlled access;

-C- Exhibit 6 contains a signed letter from Novant Health's Vice President of Design and Construction Services documenting that ICU services will be operated in an area that is organized as a physically and functionally distinct entity, separate from the rest of the facility, with controlled access.

(8) documentation to show that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;

-C- Exhibit 6 contains a letter from Novant Health's Vice President of Design and Construction Services documenting that the services will be offered in a physical environment that conforms to the requirements of federal, state and local regulatory bodies.

(9) a floor plan of the proposed area drawn to scale; and

-C- Exhibit 13 contains a floor plan.

(10) documentation of a means for observation by unit staff of all patients in the unit from at least one vantage point.

-C- Exhibit 6 contains a letter from Novant Health's Vice President of Design and Construction Services documenting direct visual observation by unit staff of all patients from at least one vantage point. Exhibit 13 contains a line drawing as further documentation.

10A NCAC 14C .1203 PERFORMANCE STANDARDS

(a) The applicant shall demonstrate that the proposed project is capable of meeting the following standards:

(1) the overall average annual occupancy rate of all intensive care beds in the facility, excluding neonatal and pediatric intensive care beds, over the 12 months immediately preceding the submittal of the proposal, shall have been at least 70 percent for facilities with 20 or more intensive care beds, 65 percent for facilities with 10-19 intensive care beds, and 60 percent for facilities with 1-9 intensive care beds; and

-C- On page 44, the applicant provides data showing NHHMC ICU beds, excluding neonatal ICU beds, operated at 71.0% occupancy for the 12 months immediately preceding this application. This exceeds the 60% average annual occupancy rate for facilities operating with 1-9 intensive care beds.

(2) the projected occupancy rate for all intensive care beds in the applicant's facility, exclusive of neonatal and pediatric intensive care beds, shall be at least 70 percent for facilities with 20 or more intensive care beds, 65 percent for facilities with 10-19 intensive care beds, and 60 percent for facilities with 1-9 intensive care beds, in the third operating year following the completion of the proposed project.

-C- On page 45, the applicant provides a table which illustrates that NHHMC projected ICU bed utilization (excluding neonatal ICU) is 75.7% occupancy in the third operating year following the completion of the proposed project.

(b) All assumptions and data supporting the methodology by which the occupancy rates are projected shall be provided.

-C- The applicant's assumptions and data supporting the methodology by which the ICU occupancy rates were determined are provided in Section III.1(b), pages 90-93, and Exhibit 3. The discussion regarding utilization in Criterion (3) is incorporated herein by reference.

10A NCAC 14C .1204 SUPPORT SERVICES

(a) An applicant proposing new or additional intensive care services shall document the extent to which the following items are available:

(1) twenty-four hour on-call laboratory services including microspecimen chemistry techniques and blood gas determinations;
(2) twenty-four hour on-call radiology services, including portable radiological equipment;
(3) twenty-four hour blood bank services;
(4) twenty-four hour on-call pharmacy services;
(5) twenty-four hour on-call coverage by respiratory therapy;
(6) oxygen and air and suction capability;
(7) electronic physiological monitoring capability;
(8) mechanical ventilatory assistance equipment including airways, manual breathing bag and ventilator/respirator;
(9) endotracheal intubation capability;
(10) cardiac pacemaker insertion capability;
(11) cardiac arrest management plan;
(12) patient weighing device for bed patients; and
(13) isolation capability.

-C- Exhibit 6 contains a letter from the Senior Director of Professional & Support Services, documenting the availability of the items listed in (1) through (13) above at NHHMC.

(b) If any item in Subparagraphs (a)(1) - (13) of this Rule will not be available, the applicant shall document the reason why the item is not needed for the provision of the proposed services.

-NA- In Exhibit 6, the applicant documents the availability of the items listed in (1) through (13) above at NHHMC.

10A NCAC 14C .1205 STAFFING AND STAFF TRAINING

The applicant shall demonstrate the ability to meet the following staffing requirements:

(1) nursing care shall be supervised by a qualified registered nurse with specialized training in the care of critically ill patients, cardiovascular monitoring, and life support;

-C- Exhibit 6 contains a letter from the ICU Nurse Manager documenting that nursing services in the ICU are and will continue to be supervised by a nurse with specialized training in the care of critically ill patients, cardiovascular monitoring, and life support. Exhibit 6 also contains a copy of the ICU Nurse Manager's resume.

(2) direction of the unit shall be provided by a physician with training, experience and expertise in critical care;

-C- Exhibit 6 contains a letter from Dr. Zachary J. Anderson, a board certified physician, who has and will continue to provide on-site direction for NHHMC's ICU.

(3) assurance from the medical staff that twenty-four hour medical and surgical on-call coverage is available; and

-C- Exhibit 6 contains a letter from the Assistant Chief of the Medical Staff documenting the availability of 24-hour medical and surgical coverage.

(4) inservice training or continuing education programs shall be provided for the intensive care staff.

-C- Exhibit 6 contains a letter from the ICU Nurse Manager, documenting that continuing education programs for intensive care staff will continue to be provided.

SECTION .1400 – CRITERIA AND STANDARDS FOR NEONATAL SERVICES

10A NCAC 14C .1402 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to develop a new Level I nursery or increase the number of Level II, III or IV neonatal beds shall use the Acute Care Facility/Medical Equipment application form.

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

(b) An applicant proposing to develop a new Level I nursery service or to increase the number of Level II, III or IV neonatal beds shall provide the following additional information:

(1) the current number of Level I nursery bassinets, Level II beds, Level III beds and Level IV beds operated by the applicant.

-C- On page 49, the applicant provides the current number of Level I and III beds operated by NHHMC, as follows:

NICU Beds	
Level I Beds	20
Level III Beds	2

The applicant states: *"NHHMC utilizes a rooming in concept for newborns and moms. There are 12 post-partum OB private rooms all of which included newborn bassinets."*

(2) the proposed number of Level I nursery bassinets, Level II beds, Level III beds and Level IV beds to be operated following completion of the proposed project.

-C- On page 49, the applicant provides the proposed number of Level I beds and Level III beds, as 20 and 4, respectively, following completion of the proposed project.

(3) (a) the number of obstetrical patients treated at the acute care facility.

-C- On page 50, the applicant states NHHMC treated 1,291 OB patients in Fiscal Year (FY) 2015.

(b) the number of neonatal patients treated in Level I nursery bassinets, Level II beds, Level III beds and Level IV beds, respectively.

-C- On page 50, the applicant provides the number of neonatal patients treated in Level I (newborns) and Level III beds during the past twelve months (FY2015), as 1,209 and 82, respectively.

(c) *the number of inpatient days at the facility provided to obstetrical patients.*

-C- On page 50, the applicant states that during the past twelve months (FY2015), 2,694 inpatient days were provided to obstetrical patients at NHHMC.

(d) the number of inpatient days provided in Level II beds, Level III beds and Level IV beds, respectively.

-C- On page 50, the applicant provides the number of inpatient days provided in Level I (newborn) and Level III beds during the past twelve months, 1,888 and 781, respectively.

(e) the number of high-risk obstetrical patients treated at the applicant's facility and the number of high-risk obstetrical patients referred from the applicant's facility to other facilities or programs.

-C- On page 50, the applicant states NHHMC treated 390 (30% of 1,300 = 390) high risk obstetrical patients in FY2015. Twelve were transferred to other facilities or programs.

(f) the number of neonatal patients referred to other facilities for services, identified by required level of neonatal service (i.e. Level II, Level III or Level IV).

-C- On page 50, the applicant states 14 neonatal patients requiring Level IV NICU care were referred to other facilities in FY2015.

(4) the projected number of neonatal patients to be served identified by Level I, Level II, Level III and Level IV neonatal services for each of the first three years of operation following the completion of the project, including the methodology and assumptions used for the projections.

-C- On page 50, the applicant provides the projected number of neonatal patients to be served during the first three years of operation for the proposed project, as illustrated in the table below.

	FY 20 PY 1	**FY 21 PY 2**	**FY 22 PY 3**
Level I Beds	1,279	1,295	1,312
Level III Beds	120	122	123

(5) the projected number of patient days of care to be provided in Level I bassinets, Level II beds, Level III beds, and Level IV beds, respectively, for each of the first three years of operation following completion of the project, including the methodology and assumptions used for the projections."

-C- On page 51, the applicant provides the projected number of patient days of care to be provided for Level I and III beds for each of the first three years of operation for the proposed project, as illustrated in the table below.

	FY 20 PY 1	**FY 21 PY 2**	**FY 22 PY 3**
Level I Beds	2,102	2,129	2,156
Level III Beds	1,146	1,161	1,175

The assumptions used for the projections are provided in Section III, pages 91-93 and Exhibit 3.

(6) if proposing to provide Level I or Level II neonatal services, in the facility for the first time documentation that at least 90 percent of the anticipated patient population is within 30 minutes driving time one-way from the facility

-NA- NHHMC is an existing hospital that currently provides Level I and Level III neonatal services. The proposed project involves no change to existing Level I services. The applicant proposes to add two neonatal beds to its Level III services.

(7) if proposing to provide new Level I or Level II neonatal services, in the facility for the first time documentation of a written plan to transport infants to Level III or Level IV neonatal services as the infant's care requires.

-NA- NHHMC currently provides Level I and III neonatal services. The applicant does not plan to add any additional Level I beds to its complement of services. The applicant proposes to add two neonatal beds to its Level III services.

(*8) evidence that the applicant shall have access to a transport service with at least the following components:*

- *(A) trained personnel;*
- *(B) transport incubator;*
- *(C) emergency resuscitation equipment;*
- *(D) oxygen supply, monitoring equipment and the means of administration;*
- *(E) portable cardiac and temperature monitors; and*
- *(F) a mechanical ventilator."*

-C- Exhibit 7 contains a letter from the Nurse Manager of Women's Services documenting the availability of the items listed in (A) through (F) above at NHHMC.

(9) documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity with controlled access.

-C- See Exhibit 7 for documentation from the Vice President of Design and Construction stating that the proposed service will be operated in an area organized as a physically and functionally distinct entity with controlled access.

(10) documentation to show that the new or additional Level I, Level II, Level III or Level IV neonatal services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies.

-C- Exhibit 7 contains a letter from the Vice President of Design and Construction documenting that the Level III services will be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies.

(11) a detailed floor plan of the proposed area drawn to scale.

-C- See Exhibit 13 for a detailed floor plan.

(12) documentation of direct or indirect visual observation by unit staff of all patients from one or more vantage points.

-C- Exhibit 7 contains a letter from the Vice President of Design and Construction documenting that the Level III services will have direct visual observation by unit staff of all patients from one or more vantage points.

(*13) documentation that the floor space allocated to each bed and bassinet shall accommodate equipment and personnel to meet anticipated contingencies.*

-C- See Exhibit 7 for documentation from the Vice President of Design and Construction stating that the proposed floor plan allocates the space needed to accommodate equipment and personnel to meet anticipated contingencies. Also see Exhibit 13 for a copy of the floor plan.

(c) *If proposing to provide new Level III or Level IV neonatal services in the facility for the first time the applicant shall also provide the following information:*

(1) documentation that at least 90 percent of the anticipated patient population is within 90 minutes driving time one-way from the facility, with the exception that there shall be a variance from the 90 percent standard for facilities which demonstrate that they provide very specialized levels of neonatal care to a large and geographically diverse population, or facilities which demonstrate the availability of air ambulance services for neonatal patients;

(2) evidence that existing and approved neonatal services in the applicant's defined neonatal service area are unable to accommodate the applicant's projected need for additional Level III and Level IV services;

(3) an analysis of the proposal's impact on existing Level III and Level IV neonatal services which currently serve patients from the applicant's primary service area;

(4) the availability of high risk OB services at the site of the applicant's planned neonatal service;

(5) copies of written policies which provide for parental participation in the care of their infant, as the infant's condition permits, in order to facilitate family adjustment and continuity of care following discharge; and

(6) copies of written policies and procedures regarding the scope and provision of care within the neonatal service, including but not limited to the following:

(A) the admission and discharge of patients;

(B) infection control;

(C) pertinent safety practices;

(D) the triaging of patients requiring consultations, including the transfer of patients to another facility; and

(E) the protocols for obtaining emergency physician care for a sick infant.

-NA- NHHMC currently provides Level III neonatal services.

10A NCAC 14C .1403 PERFORMANCE STANDARDS

(a) *An applicant shall demonstrate that the proposed project is capable of meeting the following standards:*

(1) if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II, Level III and Level IV beds), the overall average annual occupancy of the total combined number of all existing Level II, Level III and Level IV beds in the facility is at least 75 percent, over the 12 months immediately preceding the submittal of the proposal.

-C- On page 53, the applicant provides the overall average daily occupancy for NHHMC's existing Level III beds for the 12 months (FY2015) immediately preceding the submittal of the proposal, as illustrated in the table below.

FY 2015	
Level III – NICU Patient Days	781
Average Daily Census (ADC)	2.14
Bed Capacity	2
Utilization	106.9%

See Exhibit 3, Table 20 for additional information. The discussion regarding utilization of NHHMC's neonatal beds in Criterion (3) is incorporated herein by reference.

(2) if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II, Level III and Level IV beds), the projected overall average annual occupancy of the total combined number of all Level II, Level III and Level IV beds proposed to be operated during the third year of operation of the proposed project shall be at least 75 percent.

-C- On page 54, the applicant projects the overall average annual occupancy for NHHMC's Level III beds during the first three project years, as illustrated in the table below.

	PY 1 FY 20	**PY 2 FY 21**	**PY 3 FY 22**
Level III	1,146	1,161	1,175
ADC	3.14	3.18	3.22
Proposed Bed Capacity	4	4	4
Utilization	78.5%	79.5%	80.5%

The applicant projects that its overall average annual occupancy will be 80.5% for Level III beds during the third year of operation which exceeds the 75% required by this rule. The discussion regarding utilization of NHHMC's neonatal beds in Criterion (3) is incorporated herein by reference.

(3) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this rule.

-C- The applicant's assumptions and methodology are provided in Section II, pages 54-55 and Section III, pages 91-93.

(b) *If an applicant proposes to develop a new Level III or Level IV service, the applicant shall document that an unmet need exists in the applicant's*

defined neonatal service area, unless the States Medical Facilities Plan includes a need determination for neonatal beds in the service area. The need for Level III and Level IV beds shall be computed for the applicant's neonatal service area by:

(1) identifying the annual number of live births occurring at all hospitals within the proposed neonatal service area, using the latest available data compiled by the States Center for Health Statistics;

(2) identifying the low birth weight rate (percent of live births below 2,500 grams) for the births identified in (1) of this Paragraph, using the latest available data compiled by the States Center for Health Statistics;

(3) dividing the low birth weight rate identified in (2) of this Paragraph by .08 and subsequently multiplying the resulting quotient by four; and

(4) determining the need for Level III and Level IV beds in the proposed neonatal service area as the product of:

(A) the product derived in (3) of this Paragraph, and

(B) the quotient resulting from the division of the number of live births in the initial year of the determination identified in (1) of this Paragraph by the number 1000.

-NA- NHHMC does not propose to develop new Level III neonatal services.

10A NCAC 14C .1404 SUPPORT SERVICES

An applicant proposing to provide new Level I, Level II, Level III or Level IV services shall document that the following items shall be available, unless an item shall not be available, then documentation shall be provided obviating the need for that item:

(1) competence to manage uncomplicated labor and delivery of normal term newborn;

(2) capability for continuous fetal monitoring;

(3) a continuing education program on resuscitation to enhance competence among all delivery room personnel in the immediate evaluation and resuscitation of the newborn and of the mother;

(4) obstetric services;

(5) anesthesia services;

(6) capability of cesarean section within 30 minutes at any hour of the day; and

(7) twenty-four hour on-call blood bank, radiology, and clinical laboratory services.

(b) An applicant proposing to provide new Level III Level IV services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:

(1) competence to manage labor and delivery of premature newborns and newborns with complications;
(2) twenty-four hour availability of microchemistry hematology and blood gases;
(3) twenty-four hour coverage by respiratory therapy;
(4) twenty-four hour radiology coverage with portable radiographic capability;
(5) oxygen and air and suction capability;
(6) electronic cardiovascular and respiration monitoring capability;
(7) vital sign monitoring equipment which has an alarm system that is operative at all times;
(8) capabilities for endotracheal intubation and mechanical ventilatory assistance;
(9) cardio-respiratory arrest management plan;
(10) isolation capabilities;
(11) social services staff;
(12) occupational or physical therapies with neonatal expertise; and
(13) a registered dietician or nutritionist with training to meet the special needs of neonates.

(c) An applicant proposing to provide new Level IV services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:

(1) pediatric surgery services;
(2) ophthalmology services;
(3) pediatric neurology services;
(4) pediatric cardiology services;
(5) on-site laboratory facilities;
(6) computed tomography and pediatric cardiac catheterization services;
(7) emergency diagnostic studies available 24 hours per day;
(8) designated social services staff; and
(9) serve as a resource center for the statewide perinatal network.

-NA- NHHMC does not propose to develop new Level I-IV neonatal services.

10A NCAC 14C .1405 STAFFING AND STAFF TRAINING

An applicant shall demonstrate that the following staffing requirements for hospital care of newborn infants shall be met:

(1) If proposing to provide new Level I or II services the applicant shall provide documentation to demonstrate that:

(a) the nursing care shall be supervised by a registered nurse in charge of perinatal facilities;

(b) a physician is designated to be responsible for neonatal care; and

(c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.

(2) If proposing to provide new Level III services the applicant shall provide documentation to demonstrate that:

(a) the nursing care shall be supervised by a registered nurse;

(b) the service shall be staffed by a pediatrician certified by the American Board of Pediatrics; and

(c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.

(3) If proposing to provide new Level IV services the applicant shall provide documentation to demonstrate that:

(a) the nursing care shall be supervised by a registered nurse with educational preparation and advanced skills for maternal-fetal and neonatal services;

(b) the service shall be staffed by a full-time board certified pediatrician with certification in neonatal medicine; and

(c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.

-NA- NHHMC does not propose to develop new Level I-IV neonatal services.

(4) All applicants shall submit documentation which demonstrates the availability of appropriate in-service training or continuing education programs for neonatal staff.

-C- Exhibit 7 contains a letter from the Neonatal ICU RN documenting the availability of appropriate in-service training or continuing education programs for all neonatal staff.

(5) All applicants shall submit documentation which demonstrates the proficiency and ability of the nursing staff in teaching parents how to care for neonatal patients following discharge to home.

-C- Exhibit 7 contains documentation that demonstrates the proficiency and ability of the nursing staff in teaching parents how to care for neonatal patients following discharge to home.

(6) All applicants shall submit documentation to show that the proposed neonatal services will be provided in conformance with the requirements of federal, states and local regulatory bodies.

-C- Exhibit 7 contains documentation that demonstrates service will be provided in conformance with the requirements of federal, state and local regulatory bodies.