

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 21, 2012

PROJECT ANALYST: Jane Rhoe-Jones
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: G-8831-12 / Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center / Add one fixed C-Arm angiography system to an existing operating room to develop a hybrid operating room/ Forsyth County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center (FMC), proposes to acquire one vascular interventional radiology unit (angiography equipment) to create a hybrid operating room (OR) in existing OR space located at 3333 Silas Creek Parkway, Winston Salem, North Carolina. The applicant does not purpose to increase the number of licensed beds in any category, add services, or acquire equipment for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP). However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 40 of the 2012 SMFP, is applicable to the review of this proposal. Policy GEN-4 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."

In Section III.2, page 56, the applicant addresses Policy GEN-4 and the hospital's plan for energy efficiency and water conservation. The applicant states:

"FMC proposes to improve the efficient use of energy resources throughout its campus by creating, implementing, and following an effective Sustainable Energy Management Plan ("SEMP"). ... This SEMP covers all services offered at FMC, including the proposed hybrid operating room.

The objective of FMC SEMP is to promote good stewardship of our environment, community resources, and maintain an effective energy management program to reduce operating costs and enable us to provide compassionate service to a greater number of persons throughout the community.

...

Taking a Strategic Approach consists of actively managing energy costs by continuously for opportunities to reduce consumption by more efficiently utilizing our energy resources.

...

If FMC is awarded a Certificate of Need for an acquisition of one new ... multi-axis Angiography System to place in existing FMC Hospital Operating Room (OR # 17) as proposed in this CON Application, then FMC will comply with SMFP Policy GEN-4 requirement to submit a Plan for Energy Efficiency and Water Conservation to the DHHS Construction Section, which [sic] Plan will be consistent with FMC's representations made pursuant to Paragraph 1 of SMFP Policy GEN-4."

In addition, the applicant includes a copy of its “Sustainable Energy Management Plan” in Exhibit 13. The applicant adequately demonstrates that the proposal includes a plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, Forsyth Medical Center, whose parent company is Novant Health, Inc., currently has 35 operating rooms, including three dedicated inpatient, two dedicated C-Section, eight dedicated ambulatory surgery and 22 shared operating rooms; as well as six endoscopy rooms. In this application, the applicant proposes to renovate 1246 square feet in OR # 17 and to acquire and install a specialized angiography system to create a hybrid OR.

In Section II.1(a), page 14, the applicant states:

“Forsyth Medical Center in Winston-Salem proposes to create a Hybrid Operating Room (OR) by acquiring a specialized fixed C-arm angiography system to be installed in an existing general use, licensed operating room (OR # 17). The proposed project does not create in [sic] any addition to FMC’s inventory of licensed operating rooms and does not create any “new institutional health service,” as that term is defined in the CON law.”

Services Proposed - Hybrid Operating Room

In Section II.1(a), page 14, the applicant states:

“A Hybrid OR is a room where providers are able to perform open surgical procedures, as well as image-guided vascular and cardiac procedures. The proposed angiography imaging system permits FMC to meaningfully advance its provision of modern surgical services and support the evolution of clinical care at FMC. At present, vascular and cardiac conditions requiring interventions are treated with either open surgery in an OR and/or a minimally invasive approach in an OR, cath lab, or angiography suite. Endovascular procedures are essential for patients who are not able to tolerate full-scale surgery. Just as important is the capacity to perform these types of procedures in a clinical setting that offers the ability to transition to an open or minimally invasive surgical procedure, if circumstances require it. For example, some FMC patients may start out in the angiography or cardiac catheterization suite prior and must be transferred to an OR for a more, complex invasive procedure. FMC is a proponent of the

approach that the best care is to provide a fully equipped and staffed venue where these methods are combined.”

In Section II, page 15, the applicant states:

“At the most basic level, a Hybrid OR is a sterile setting with a fixed angiography system. The Hybrid OR must be renovated to include lead-lined walls, an externally housed scrub sink, an adjacent control room, adequate air-exchange rate, access to sterile processing, and sufficient supply and equipment storage

The FMC hybrid OR will combine a fixed c-arm with appropriate surgical lighting and specialty surgical table, low level interventional lighting, equipment booms for endovascular equipment, ceiling mounted flat panel monitors, anesthesia equipment, perfusion console, designated sterile field and other components included in standard OR suites.”

Angiography Equipment

In Section II, page 14, the applicant states:

“The proposed multi-access angiography imaging system is a sophisticated c-arm system that is primarily used for fluoroscopic imaging, or angiography of blood vessels. The c-arm produces real-time images that are projected on to a TV screen monitor in the OR. The surgeon or interventionalist uses these imaging [sic] as guidance [sic] surgical or interventional procedures. Access to accurate visualization of the patient’s vascular structures in real-time during the course of a procedure is an invaluable tool for the provider in maximizing the safety and effectiveness of an advanced, delicate, and time-sensitive procedure and in achieving the best patient outcome, especially for complex and fragile cardiac and vascular patients, who are not candidates for open procedures.

... a high resolution c-arm angiography system, ... provides vastly superior imaging capabilities compared to a mobile c-arm or even c-arms used for other non-vascular surgical procedures. The robotic arm on FMC’s proposed angiography system includes a high-powered x-ray unit that is specifically designed to fully rotate around the patient, to deliver detailed cross-sectional and three-dimensional images in a few seconds. This system provides surgeons and Interventionalists with the best possible imaging experience when performing intricate procedures.”

In Section VIII.2.(a), page 105, the applicant proposes to acquire the following equipment to develop the proposed hybrid OR.

- Angiography Unit
- Surgical Display Monitor
- Shielding
- Surgical Lights/LED
- Carts and Shelves

- Desktop Computer
- 10 Protective Aprons

Population to be Served

In Section III.5(a), page 60, the applicant states:

“FMC determined the geographic boundaries of the service area based on internal data for patients whose surgical cases include ICD-9 procedure codes eligible for the hybrid OR and FMC’s patient origin.”

The following table illustrates historical and projected patient origin for patients with hybrid OR appropriate procedures at FMC, as reported by the applicant in Section III.4(b), page 60, and Section III.5(c), page 61.

Forsyth Medical Center Historical and Projected Patient Origin		
County	Historical Percent of Total	Projected Percent of Total
Forsyth	47.2%	47.2%
Davidson	9.3%	9.3%
Surry	9.0%	9.0%
Stokes	7.5%	7.5%
Yadkin	6.0%	6.0%
Davie	5.4%	5.4%
Wilkes	3.4%	3.4%
Rowan	.3%	.3%
Western Guilford County Zip Codes		
27235	.2%	.2%
27265	.3%	.3%
27310	.2%	.2%
All Other	11.1%	11.1%
Totals	100%	100%

The applicant adequately identifies the population it proposes to serve.

Need for the Proposed Project

In Section III.1(a), beginning on page 33, the applicant states:

“...The need for the proposed hybrid operating room equipped with a ... Angiography System is substantiated by the following factors:

- Forsyth Cardiac and Vascular Center at Forsyth Medical Center
- Trends in Surgical Approaches for Complex Procedures
- Invention and Innovation ...
- Transcatheter Aortic Valve Implant (TAVI) ...
- Minimally Invasive Spine Surgery using the Siemens Artis Zeego
- Population Growth in Forsyth and Surrounding Counties – Particularly Among Older Residents”

Forsyth Cardiac and Vascular Center at Forsyth Medical Center

The Forsyth Cardiac and Vascular Center at Forsyth Medical Center is now affiliated with the Cleveland Clinic. This affiliation affords FMC’s patients access to cardiovascular prevention programs and treatment options available at the Cleveland Clinic.

The first table below depicts the diagnostic and therapeutic cardiac catheterizations as reported by the applicant in the two most recent hospital license renewal applications. The second table depicts the open heart surgery procedures: heart-lung bypass and without heart-lung bypass, as reported by the applicant. The applicant performs the cardiac catheterizations using eight units of fixed equipment; the electrophysiology procedures using two units of fixed equipment and open heart surgery procedures with three heart-lung bypass machines.

Forsyth Memorial Hospital Cardiac Catheterization and Electrophysiology Procedures			
Cardiac Cath	Diagnostic	Interventional	Electrophysiology
FFY 2011	2,541	1,463	1,043
FFY 2012	2,315	1,277	1,035
Total	4,856	2,740	2,078

Source: 2011 and 2012 Renewal Application for Hospital: Forsyth Memorial Hospital

Forsyth Memorial Hospital Open Heart Surgery Procedures			
Open Heart	Heart Lung Bypass	No Heart Lung Bypass	Total
FFY 2011	611	19	630
FFY 2012	568	8	576
Total	1,179	27	1,206

Source: 2011 and 2012 Renewal Application for Hospital: Forsyth Memorial Hospital

The data in the above two tables indicate that FMC had slight decreases in both the number of cardiac catheterization and open heart surgery procedures during the last two Federal Fiscal years of reporting. The decreases are not of a significant nature to negatively impact the applicant’s stated need for the hybrid OR.

Trends in Surgical Approaches for Complex Procedures

The applicant states:

“Physicians and surgeons are faced with a number of challenges in the current medical environment. Those challenges include significant changes in the demographics of the patients treated, rapid advances in technology, increased costs to provide these services, and the need for a working environment that can allow for the adaptation of the process.

Increasingly, clinicians require more versatile environments that can enable them to carry out complex minimally invasive procedures with the flexibility to perform both open and sophisticated minimally invasive surgical procedures in the same room. Hospitals today need to reconfigure their operating rooms so they can adapt easily to different surgical procedures and accommodate current and future surgical technologies as needed.

Hybrid operating rooms provide versatile solutions that save hospitals critical time and add flexibility to perform open and minimally invasive cardiovascular, thoracic, and vascular procedures in the same room. An advanced hybrid room is the perfect place to perform complex procedures, within a well planned and equipped hybrid surgical suite which delivers the necessary diagnostic and advanced surgical equipment at the fingertips of the clinicians, based upon high risk patient presentations and diagnosis.

... Developed for patients with cardiovascular and vascular conditions, the FMC hybrid OR will result in:

- *More minimally invasive procedures*
- *Fewer surgical complications*
- *Shorter hospital stays*
- *Faster recovery time*
- *Improved patient outcomes*
- *Treatment for patients who otherwise would not have an option”*

Invention and Innovation

The applicant describes the strides made in cardiac surgery and sums the progress up as follows:

<i>“1940s</i>	<i>Palliative Congenital Heart Surgery</i>
<i>1950s</i>	<i>Open Congenital Heart Surgery</i>
<i>1960s</i>	<i>Valve Surgery</i>
<i>1970s</i>	<i>Coronary Artery Surgery</i>
<i>1980s</i>	<i>Cardiac Transplantation</i>
	<i>Mechanical Circulatory Assistance</i>
	<i>Cardiac Arrhythmia Surgery</i>

1990s *All of the above using Minimally Invasive Techniques”*

The applicant states:

“It is too early to know how the first decade of the 21st century will be characterized. Certain principles regarding the development and adoption of new operative techniques and procedures made during the first 50 years of cardiac surgery are likely to remain unchanged.

...

The potential decrease in thoracic aortic surgery, however, maybe offset by the aging of the population, especially as ‘baby boomers’ are entering their 60’s. The percentage of the population over the age of 654 years was 4.1% in 1900 and 12.6% in 2000 and is projected to be 20% by 2030 (Gavrilov LA & Heuveline P). ... In 2011 the baby boomer generation will be entering the Medicare years. That impact will be felt by a 50% increase in Medicare eligible individuals in the United States (13 million persons). ... Cardiothoracic surgery deals with a disproportionate number of Medicare-aged patients who have cardiothoracic disease. These numbers will translate into greater absolute numbers of patient with thoracic aortic disease in the future; the net effect on surgical volume of the competing factors of population aging and non-surgical innovation remains to be seen. The potential for innovation in the other areas of cardiac surgery varies with the specific field but overall provides fertile ground for surgeons who are inclined to accept the challenge.”

Transcatheter Aortic Valve Implant (TAVI)

The applicant states:

“Degenerative aortic stenosis is the most frequent acquired heart valve disease, with a prevalence of 4.6% aged 75 years or more (Aronow WS & Kronzon I.). It is caused by thickening, fusion and sometimes calcification of the valve leaflets (news.yahoo.com). It affects both men and woman [sic] equally. ...

Unfortunately aortic stenosis cannot be treated with medicines, and in the majority of cases it is better to relieve the narrowing of the valve. Traditionally this has been exclusively through open heart surgery to remove the narrowed valve and replace it with a new man-made valve. Although open surgical aortic valve replacement has been the gold standard treatment for severe aortic stenosis, many patients do not have this option due to severe co-morbidities. About one third of patients are considered inoperable due to unacceptable surgical risk (Id). Under medical treatment alone these patients have a very poor prognosis with a mortality rate of 50% at 2 years (Salinas P, Moreno R & Lopez-Sendon JL).

...

The main advantage of TAVI is that it avoids the need for open heart surgery ... TAVI cannot be performed without the technology available in a hybrid operating room.”

Population Growth in Forsyth and Surrounding Counties – Particularly Among Older Residents

Beginning at page 42, the applicant describes the expected steady growth in service area population for ages 55+ and 65+ during the years 2015-2017.

Forsyth Medical Center Projected Population 65+ 2012-2017			
	2012	2017	CAGR 2012-2017
Forsyth County	48,993	57,325	3.2%
Service Area	160,289	187,789	-
Total	209,282	245,114	3.2%
North Carolina	1,356,133	1,634,142	3.8%
Forsyth Medical Center Projected Population 55+ 2012-2017			
	2012	2017	CAGR 2012-2017
Forsyth County	92,915	105,825	2.6%
Service Area	298,393	339,540	-
Total	391,308	445,365	2.6%
North Carolina	2,565,369	2,974,967	3.0%

The table indicates that the CAGR for the Forsyth County 65+ population is 3.2% and for the 55+ population is 2.6% and both mirror the national growth patterns. The applicant asserts that 65+ and 55+ age groups represent 47.7% and 73.1% of the surgical case volumes at FMC; and will continue to represent large percentages of the eligible hybrid OR surgery patients.

In Exhibit 2, page 152, the applicant provides the following data showing the three year growth in cases that would be appropriate for the proposed hybrid OR.

Forsyth Medical Center Historical Utilization Cardiac and Vascular Cases					
	2009	2010	2011	2012 (YTD)	CAGR 2009-2011
Cardiac & Vascular Cases Appropriate for Hybrid OR	1378	1667	1577	232	1.8%

The above table shows the historical three year trend for appropriate procedures (based on ICD-9 Procedure Codes) show a decrease in case volume from 2010 to 2011, but an overall 1.8% CAGR for the three years.

Projected Utilization

In Section IV.1(c), page 64, the applicant provides historical surgical cases appropriate for the hybrid OR and projected utilization as illustrated below in the table:

Forsyth Medical Center Historical Volume Surgical Case Appropriate for Hybrid OR and Total Projected Utilization of Hybrid OR January 1, 2010 – September 30, 2016							
	2010	2011	2012	2013	2014	2015	2016
Total Eligible Cases	1,577	1,605	1,633	1,662	1,692	1,722	1,577
					PY 1 10/13- 9/14	PY 2 10/14- 9/15	PY 3 10/15- 9/16
Total Projected Cases in Hybrid OR					841	857	872

The applicant's assumptions and methodology used to project utilization are provided in Section III.1(b), beginning on page 44. The methodology is summarized as follows:

$$(CY\ 2011\ FMC\ ICD-9\ Procedures\ Appropriate\ for\ Hybrid\ Equipment\ \times\ Historical\ CAGR) + Estimated\ New\ Procedures = Future\ Hybrid\ OR\ Utilization$$

The following table reflects the need for the hybrid OR at FMC based upon this methodology.

Forsyth Medical Center Projected Hybrid OR Cases						
Calendar Year	2011	2012	2013	2014	2015	2016
Total Eligible Cases	1,577	1,605	1,633	1,662	1,692	1,722
Historical Procedure CAGR	1.8%	1.8%	1.8%	1.8%	1.8%	1.8%
Converted to Project Years				PY 1 FY 2014	PY 2 FY 2015	PY 2 FY 2014
Eligible Cases Converted to Project Years				1,655	1,684	1,714
Percent of Eligible Cases to be Performed in Hybrid OR				50%	50%	50%
Hybrid OR Cases (existing volume shift)				828	842	857
TAVI Cases (new cases)				13	15	15
Total Projected Cases				841	857	872

As shown in the above table, FMC projects that in Project Year 3, there will be 872 cases performed in the hybrid OR.

The applicant provides detailed methodology and assumptions (Steps 1 through 7) for the projections in the previous table, beginning on page 45 of the application. Below are excerpts.

“Step 1: Identify Potential ICD-9 Procedure Codes Appropriate for the Hybrid OR

Representatives of the Forsyth Cardiac and Vascular Center clinical operations team identified patients whose surgical cases would be performed appropriately in the hybrid OR by ICD-9 procedure code.

Step 2: Determine the Volume on which to Base Projections

FMC reviewed historical internal data for the last four calendar years to determine its experience performing the ICD-9 procedure codes identified as eligible for the hybrid OR. The surgical case volume in the following table includes patients of all ages at FMC.

Forsyth Medical Center Surgical Volume for ICD-9 Procedure Codes Eligible for Hybrid OR January 2, 2008 – December 31, 2011					
ICD-9 Procedure Code	ICD-9 Procedure Description	2008	2009	2010	2011
35.12	Opn mitral valvuloplast	34	30	31	30
35.14	Opn tricus valvuloplast	9	6	13	4
35.22	Opn/oth rep aortic valve	56	58	48	61
36.14	Aortcor bypass-4+ cor ar	81	38	62	47
36.15	1 in mam-cor art bypass	471	421	423	403
37.75	Revision of lead	18	25	13	16
38.18	Lower limb endarterect	37	31	49	34
38.7	Interruption vena cava	131	150	162	137
39.49	Vasc proc revision NEC	145	105	119	99
39.71	Endo imp oth grf abd ao	45	44	41	43
39.73	Endo imp grft thor aorta	2	6	5	3
39.79	Oth endo proc oth vessel	81	84	73	72
86.07	Insert vasc access dev	386	380	628	628
Total Cases		1,496	1,378	1,677	1,577

Source: Exhibit 2, Table 1

As shown in the previous table, FMC’s surgical volume for the identified ICD-9 procedure codes has fluctuated over the last four calendar years, but overall has increased.

Step 3: Determine the Growth Rate for Projecting Future Volume

FMC reviewed its surgical volume in the ICD-9 procedure codes eligible for the hybrid OR and population growth rates to determine the most reasonable growth rate on which to project future volume.

A. Growth of Surgical Case Volume for ICD-9 Procedure Codes Eligible for

Hybrid OR

The following table shows historical growth of surgical case volume for the ICD-9 procedure codes eligible for the hybrid OR for patients of all ages, patients 65+, and patients 55+, respectively, during the last four calendar years.

Forsyth Medical Center Surgical Case Volume ICD-9 Procedure Codes Eligible for Hybrid OR January, 2008 – December 31, 2011					
Calendar Years	2008	2009	2010	2011	CAGR 2008-2011
<i>All ages</i>	1,496	1,378	1,667	1,577	1.8%
<i>65+</i>	678	746	828	753	3.6%
<i>55+</i>	1,008	1,106	1,228	1,152	4.6%

Source: Exhibit 2, Tables 1, 2, 3

...

FMC expects that patients in age groups 55+ and 65+, respectively, will have a higher volume of procedures eligible for the hybrid OR because those age groups are more likely to be diagnosed with a medical condition for which surgery in one or more [sic] the ICD-9 procedure codes is necessary. However, the future volume for the proposed FMC Hybrid OR was projected using the more conservative overall CAGR of 1.8%

B. Projected Growth Rates for Vascular and Cardiothoracic Surgery from Advisory Board Company Market Estimator Tools 2012-2020.

The Advisory Board Company is a global research, consulting, and technology firm

The Advisory Board Company Market Estimator Tools Projected Growth Rates for Vascular & Cardiothoracic Surgery 2012-2020		
Surgery Service	Projected Growth 2010-2015	Projected Growth 2010-2015
<i>Inpatient Cardiac (Open Heart)</i>	0%	2%
<i>Inpatient Vascular</i>	5%	11%
<i>Inpatient Thoracic</i>	12%	25%
<i>Outpatient Vascular</i>	17%	42%
<i>Outpatient Thoracic</i>	24%	59%

Source: CON Project I.D. # G-8700-11 Moses Cone Hybrid OR CON

C. Weighted Growth of Defined Service Area Population

FMC reviewed patient origin and projected population growth in its service area. Due to the large number of counties in that service area, FMC calculated a weighted population growth rate based upon each county's population growth rate and FMC's patient origin percentage from the county, as shown in the following table.

Forsyth Medical Center Hybrid OR Service Area Weighted Projected Population Growth Rate 2012-2017	
Population	Weighted Projected Population Growth Rate
All Ages	1.1%
Ages 55+	2.7%
Ages 65+	3.3%

Source: Exhibit 2, Tables 8, 9, 10

... Weighted projected population for age cohorts 65+ (3.3%) and 55+ (2.7%), respectively, as shown in the previous table, reflect the significant growth of the primary population which will be served by the proposed equipment in the hybrid OR.

D. Growth Rate Used in Projections

... FMC determined that using the 2008-2011 CAGR of 1.8% for ICD-9 procedure codes case volume for patients of all ages is the most reasonable growth rate to use for projections because it is:

- ...
- Less than all of the above, any of which would be appropriate to project future utilization for the proposed new angiography equipment for the FMC Hybrid OR

Step 4: Project Surgical Volume Appropriate for Hybrid OR

FMC multiplied the CY 2011 ICD-9 procedure code case volume (Step 2) by an annual growth rate of 1.8% (Step 3) through CY 2016 to project surgical volume eligible for the hybrid OR as shown in the following table.

Forsyth Medical Center Projected Surgical Volume Eligible for Hybrid OR January 1, 2011 – December 30, 2016						
Calendar Year	2011 Actual	2012	2013	2014	2015	2016
Total Cases Eligible for Hybrid OR	1,577	1,605	1,633	1,662	1,692	1,722
2008-2011 ICD-9 Procedure Codes Case Volume CAGR	1.8%	1.8%	1.8%	1.8%	1.8%	1.8%

Source: Exhibit 2, Table 11

FMC expects that the equipment will be installed and the hybrid OR will open on October 1, 2013.

Step 5: Determine Percentage of Cases Appropriate to be Performed in the Hybrid OR

It is important to note that the hybrid OR will not have capacity to perform 100% of eligible surgical cases. Due to capacity constraints, FMC reasonably believes that only 50% of appropriate surgical cases will be performed in the hybrid OR. Cases selected for the hybrid OR will be complex, will involve high risk patients,

Forsyth Medical Center Projected Utilization of Hybrid OR October 1, 2013 – September 30, 2016			
	PY 1 10/13- 9/14	PY 2 10/14- 9/15	PY 3 10/15- 9/16
<i>Cases Eligible for Hybrid OR</i>	1,203	1,209	1,213
<i>Percent of Eligible Cases to be Performed in Hybrid OR</i>	50%	50%	50%
<i>Hybrid OR Cases</i>	828	842	857

Source: Exhibit 2, Table 11

The previous table shows the number of projected surgical cases to be performed in the hybrid OR in each of the first three Project Years.

Step 6: Determine Number of Transcatheter Aortic Valve Implant/TAVI Cases in the Hybrid OR

... there is a 1:4 ratio of TAVI to open valve replacement cases.

... The following table shows estimated TAVI cases based pm FMC physician analysis of current patient population who would be eligible for a TAVI based on TAVI criteria.

Forsyth Medical Center Estimated TAVI Cases October 1, 2013 – September 30, 2016			
	PY 1 10/13-9/14	PY 1 10/14-9/15	PY 3 10/15-9/16
<i>TAVI Cases per Vendor 1:4 Ratio</i>	24	24	24
<i>TAVI Cases per FMC MD Estimates</i>	13	6	6
<i>Avg. TAVI Cases per Vendor 1:4 Ratio & FMC MD Estimates</i>	13	15	15

Source: Exhibit 2, Table 12

Step 7: Determine Total Projected Surgical Volume in Hybrid OR

Based upon discussion with the Forsyth Cardiac and Vascular Center clinical operations team, the capacity of the hybrid OR will be 2,500 cases per year. That capacity is based upon the type of surgical procedures to be performed during the scheduled hours of operation, which are M-F, 7 am to 5 pm (50 hours/week), 52 weeks per year. Cases are estimated to last three hours.

Forsyth Medical Center Projected Utilization of Hybrid OR October 1, 2013 – September 30, 2016			
	PY 1 10/13-9/14	PY 2 10/14-9/15	PY 3 10/15-9/16
<i>Hybrid OR Cases (existing volume shift)</i>	828	842	857
<i>TAVI Cases</i>	13	15	15
<i>Total Projected Cases</i>	841	857	872
<i>Weighted Cases using Average Case Time = 3 Hrs</i>	2,522	2,572	2,617
<i>Hybrid OR needed at 2,500 Hours/Year</i>	1.01	1.03	1.05

Source: Exhibit 2, Table 11

The projected annual case volume shown in the previous table is sufficient to support development of one hybrid OR at FMC.”

The applicant adequately demonstrates the need to develop a hybrid OR. According to the applicant in Section III, page 37, *“The cutting-edge hybrid OR allows surgeons to address patient needs quickly, eliminating the hassle of scheduling additional surgical procedures. The ability to handle and minimize high-risk situations with the most efficient treatments available to save lives is optimized in the hybrid OR setting. The hybrid OR design chosen by FMC will deliver optimal efficiency and clinical flexibility. A versatile design provides the use of advanced surgical equipment and diagnostic tools capable of transforming existing OR #17 from open to complex minimally invasive surgical procedures within the same room.*

Furthermore, the applicant adequately demonstrates the need for the proposal for all of the following reasons:

- 1) Projected utilization based on a seven-step methodology initially based on the hospital’s historical experience performing 13 vascular procedures over a four year period. The cases were projected based on a reasonable percentage of future growth and adjusted for appropriateness of treatment in a hybrid OR.
- 2) The applicant does not propose to increase the number of ORs as part of this project;
- 3) The hybrid OR will allow the team of anesthesiologists and surgeons to transition seamlessly from invasive to open surgical procedures (when necessary, thereby minimizing the risk to patients and the overall time in the hospital); and

- 4) Use of the advanced hybrid therapies within the hybrid OR will enable FMC's clinicians to apply their talents and expertise using the hybrid OR tools to provide the safest, most effective, and least invasive care.

In summary, the applicant adequately identifies the population to be served and demonstrates the need the population has for each component of the project. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

C

In Section III.3, pages 58-59, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo and not developing its first hybrid OR. Continuing the status quo was not acceptable because of concerns about quality, patient safety, efficiency, and the needs of the patients, surgeons and staff.
- 2) Using existing fixed and portable c-arm equipment which is currently used for interventional angiography, cardiac catheterization or orthopedic surgical procedures. The alternative was rejected because the existing equipment is not designed for use in a cardiac and vascular operating room and would not provide the benefits of angiography equipment specifically designed for a hybrid OR.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this and all other applicable statutory and regulatory review criteria, and approved subject to the following conditions:

- 1. Forsyth Memorial Hospital Inc. d/b/a Forsyth Medical Center shall materially comply with all representations made in its certificate of need application.**
- 2. Forsyth Memorial Hospital Inc. d/b/a Forsyth 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. Forsyth Memorial Hospital Inc. d/b/a Forsyth Medical Center shall not perform cardiac catheterization procedures that are routinely performed in a cardiac catheterization room on the angiography equipment in the hybrid operating room.**
 - 4. Forsyth Memorial Hospital Inc. d/b/a Forsyth Medical Center shall acquire no more than one endovascular imaging equipment system to be installed in an existing operating room.**
 - 5. Upon completion of the project, Forsyth Memorial Hospital Inc. d/b/a Forsyth Medical Center shall be licensed for no more than 35 operating rooms, including three dedicated inpatient, two dedicated C-Section, eight dedicated ambulatory surgery and 22 shared operating rooms; as well as four gastrointestinal endoscopy rooms.**
 - 6. Prior to issuance of the certificate of need, Forsyth Memorial Hospital Inc. d/b/a Forsyth Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In the projected capital cost sheet in Section VIII, page 107, the applicant lists the total capital cost of the project as \$2,699,700, including \$1,906,673 for the Angiography Imaging System and \$720,247 to renovate the existing OR. In Section IX, page 115, the applicant states, "... FMC is an existing licensed acute care hospital that does not require start-up and initial operating expenses for this project ..."

In Section VIII.3, page 108, the applicant states that the project will be funded from the accumulated reserves of the parent company, Novant Health, Inc., in the amount of \$2,699,700. Exhibit 5 contains a May 1, 2012 letter signed by the Senior Vice President, Financial Planning and Analysis for Novant Health, Inc. which states in part:

"This letter will serve to confirm that Novant Health will be funding the capital cost of \$2,699,700 for the proposed new medical equipment to create a hybrid OR in an existing licensed FMC operating room. There are no start-up and working capital needs as defined in CON Application Section IX, as FMC is an existing and ongoing operation. In addition, Novant also reserves the right to seek tax exempt bond funding for all or part of this project as discussed in Section VIII of our CON

Application. I have considered Novant Health's current and anticipated future capital needs and in my opinion Novant will be able to fund this project."

Exhibit 5 contains the audited financial statements for Novant Health, Inc. and Affiliates for the years ending December 31, 2011 and December 31, 2010. As of December 31, 2011, Novant Health had \$301,708,000 in cash and cash equivalents, \$1,081,962,000 in long term investments and \$1,877,290,000 in total net assets (total assets less total liabilities).

Exhibit 5 also contains a May 2, 2012 letter from Forsyth Medical Center President stating that FMC is committed to receiving the capital funds of \$2,680,265 from Novant Health for the proposed new medical equipment to create a hybrid OR in an existing licensed FMC operating room.

The applicant provided pro forma financial statements for the first three years of the project, for the entire medical system, Novant Health, Inc., Forsyth Medical Center and the proposed hybrid OR. The applicant projects that revenues will exceed operating expenses in each of the first three operating years for the hybrid operating room and Forsyth Medical Center. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable including projected utilization, proposed charges and expected reimbursement. See the ProForma Tab of the application for the pro formas and assumptions, which are based on reasonable utilization projections.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project. Further, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. 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

The applicant proposes to acquire an angiography imaging equipment system that will be installed in an existing OR to create a hybrid OR. The applicant has no existing hybrid ORs. The applicant does not propose any new services or additional beds or equipment. The specialized fixed C-arm angiography system, to be located in an existing OR, will allow FMC to perform open cardiovascular surgical procedures as well as image guided endovascular procedures in the same operating room.

The following table shows the availability of other hybrid ORs in the in the state.

Hybrid ORs in North Carolina		
Facility	County / Number	CON Status/CON Project ID #
FMC Service Area Forsyth Medical Center	Winston Salem, Forsyth /1	Approved / G-8831-12

Other NC		
First Health Regional Hospital	Pinehurst, Moore /1	Approved / H-7879-07
Duke University Medical Center	Durham, Durham /1	Approved / J-8288-09
Carolinas Medical Center	Charlotte, Mecklenburg /1	Approved / F-8440-09
Mission Hospital	Asheville, Buncombe /1	Approved / B-8475-10
Moses Cone	Greensboro, Guilford /1	Approved / G-8700-11
Vidant Medical Center	Greenville, Pitt /1	Approved / Q-8706-11
Presbyterian Hospital	Charlotte, Mecklenburg /1	Proposed / F-10009-12

Source: Certificate of Need, DHSR, North Carolina DHHS

As shown in the table above, there are six approved hybrid ORs in various stages of development in the State. There will be seven hybrid ORs with development of the FMC proposed project. The complement of current and proposed hybrid ORs represents a distribution that covers most geographic regions of the State.

In Section III of the application, FMC adequately demonstrates the need to acquire the proposed specialized angiography system to create a hybrid OR in an existing OR. FMC uses a multi-step methodology that is based on the hospital's historical experience performing 13 distinct vascular procedures over a four year period; and reasonably projects utilization based on population-based growth rates and appropriateness of the technology to treat patients. The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing and approved services. Therefore, 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(a), page 94, the applicant states, *“There is no hybrid OR such as the one proposed in this application currently in operation at Forsyth Medical Center. Thus, there is no current staffing to be provided.”*

In Section VII.1(b), pages 93-94, the applicant provides the projected staffing (and staffing notes) during the second full fiscal year for the hospital's hybrid operating room, as illustrated below in the table.

FORSYTH MEDICAL CENTER Hybrid OR Projected FTEs FFY 2015	
Certified Nurse Anesthetist	C
Anesthesia Technologist	1.0
Cardiovascular Invasive Specialists- RNs	3.0
Surgical Technologist	2.0
Surgical Partner	1.0
Interventional Radiology Technicians	2.0
Certified Pulmonary Technologist (Perfusionist)	C
Physician Assistant Certified	C
Total FTEs	9.0

C = Contracted/not employed by FMC

In the Notes to Table VII.1(b), page 94, the applicant discusses staffing – FMC staff and contractual staffing arrangements, as well as defines staff roles planned for the hybrid OR.

In Section VII.3(a), page 98, the applicant states:

“The proposed Hybrid OR will not add any new FTEs, as existing FMC vascular and cardiothoracic surgery, cardiac cath lab, and interventional radiology staff will be merged into a team that will staff the Hybrid OR with all the necessary expertise (interventional radiology, interventional cardiology, vascular and cardiothoracic, surgical nurses, surgical technologist, surgical partner, anesthesia technologists and CRNAs, perfusionists).”

In addition, the creation of the Hybrid OR will not result in an increase in the number of operating rooms at FMC, so existing staff can be utilized, reconfigured in the manner described above. Also, many of the cases to be performed in the Hybrid OR are currently performed today in other settings and will be relocated to the Hybrid OR when clinically appropriate. Thus, it is not anticipated an increase is [sic] staff for the Hybrid OR is needed.”

In Section VII.3(b), page 98 and VII.6(a), page 100, the applicant discusses its recruitment and staff retention plan, including its salaries and benefits practices, as well as its relationships with area nursing schools and allied health profession programs. In Section VII.8(a), pages 102 and 103, the applicant states that Dr. Stan Fuller (Colon & Rectal Surgery) is President of the Medical Staff. The Clinical Department Heads relevant to this project are: Dr. Workman (Vascular Surgery), Dr. Motew (Vascular Surgery), Dr. Joel Morgan (Cardiothoracic Surgery) and Dr. Givens (Cardiology). In Section VII.7(c), page 102, the applicant states, *“Physicians and surgeons expected to use the FMC Hybrid OR are and will continue to be members in good standing of the Forsyth Medical Center medical-dental staff with privileges to practice at FMC.”*

Exhibit 11 provides letters of support from physicians and surgeons and documents their active status on the FMC medical staff. Exhibit 18 includes Medical Staff Bylaws and Rules & Regulations. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed service, and 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 provides cardiac and vascular services and the necessary ancillary and support services are currently available. In Section II.2(a), page 16, the applicant states:

“As a full-service, existing tertiary acute care hospital, Forsyth Medical Center, has on its campus in Winston-Salem, all ancillary and support services to support hospital operations, including the proposed operation of a Hybrid OR, that will serve both cardiac and vascular patients. No incremental expansion of these ancillary and support services will be required to support the operation of the new angiography [sic] in an existing FMC OR, which will become the Hybrid OR.

Clinical and non-clinical ancillary and support services that exist currently at FMC and will be used to support the care of Hybrid OR patients in the future include, but are not limited to:

- *Pre- and Post-Surgical Care Services*
- *Anesthesiology Services*
- *Patient Transport*
- *Pharmacy*
- *Radiology*
- *Lab and Pathology*
- *Cardiac Catheterization Lab*
- *Open Heart ORs*
- *Rehabilitation services*
- *Inpatient Care: Acute and Intensive Care*
- *Observation services*
- *Respiratory Therapy Services*
- *Emergency Services*
- *Wound Care Services*
- *Case Management*
- *Nutrition & Dietary Services*
- *Housekeeping*
- *Medical Records*
- *Scheduling/Registration*

- *Billing*
- *Strategic Sourcing/Materials Management*
- *Other Diagnostic Services (EKG, EP, ECHO, EEG)*

FMC presently provides all of the above services listed in the response above to Question II.2(a) as part of its current continuum of care. Upon completion of the proposed Hybrid OR project, these services will continue to support patients that have their surgery in the FMC hybrid OR.”

See Exhibit 3 for a copy of the letter from the Senior Vice President and Chief Operating Officer attesting to the availability of ancillary and support services. Exhibits 11 and 17 contain letters of support from physicians, surgeons, board and community for the proposed hybrid OR. 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.

NA

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

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

C

In Section VI.12 and VI.13, pages 91 and 92, the applicant provides the payor mix during Calendar Year 2011, the last full fiscal year for the entire FMC and the hospital vascular and open heart surgery ORs, and for the cases eligible to have been performed in the hybrid OR. This information is illustrated in the table below:

FMC Payor Mix Percent of Total Utilization CY2011			
	FMC	Open Heart Surgery ORs Cases	Eligible Hybrid OR Cases
Self Pay/Indigent/Charity	12.64 %	2.91%	2.91%
Medicare/Medicare Managed Care	35.55 %	62.55%	62.55%
Medicaid	18.20%	6.13%	6.13%
Commercial Insurance	1.21%	0.32%	0.32%
Managed Care	29.88%	27.04%	27.04%
Other(Other Gov, /Worker Comp)	2.52%	1.05%	1.05%
Total	100.0%	100.0%	100.0%

In Section VI.2, page 80, the applicant states:

“It is the policy of all the Novant Health facilities and programs, including Forsyth 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 against the above-listed persons, or other medically underserved persons, regardless of their ability to pay”

Exhibit 6 contains the Novant Health Charity Care policies which apply to FMC and the surgeons and physicians who will support the FMC hybrid OR project. Novant also offers financial counseling and financial assistance to patients in need. Exhibit 7

provides a copy of Novant Health's interpreter and sign language policy and procedures. The applicant states that FMC conforms and will continue to conform to all requirements of North Carolina handicap requirements and the Americans with Disabilities Act.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of August 2011 and CY 2009, respectively. The data in the table was obtained on August 31, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available. Forsyth County comprises 47% percent of the projected patient origin for the proposed service.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Forsyth County	15.6%	5.5%	19.5%
Statewide	17.0%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the cardiac and vascular surgical services proposed for the Hybrid OR.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger (Forsyth County percentage was 50.4% for those age 20 and younger) and 31.6% for those age 21 and older (Forsyth County percentage was 30.8% and for those age 21 and older). Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The NC OSBM website provides historical and projected population data for each county in North Carolina. 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 or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

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

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 89, the applicant states:

“Novant Health’s tertiary hospitals (Forsyth Medical Center/FMC and The Presbyterian Hospital /TPH) fulfilled their Hill-Burton obligations long ago. . . . FMC, TPH 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.”

The applicant further discusses that Novant’s Charity Care policies (Exhibit 6) are among the most generous in this state. The applicant provided \$79,664,000 in Charity Care in CY 2011. This amounts to 12.5% of Net Revenue for CY2011. The applicant projects 12.0% of Net Revenue in Charity Care in the proposed Hybrid OR. Exhibit 8 contains the applicant’s Admissions Policy which states,

“It is the policy of Novant Health to admit patients and to provide services only at the direction of a member of the Medical/Dental staff. Patients whose physicians have classified their need as emergency or urgent will be given first priority for admission and services. Persons shall be admitted and receive services without regard to race, color, religion, sex, age, national origin, handicap or ability to pay (if emergency or urgent) and the facility will maintain compliance with federal guidelines such as EMTALA and HIPAA.”

A complaint was filed in July 2007 alleging that Presbyterian Orthopaedic Hospital discriminated based on a hearing impairment in violation of Section 504 of the Rehabilitation Act. The Office of Civil Rights investigated and determined that Presbyterian Orthopaedic Hospital did not violate Section 504 of the Rehabilitation Act. 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)(b) and VI.15(a), page 92, the applicant provides the projected payor mix for the second full fiscal year of operations for the entire facility and the Hybrid OR, as illustrated below in the table:

FMC Payor Mix		
Percent of Total Utilization FFY 2015-2016		
	Entire Facility Patients	Proposed Hybrid OR Cases
Self Pay/Indigent/Charity	12.64 %	2.91%
Medicare/Medicare Managed Care	35.55 %	62.55%
Medicaid	18.20%	6.13%
Commercial Insurance	1.21%	0.32%
Managed Care	29.88%	27.04%
Other(Other Gov, /Worker Comp)	2.52%	1.05%
Total	100.0%	100.0%

The applicant projects no change in the payor mix from historical reimbursement.

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(a), page 88, the applicant states:

“An individual will have access to services in the proposed FMC Hybrid Operating Room by the following means:

- *Physician referral by a FMC medical staff member to an FMC surgeon and/or cardiologist credentialed to practice in the hybrid OR;*
- *Physician referral and inpatient admission by an FMC hospitalist physician or by another admitting physician with privileges on the FMC medical staff;*
- *Referral by the patient’s primary care physician to a surgeon who is a member of the FMC medical staff with privileges to practice in the FMC hybrid OR;*
- *Referral to FMC by physicians who practice at other Novant acute care hospitals;*
- *Patients presenting in the FMC Emergency Department, who following assessment and triage are assigned to and [sic] FMC surgeon with privileges to practice in the FMC hybrid OR; and*

- *Physicians who are not on the FMC medical staff by referral to [sic] member of the FMC medical staff with privileges to practice in the FMC Hybrid OR.”*

The applicant adequately identifies the range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section V.1(a), page 67, the applicant states in part:

“FMC will continue to serve as an educational site [sic] will benefit local healthcare professional training programs. FMC and its proposed Hybrid OR for vascular and cardiac cases presents a unique training opportunity for health professions students, since it will be a location that will use a multi-disciplinary team approach to deliver sophisticated care using modern powerful imaging technology and minimally invasive surgical techniques. ...”

On page 66, the applicant provides a list of 23 existing clinical education agreements with which FMC and Novant Health have with health professional training programs in Forsyth and surrounding counties. Also see Exhibit 10.

The applicant demonstrates that the facility will continue to accommodate the clinical needs of health professional training programs in the area. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant discusses the elements of this criterion in Sections II.7, III.1, III.3, III.6(b), V.7, VI, X.1, XI.7, Exhibit 13 (sustainable energy management plan), and Exhibit 15 (quality documentation). The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that acquisition of the angiography system to create a hybrid OR would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The angiography imaging equipment is needed and the proposal is a cost effective alternative to meet the need to have cutting edge technology at Forsyth Medical Center;

In Section III.6(b), page 62, the applicant states:

“The purpose of the proposed project for a hybrid OR at FMC in Winston-Salem is to provide more technologically advanced and sophisticated surgical care to existing FMC patients and to meet the needs of FMC medical staff members for state-of-the-art equipment. Thus, this need cannot be met by another provider.”... “This project is necessary to accommodate current and future patient demand at FMC. As such, the need for this project lies solely within FMC’s existing facility.”

- The applicant has and will continue to provide quality services;

In Section V.7, page 72, the applicant states:

“First, Novant embraces the reality that increasing quality and decreasing costs go hand in hand, which lead to parallel strategies:

- a. Creating a Remarkable Patient Experience*
- b. Moving toward a Payer Neutral Revenue (PNR) System (Hospitals and Health Networks)*

Novant’s goal was and continues to be to develop services that are:

- *Safer and higher quality*
 - *More patient-focused*
 - *More integrated*
 - *More affordable”*
- The applicant has and will continue to provide adequate access to medically underserved populations.

In Section VI.2, page 80, the applicant states:

“It is the policy of all the Novant Health facilities and programs, including Forsyth 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 against the above-listed

persons, or other medically underserved persons, regardless of their ability to pay.”

The applicant adequately documents that FMC will provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

Forsyth Medical Center is accredited by the Joint Commission, certified for Medicare and Medicaid participation and licensed by the NC Department of Health and Human Services. In Section I.12(e), page 10 through 13, FMC lists numerous awards, recognitions and certifications that address the provision of quality care. According to the files in the Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for Major Medical Equipment, promulgated in 10A NCAC 14C .3100. The specific criteria are discussed below.

SECTION .3100 - CRITERIA AND STANDARDS FOR MAJOR MEDICAL EQUIPMENT

10A NCAC 14C .3101 PURPOSE AND SCOPE

The rules set forth in this Section shall apply to applications for major medical equipment, including new major medical technology, for which specific criteria and standards have not otherwise been promulgated in 10A NCAC 14C.

- C- Forsyth Medical Center seeks approval for the acquisition of major medical technology, for which specific criteria and standards have not otherwise been promulgated in 10A NCAC 14C.

10A NCAC 14C .3102 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Essential" means those items which are indispensable, the absence of which renders the equipment useless.
- (2) "Major Medical Equipment" is defined in G.S. 131E-176(14f).
- (3) "Mobile Major Medical Equipment" means major medical equipment and transporting equipment which is moved to provide services at two or more host facilities.
- (4) "New Major Medical Technology" means major medical equipment that:
 - (a) has been approved for clinical use by the U.S. Food and Drug Administration or shall be operated in accordance with protocols approved by an institutional review board whose membership is consistent with the U.S. Department of Health and Human Services' regulations;
 - (b) is intended for use in the diagnosis or treatment of medical conditions;
 - (c) meets the definition of major medical equipment in G.S. 131E-176(14f); and
 - (d) is so new that no state or national utilization data is readily available to the Agency for the development of specific criteria and standards.

- C- The applicant states, "This application is prepared in compliance with the definitions stated in 10 NCAC 14C .3102.

10A NCAC 14C .3103 INFORMATION REQUIRED OF APPLICANT

- (a) An applicant proposing to acquire new major medical technology or major medical equipment shall use the Acute Care Facility/Medical Equipment application form.
- C- FMC used the Acute Care Facility/Medical Equipment application form.
- (b) An applicant shall define a proposed service area for the major medical equipment or new major medical technology which shall be similar to the applicant's existing service area for other health services, unless the applicant documents that other providers outside of the applicant's existing service area are expected to refer patients to the applicant.
- C- In Section II, page 26, the applicant defined the service area for the proposed hybrid OR based on historical patient origin for the type of surgical cases which will be performed in the proposed FMC hybrid OR, and total patient

origin at FMC-Winston Salem and FMC-Kernersville. The applicant states the proposed service area includes Forsyth, Davie, Davidson, Surry, Stokes, Wilkes, Yadkin, and Rowan Counties, and three zip codes in Western Guilford County (27235, 27265, and 27310).

Historical Patient Origin Cases FMC Designated Eligible for Hybrid OR	
County	% of Total
Forsyth	47.2%
Davidson	9.3%
Surry	9.0%
Stokes	7.5%
Yadkin	6.0%
Davie	5.4%
Wilkes	3.4%
Rowan	0.3%
Western Guilford County Zip Codes	
27265	0.3%
27235	0.2%
27310	0.2%
Other	11.1%
Total	100%

Source: Exhibit 2, Table 4

The table shows patient origin data for ICD-9 surgical cases that are eligible to be performed in the hybrid OR. In Guilford County, the FMC-Kernersville service area is included.

- (c) An applicant shall document its current experience in providing care to the patients to be served by the proposed major medical equipment or new major medical technology.

- C- In Section II, page 26, the applicant describes its experience in providing care to the patients to be served by the proposed project. The applicant states,

“FMC has a long history of providing cardiac and vascular services to patients of the defined service area

... Representatives of the Forsyth Cardiac and Vascular Center at Forsyth Medical Center identified patients receiving cardiac and vascular services at FMC who would benefit from care delivered in the hybrid OR using the proposed equipment. Representatives of the Forsyth Cardiac and Vascular Center clinical operations team also identified by ICD-9 procedure code, patients with surgeries that would be clinically appropriate to be performed in the hybrid OR. ...”

The applicant provides data which illustrate FMC experience in providing care to patients with cases eligible for the hybrid OR. The data represent the last four calendar years.

Forsyth Medical Center Historical Surgical Volume for ICD-9 Procedure Codes Eligible for Hybrid OR January 2, 2008 – December 31, 2011					
ICD-9 Procedure Code	ICD-9 Procedure Description	2008	2009	2010	2011
35.12	<i>Opn mitral valvuloplast</i>	34	30	31	30
35.14	<i>Opn tricus valvuloplast</i>	9	6	13	4
35.22	<i>Opn/oth rep aortic valve</i>	56	58	48	61
36.14	<i>Aortcor bypass-4+ cor ar</i>	81	38	62	47
36.15	<i>1 in mam-cor art bypass</i>	471	421	423	403
37.75	<i>Revision of lead</i>	18	25	13	16
38.18	<i>Lower limb endarterect</i>	37	31	49	34
38.7	<i>Interruption vena cava</i>	131	150	162	137
39.49	<i>Vasc proc revision NEC</i>	145	105	119	99
39.71	<i>Endo imp oth grf abd ao</i>	45	44	41	43
39.73	<i>Endo imp grft thor aorta</i>	2	6	5	3
39.79	<i>Oth endo proc oth vessel</i>	81	84	73	72
86.07	<i>Insert vasc access dev</i>	386	380	628	628
<i>Total Cases</i>		<i>1,496</i>	<i>1,378</i>	<i>1,677</i>	<i>1,577</i>

Source: Exhibit 2, Table 1

On page 27, the applicant states:

“At present, cases shown in the previous table are performed in existing FMC operating rooms. Cases selected for the hybrid OR will be complex, will focus on higher risk patients, and will be patients who will benefit most from use of the ... Angiography System and the interdisciplinary care that can be delivered in a single location in the hybrid OR.”

- (d) An applicant shall document that the proposed new major medical technology or major medical equipment, its supplies, and its pharmaceuticals have been approved by the U.S. Food and Drug Administration for the clinical uses stated in the application, or that the equipment shall be operated under protocols of an institutional review board whose membership is consistent with the U. S. Department of Health and Human Services' regulations.
- C- See Exhibit 3 for documentation that the proposed equipment is approved for use by the U.S. Food and Drug Administration.

- (e) An applicant proposing to acquire new major medical equipment or new major medical technology shall provide a floor plan of the facility in which the equipment will be operated that identifies the following areas:
 - (1) receiving/registering area;
 - (2) waiting area;
 - (3) pre-procedure area;
 - (4) procedure area or rooms;
 - (5) post-procedure areas, including observation areas; and
 - (6) administrative and support areas.

- C- In Section II, page 28, the applicant states, *“Please see Exhibit 12 for line drawings of floor plans of the hybrid OR (OR #17) in which the ... Angiography System will be installed. The line drawings identify each of the areas described in subsections (1) through (6).”*

- (f) An applicant proposing to acquire major medical equipment or new major medical technology shall document that the facility shall meet or exceed the appropriate building codes and federal, state, and local manufacture's standards for the type of major medical equipment to be installed.

- C- In Section II, page 28, the applicant states, *“Please see Exhibit 3 for a letter from Laura MacFadden, Novant Health, Senior Director, Design and Construction, documenting that FMC meets or exceeds the appropriate building codes and federal, state, and local manufacture’s [sic] standards for the ... Angiography System hybrid OR.”*

10A NCAC 14C .3104 NEED FOR SERVICES

- (a) An applicant proposing to acquire major medical equipment shall provide the following information:
 - (1) the number of patients who will use the service, classified by diagnosis;

- C- The applicant provides the number of patients who will use the service, classified by diagnosis in Exhibit 2, Table 14, pages 157-159 (See Section II, page 28). The following table shows the projected utilization by principal diagnosis codes for each surgical type.

Forsyth Medical Center Principal Diagnostic Codes							
Code	# Patients			Code	# Patients		
	PY 1	PY 2	PY 3		PY 1	PY 2	PY 3
414.01	155	159	161	188.9	3	3	3
174.9	41	42	42	153.8	3	3	3
996.73	41	41	42	578.9	3	3	3
162.9	38	38	39	204.1	3	3	3
410.71	35	36	36	174.4	3	3	3
441.4	26	27	27	V57.89	2	2	2
183.0	23	23	23	996.72	2	2	2
174.8	21	22	22	491.21	2	2	2
415.9	19	20	20	151.9	2	2	2
424.1	22	23	23	562.12	2	2	2
996.74	15	16	16	197.0	2	2	2
162.8	14	14	14	340	2	2	2
424.0	12	13	13	150.8	2	2	2
153.9	12	12	12	518.81	2	2	2
202.80	11	11	11	453.42	2	2	2
453.41	9	9	10	584.9	2	2	2
157.9	8	9	9	198.5	2	2	2
154.1	8	8	8	410.01	2	2	2
162.3	8	8	8	195.0	2	2	2
182.0	7	7	7	153.4	2	2	2

410.41	6	6	6	427.31	2	2	2
203.00	6	6	6	162.5	2	2	2
440.22	5	5	5	441.2	2	2	2
150.9	5	5	5	238.75	2	2	2
V58.81	5	5	5	157.8	2	2	2
V58.11	4	4	5	198.3	2	2	2
453.40	4	4	5	202.81	2	2	2
197.9	4	4	5	996.1	2	2	2
146.0	4	4	5	155.1	2	2	2
440.21	4	4	4	201.90	2	2	2
444.22	4	4	4	189.0	2	2	2
440.23	4	4	4	441.3	2	2	2
038.9	4	4	4	205.00	2	2	2
410.91	4	4	4	996.62	1	1	1
410.11	3	3	3	428.0	1	1	1
442.2	3	3	3	414.02	1	1	1
157.0	3	3	3	996.04	1	1	1
185	3	3	3	403.91	1	1	1
396.2	3	3	3	162.2	1	1	1
153.3	3	3	3	440.20	1	1	1
440.31	3	3	3	154.0	1	1	1
218.9	3	3	3	410.21	1	1	1
414.00	3	3	3	146.9	1	1	1
188.9	3	3	3	158.9	1	1	1
153.8	3	3	3	202.83	1	1	1
440.31	3	3	3	180.9	1	1	1
218.9	3	3	3	250.80	1	1	1
414.00	3	3	3	Other	146	143	148
TOTAL					841	857	872

(2) the number of patients who will use the service, classified by county of residence;

-C- In Section II, page 29, the applicant provides the following number of patients who will use the service, by county for the first three years of operations of the proposed hybrid OR:

Forsyth Medical Center Patient Origin – Hybrid OR October 1, 2013 – September 30, 2016				
County	Percent	PY 1	PY 2	PY3
Forsyth	47.2%	397	404	412
Davie	9.3%	78	79	81
Davidson	9.0%	76	77	78
Surry	7.5%	63	64	66
Stokes	6.0%	51	52	53
Wilkes	5.4%	46	47	47
Yadkin	3.4%	29	29	30
Rowan	0.3%	3	3	3
Western Guilford County				
27265	0.3%	3	3	3
27135	0.2%	2	2	2
27310	0.2%	2	2	2
Other Guilford County	1.4%	12	12	12
Other NC Counties	5.9%	50	51	52
Iredell				
Alleghany				
Ashe				
Alexander				
Randolph				
Catawba				
Rockingham				
Wake				
Avery				
Watauga				
Burke				
Mecklenburg				
Cleveland				
Cabarrus				
Jackson				
Other States	3.8%	32	33	33
Virginia				
West Virginia				
South Carolina				
Total	100%	841	857	872

Source: Exhibit 2, Table 4

- (3) documentation of the maximum number of procedures that existing equipment that is used for similar procedures in the facility is capable of performing;

-C- FMC currently does not operate a hybrid OR. In Section II, page 29, the applicant provides the methodology for the maximum number of procedures that the proposed hybrid OR is capable of performing. The applicant states:

*“Normal Operating Hours: 10 hours per day x 5 days per week x 52 weeks per year = 2,600 hours per year
 Average Procedure Time: 3.0 hours
 Maximum Procedure Per Year: 2,600 hours per year / 3.0 hours per procedure = 867 procedures per year”*

- (4) quarterly projected utilization of the applicant's existing and proposed equipment three years after the completion of the project; and

-C- In Section II, page 30, the applicant states that FMC does not have an existing hybrid OR Angiography System and provides the following projected quarterly utilization for the proposed hybrid OR during the first three Project Years.

Forsyth Medical Center Projected Quarterly Hybrid OR Utilization October 1, 2013 – September 30, 2016				
	Q1	Q2	Q3	Q4
PY 1 CY 2014	210	210	210	210
PY 2 CY 2015	214	214	214	214
PY 3 CY 2016	218	218	218	218

Source: Exhibit 2, Table 13

- (5) all the assumptions and data supporting the methodology used for the projections in this Rule.

-C- The applicant provides the assumptions in Section III.1.(a) pages 33-44 and Exhibit 2, Tables 1-14. Detailed methodology Steps 1 through 7 for projected utilization are provided on pages 44-53.

- (b) An applicant proposing to acquire new major medical technology shall provide the following information:
 - (1) the number of patients who will use the service, classified by diagnosis;
 - (2) the number of patients who will use the service, classified by county of residence;
 - (3) quarterly projected utilization of the applicant's proposed new major medical technology three years after the completion of the project;
 - (4) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies;
 - (5) documentation of the effect the new major medical technology may have on existing major medical technology and procedures offered at its facility and other facilities in the proposed service area; and
 - (6) all the assumptions and data supporting the methodology used for the projections in this Rule.

- NA- In Section II, page 32, the applicant states, “*FMC is not proposing to acquire ‘new major medical technology’ as that term is defined in 10A NCAC 14C .3102(4). ...*”

10A NCAC 14C .3105 SUPPORT SERVICES

An applicant proposing to acquire major medical equipment or new major medical technology shall identify all ancillary and support services that are required to support the major medical equipment or new major medical technology and shall document that all of these services shall be available prior to the operation of the equipment.

- C- In Section II, page 30, the applicant states, “*Please see the response to Section II.2(a) above and Exhibit 3 which provides detailed responses about ancillary and support services at Forsyth Medical Center in Winston-Salem.*”

An analysis of clinical services currently involved in caring for patients requiring hybrid OR appropriate procedures revealed these patients use a host of services at FMC. These clinical services include (but are not limited to):

- *Pathology and Laboratory services*
- *Pharmacy services*
- *Rehabilitation services*
- *Cardiac Rehabilitation*
- *Inpatient care services (general, intermediate, and ICU level)*
- *Operative services (pre-op, post-op, and operating room services)*
- *Observation services*
- *Respiratory therapy services*
- *Emergency services*
- *Medical Surgical and Cardiac Intensive Care Units*
- *Stroke Care*
- *Wound Care services*
- *Radiology services (Interventional Radiology, PET/CT, MRI, X-ray, CT, Nuclear Medicine, and Ultrasound)*
- *Other diagnostic services (EKG, ECG, EP, and ECHO)*
- *Open Heart Operating Rooms*
- *Anesthesiology services*
- *Cardiac catheterization*

FMC currently provides all of these services as part of its current complement. Upon completion of the proposed project, these services will continue to support patients that receive procedures in the proposed hybrid OR.”

See Exhibit 3 for a letter from the FMC Senior Vice-President and Chief Operating Officer documenting the existence of the above listed support services.

10A NCAC 14C .3106 STAFFING AND STAFF TRAINING

- (a) An applicant proposing to acquire major medical equipment or new major medical technology shall document that:
 - (1) trained and qualified clinical staff shall be employed, and
 - (2) trained technical staff and support personnel to work in conjunction with the operators of the equipment shall be employed.

-C- In Section II, page 31, the applicant states,

“... FMC’s hybrid OR staff will work with the FMC Radiology Department to assure that qualified personnel are available to operate the ... Angiography System.”

The letter in Exhibit 3 from FMC’s Vice President, Cardiac Operations documents that FMC employs and will continue to employ trained and qualified clinical, technical and support staff to work in the hybrid OR.

- (b) An applicant proposing to acquire major medical equipment or new major medical technology shall provide documentation that physicians who will use the equipment have had relevant residency training, formal continuing medical education courses, and prior on-the-job experience with this or similar medical equipment.

-C- In Section II, page 32, the applicant states,

“Those FMC surgeons, interventional cardiologists, and interventional radiologists using the FMC Hybrid OR, including the angiography unit in OR #17, have the relevant residency training, formal continuing medical education courses, and prior on-the-job experience with similar medical equipment to that being acquired. In addition, ..., the equipment vendor, will provide additional training regarding the specifics of the ... Angiography System in the hybrid OR.”

The letter in Exhibit 3 from FMC’s Vice President, Cardiac Operations documents that the physicians and surgeons have relevant residency training, formal continuing medical education courses, and prior on-the-job experience with similar medical equipment. The vendor quote in Exhibit 4 (page 5 of 13) documents vendor training on the proposed equipment. Exhibit 11 contains Curriculum Vitae for physicians that will utilize the angiography system in the hybrid OR.

- (c) An applicant shall demonstrate that the following staff training will be provided to the staff that operates the major medical equipment or new major medical technology:
- (1) certification in cardiopulmonary resuscitation and basic cardiac life support; and
 - (2) an organized program of staff education and training which is integral to the operation of the major medical equipment and ensures improvements in technique and the proper training of new personnel.
- C- In his letter in Exhibit 3, page 265, the FMC Vice President, Cardiac Operations states,

“... the FMC staff that operates the proposed ... Angiography System in the FMC Hybrid OR will have (1) certification in cardiopulmonary resuscitation and basic cardiac life support; and (2) an organized program of staff education and training which is integral to the operation of the major medical equipment and ensures improvements in technique and the proper training of new personnel.”