

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 19, 2012

PROJECT ANALYST: Celia C. Inman

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10009-12 / Presbyterian Hospital / Acquire angiography equipment for hybrid OR / Mecklenburg 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

Presbyterian Hospital (PH) proposes to acquire one unit of angiography equipment to create a hybrid operating room (OR) in existing shared inpatient/outpatient OR space located at Presbyterian Hospital. The applicant does not propose 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, beginning on page 56, the applicant addresses Policy GEN-4 and the hospital's plan for energy efficiency and water conservation. The applicant states:

*"Presbyterian Hospital 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 Presbyterian Hospital, including the proposed hybrid operating room.*

*The objective of PH SEMP is to promote good stewardship of our environment and community resources. In keeping with our core values of Efficiency and Financial Responsibility, the PH energy management program will reduce operating costs and will further enable PH to provide compassionate care and service to a greater number of persons throughout the community.*

...

*Taking a Strategic Approach consists of actively managing energy costs. Specifically, the Novant Corporate Energy Engineer will provide a monthly analysis of consumption and cost by utility type (I.E. electricity, natural gas, and water) to assist PH in identifying areas for improvement, but also opportunities to reduce consumption per square foot.*

...

*If Presbyterian Hospital is awarded a Certificate of Need for an acquisition of one new Siemens Artis Zeego multi-axis Angiography System to place in [sic] existing Presbyterian Hospital Operating Room located in the second floor surgical suite, as proposed in this CON Application, then Presbyterian Hospital will comply with SMFP Policy GEN-4 requirement to submit a Plan for Energy Efficiency and Water Conservation to the DHSR Construction Section, which Plan will be consistent with Presbyterian Hospital'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 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

As of October 1, 2012, the applicant, PH, whose parent company is Novant Health, Inc., has 34 operating rooms (6 dedicated inpatient ORs, 6 ambulatory ORs, and 22 shared inpatient/outpatient ORs) under the Presbyterian Hospital acute care hospital license.

The 34 ORs are located in the following three PH surgical locations:

1. Presbyterian Hospital Charlotte – 24 ORs
  - 3 dedicated open heart ORs on the 5<sup>th</sup> floor
  - 3 dedicated C-Section ORs on the 8<sup>th</sup> floor of the Women’s Center
  - 6 shared inpatient/outpatient ORs in the PH basement
  - 12 shared inpatient/outpatient ORs in the 2<sup>nd</sup> floor Surgical Suite
2. MidTown Medical Plaza - 4 shared inpatient/outpatient ORs
3. Presbyterian Same Day Surgery – 6 dedicated outpatient ORs

In this application, the applicant proposes to renovate 986 square feet in the PH 2<sup>nd</sup> floor Surgical Suite for the proposed specialized angiography system to create a hybrid OR.

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

*“Presbyterian Hospital in Charlotte proposes to create a Hybrid Operating Room (OR) by acquiring a specialized fixed C-arm angiography system (Siemens Artis Zeego Multi-axis Angiography System) to be installed in an existing general use, licensed operating room located in the second floor operating room suite. The proposed project does not create in [sic] any addition to PH’s inventory of licensed operating rooms and does not create any “new institutional health service,” as that term is defined in the CON law.*

*A Hybrid OR is a room where providers are able to perform open surgical procedures, as well as image-guided vascular, neurosurgical, other surgical procedures (such as thoracic surgery, urological surgery, pediatric surgery, oncologic surgery). The proposed angiography imaging system permits Presbyterian Hospital's surgical program to meaningfully advance its provision of modern surgical services and support the evolution of clinical care at PH. At present, vascular and neurosurgical conditions requiring interventions are treated with either open surgery in an OR and/or a minimally invasive approach in an OR. Endovascular procedures (minimally invasive) 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 PH neurosurgical patients may start out in the Presbyterian Hospital angiography imaging room prior to surgery and then must be transferred to an OR for a more, complex invasive procedure. Presbyterian Hospital [sic] 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 room for 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 proposed 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, designated sterile field and other standard OR components. The applicant proposes to acquire a Siemens Artis Zeego Multi-axis Angiography System, a high resolution c-arm angiography system.

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 [sic] advanced, delicate, and time-sensitive surgical procedures and in achieving the best patient outcome, especially for complex and fragile vascular and neurosurgical patients, who are not candidates for open procedures."*

*As noted elsewhere in this application, a high resolution c-arm angiography system, such as the Siemens Artis Zeego Multi-axis 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 PH'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 with the best possible imaging experience when performing intricate procedures."*

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

- Siemens Artis Zeego Multi-axis Angiography System,
- Surgical LED Lights,
- In-Light LED Surgical Camera,
- Booms, and
- Video Router

#### Population to be Served

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

*"Presbyterian Hospital determined the geographic boundaries of the service area based on internal data for patients whose surgical cases include ICD-9 procedure codes appropriate for the hybrid OR. The proposed patient origin is based upon the historical patient origin for these patients, and is consistent with the tertiary service area served by PH."*

The following table illustrates historical and projected patient origin for patients with hybrid OR appropriate procedures at PH, as reported by the applicant in Section III.4(b), page 60, and Section III.5(c), page 62.

**Presbyterian Hospital  
 Historical and Projected Patient Origin**

<b>County</b>	<b>Historical Percent of Total</b>	<b>Projected Percent of Total</b>
Mecklenburg	57.5%	57.5%
Union	11.4%	11.4%
York, SC	5.6%	5.6%
Gaston	4.6%	4.6%
Cabarrus	3.4%	3.4%
Lincoln	2.1%	2.1%
Anson	1.8%	1.8%
Iredell	1.7%	1.7%
Stanley	1.5%	1.5%
Chesterfield, SC	1.5%	1.5%
Rowan	1.4%	1.4%
Lancaster, SC	1.3%	1.3%
Cleveland	1.0%	1.0%
Catawba	0.8%	0.8%
Chester, SC	0.4%	0.4%
Other NC	2.6%	2.6%
Other SC	0.8%	0.8%
All Other	0.7%	0.7%
<b>Totals</b>	<b>100%</b>	<b>100%</b>

The applicant adequately identified the population it proposes to serve.

Need for the Proposed Project

In Section III.1(a), beginning on page 35, the applicant states:

*“...The need for the proposed hybrid operating room equipped with a Siemens Artis Zeego Multi-axis Angiography System is substantiated by the following factors:*

- *Presbyterian Hospital Utilization of Vascular and Neurosurgical Services*
- *Other Surgical Specialty Utilization in the Hybrid Operating Room*
- *Trends in Surgical Approaches for Complex Procedures*
- *Vascular and Endovascular Surgery in the Hybrid OR*
- *Recent Innovations Revamp Intra-operative Imaging in Neurosurgery*
- *Minimally Invasive Spine Surgery using the Siemens Artis Zeego*

- *Thoracic Surgery/Endobronchial Procedures in a Hybrid OR*
- *Population Growth in Mecklenburg and Surrounding Counties – Particularly among Older Residents”*

▪ Vascular, Neurological, and Other Surgical Specialty Utilization

The historical three year trend for the identified vascular and neurosurgical procedures show a decrease in volume from 2009 with a rebound from 2011 to 2012. In Section III.1, page 35, the applicant provides the following data showing the three year growth, the two year growth and the current year growth in PH vascular and neurosurgical procedures that would be appropriate for the proposed hybrid OR.

**Presbyterian Hospital  
 Historical Utilization Vascular and Neurosurgical Cases**

	2009	2010	2011	2012 (Jan-May annualized )	Three Year Growth 2009-2012	Two Year Growth 2010-2012	Current Year Growth 2011-2012
Vascular Cases Appropriate for Hybrid OR	334	285	336	343	1.8%	10.0%	2.1%
Neurosurgical Cases Appropriate for Hybrid OR	624	565	491	511	-6.1%	-4.5%	4.1%

Total historical vascular and neurosurgical volumes have also increased from 2010 to 2012. The applicant attributes the increase to the commitment of vascular and neurosurgical surgeons to provide surgical services at Presbyterian Hospital.

In Section III.1(a), page 37, the applicant identifies other surgical specialties with procedures which could be more effectively performed in the hybrid OR, including “... *thoracic surgery, urology, oncology and pediatric surgery.*” The applicant further states, “...*most of these surgical procedures are not high volume procedures performed routinely and appear randomly across the years. As a result, volumes for these procedures fluctuate from year to year as reflected in the following table.*”

**Presbyterian Hospital  
 Other Specialty Surgical Cases Appropriate for Hybrid OR**

	2009	2010	2011	2012 (Jan-May Annualized)
Other Specialty Cases Appropriate for Hybrid OR	380	323	382	336

- Trends / Innovations / Surgical Approaches

The applicant states there is a need to reconfigure their operating rooms to accommodate current and future surgical technologies and meet surgeon and patient demands. 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. In Section III.1(a), page 38, the applicant states:

*“Surgeons are faced with a number of challenges in the current healthcare 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 [sic] to these challenges and changes.*

...

*Hybrid operating rooms provide versatile solutions that save hospitals critical time and add flexibility to perform open and minimally invasive vascular and neurosurgical 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.”*

Furthermore, on page 40, the applicant states:

*“By design, hybrid solutions requires the use of a high resolution c-arm and specialty imaging table, along with surgical support equipment including surgical lights, booms, float panel arms and displays, as well as advanced communications equipment to deliver surgical and radiological images when and where the [sic] are needed most.*

...

*Complex diagnostic and surgical interventions that capitalize on hybrid room design efficiency include several clinical specialties such as vascular and neurosurgery, combining radiological and surgical procedures in a dedicated vascular and neurosurgical hybrid operating room. The hybrid solution saves precious time for patients and assures that they can benefit from the collaborative talents of these specialized medical disciplines.”*

In Section III.1(a), page 41, the applicant addresses vascular and endovascular surgery in the hybrid OR and states:

*“Traditionally, patients experiencing a blockage in their veins or arteries would have imaging tests in one part of a hospital and other tests and treatment in a catheterization lab; if surgery was required, the patient then would be transferred to an operating room. Transfer is no longer necessary with a hybrid OR.”*

The applicant states innovations in C-arm technology, intra-operative imaging and smart visualization can ease and solidify decision making, which makes the hybrid OR especially useful for appropriate neurosurgical cases and spine surgery cases. On page 43, the applicant states, *“Integrated intra-operative imaging in the OR not only provides comprehensive diagnostic and therapeutic support, it also saves time and costs. In spinal implants, using Artis Zeego saves money because it avoids second operations.”*

In addition, the applicant states image-guided biopsies of suspicious lung nodules are possible with the Siemens Artis Zeego in a hybrid OR. In Section III.1(a), page 44, the applicant states,

*“With both 2D and 3D images being acquired intra-procedurally with the proposed hybrid OR equipment, with the patient in the same position and the diaphragm still, navigation is highly accurate and false-negative results can be greatly reduced. That differentiates this workflow from procedures in which biopsy planning is done based on pre-procedurally acquired CT-data and electromagnetic navigation of the biopsy forceps. ...”*

- Population Growth

Information provided by the applicant on projected population growth for the 65+ and 55+ populations from 2012 to 2017 for North Carolina counties in the defined service area is shown in the following table.

**Presbyterian Hospital Service Area  
 NC County Projected Population Growth**

<b>County</b>	<b>65+ CAGR 2012-2017</b>	<b>55+ CAGR 2012-2017</b>
Mecklenburg	4.75%	3.98%
Cabarrus	3.52%	3.35%
Stanly	3.03%	2.3%
Union	4.69%	4.45%
Anson	2.63%	1.64%
Rowan	2.09%	1.54%
Iredell	3.44%	3.19%
Lincoln	3.88%	2.98%
Gaston	2.83%	2.11%
Cleveland	2.41%	1.56%
Total	3.79%	3.22%

As shown in the table above, the 65+ and 55+ populations in the North Carolina counties in the defined service area are expected to grow at a CAGR of 3.79% and 3.22%, respectively.

Mecklenburg County, representing over 50 percent of the proposed patient origin, is expected to grow at a CAGR of 4.75% and 3.98%, respectively.

In Section III.1(a), page 44, the applicant states:

*“... The growth in population directly impacts future utilization of the proposed equipment and the hybrid OR, because over 80 % of vascular cases and over 50% of neurosurgical cases identified as appropriate for the hybrid OR equipment were performed on persons ages 55+ during the last three years. In addition, over 70% of other surgical specialty procedures identified as appropriate for the hybrid OR equipment were performed on persons ages 55+ during the last three years.”*

The applicant provides the following information in Exhibit 2, Table 10.

**Age Distribution of PH Patients  
 Receiving Procedures Appropriate for Hybrid OR**

	2009	2010	2011	2012
Vascular				
Percent 55+	77.2	78.6	76.5	80.4
Percent 65+	44.0	47.4	47.6	45.5
Neurosurgical				
Percent 55+	51.1	53.5	51.9	50.2
Percent 65+	26.8	25.7	25.36	24.9
Other Specialties				
Percent 55+	70.8	75.9	72.5	65.0
Percent 65+	42.4	46.4	44.2	36.4
Total				
Percent 55+	63.2	65.7	65.3	63.1
Percent 65+	35.5	36.7	37.5	34.1

On page 45, the applicant states, *“Presbyterian Hospital reasonably expects that patients 65+ and 55+ will continue to represent large percentages of hybrid OR surgery patients.”*

Projected Utilization

In Section IV.1(c), page 65, the applicant provides historical surgical cases appropriate for the Hybrid OR and projected utilization as illustrated in the table below.

**Presbyterian Hospital  
 Historical Volume Surgical Case Appropriate for Hybrid OR and  
 Total Projected Utilization of Hybrid OR**

	2010	2011	2012	2013	2014	2015	2016
Total Appropriate Cases	1,173	1,209	1,190	1,197	1,203	1,209	1,216
					PY 1	PY 2	PY 3
Total Projected Cases in Hybrid OR					601	725	851

The applicant's assumptions and methodology used to project utilization are provided in Section III.1(b), beginning on page 46. The methodology is summarized as follows:

[(CY 2012 Vascular ICD-9 Procedures Appropriate for Hybrid Equipment x Three Year Average Annual Growth Rate) + (CY 2012 Neurosurgical ICD-9 Procedures Appropriate for Hybrid Equipment Held Constant) + (CY 2012 Other ICD-9 Procedures Appropriate for Hybrid Equipment Held Constant) = Total PH Utilization Appropriate for Hybrid OR] x Ramp-Up Rate = Future Hybrid OR Utilization.

The following table illustrates projected utilization of the proposed hybrid OR at PH based upon the methodology described above.

**Presbyterian Hospital  
 Projected Hybrid OR Cases**

	2012 (Jan-May Annualized )	Avg Annual Growth 2009-2012	Interim Year 2013	PY 1 CY 2014	PY 2 CY 2015	PY 3 CY 2016
Vascular Cases Appropriate for Hybrid OR	343	1.8%	349	356	362	368
Neuro Cases Appropriate for Hybrid OR	511	Held Constant	511	511	511	511
Other Specialty Cases Appropriate for Hybrid OR	336	Held Constant	336	336	336	336
Projected Surgical Cases Appropriate for the Hybrid OR				1,203	1,209	1,216
Percent of Appropriate Cases to be Performed in Hybrid OR				50%	60%	70%
Total Projected Cases				601	725	851

The applicant provides a detailed description of the methodology and assumptions used for the projections in the previous table beginning on page 47 of the application (Steps 1 through 5) as follows:

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

*PH Surgeons and representatives of Presbyterian Hospital Surgical Services clinical staff identified by ICD-9 code, vascular, neurosurgical, and other specialty patients whose surgical cases would be performed appropriately in the hybrid OR. Detailed ICD-9 procedure codes appropriate to be performed in the hybrid OR are included in Exhibit 2, Tables 2, 3, and 4.*

*Step 2: Determine the Volume on which to Base Projections*

*Presbyterian Hospital reviewed historical internal data for the last three calendar years and the first five months of 2012 to determine its experience performing the ICD-9 procedure codes identified as appropriate for the hybrid OR.*

***Presbyterian Hospital  
 Surgical Volume for ICD-9 Procedure Codes Appropriate for Hybrid OR***

	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012 (Jan-May Annualized)</b>
<i>Vascular Cases Appropriate for Hybrid OR</i>	334	285	336	343
<i>Neurosurgical Cases Appropriate for Hybrid OR</i>	624	565	491	511
<i>Other Specialty Cases Appropriate for Hybrid OR</i>	380	323	382	336

*As shown in the previous table, PH’s vascular surgical volume for the identified ICD-9 procedure codes has increased over the last four calendar years. Neurosurgical volume decreased from 2009-2011, and rebounded in 2012. Other specialty surgical cases fluctuated, as discussed in response to Section III.1(a). Representatives of the PH Surgical Services clinical team reviewed the data, and confirmed that volumes in 2012 continue to increase and have increased since 2011. Therefore, PH determined it reasonable to utilize annualized 2012 surgical volumes as the base volume for each surgical specialty.*

*Step 3: Determine the Growth Rate for Projecting Future Volume*

*After careful review and analysis, PH determined that using the 2009-2012 average annual growth rate of 1.8% for vascular ICD-9 procedure code case volume is the most reasonable growth rate to use for vascular procedures to be performed in the proposed hybrid OR. That growth rate is realistic, and in fact conservative because it:*

- Is less than historical hybrid appropriate vascular procedure growth in the most current year and in the last two years.*
- Is less than historical total vascular growth in the last two years.*
- Does not include any growth associated with incremental vascular volumes estimated by PH surgeons.*
- Is less than the Advisory Board projected vascular growth rates.*

- *Is less than the 2012-2017 average population CAGR for the North Carolina county defined Hybrid OR service area residents, ages 65+ (3.79%).*
- *Is less than the 2012-2017 average population CAGR for the North Carolina county defined Hybrid OR service area residents, ages 55+ (3.22%).*
- *Is less than all of the above, any of which would be appropriate to project future utilization for the proposed equipment in the hybrid OR.*

*For neurosurgical ICD-9 procedure code case volume, PH determined that it would be reasonable to hold volume constant at CY 2012 annualized volume. That determination is realistic and in fact conservative because it:*

- *Is less than historical hybrid OR-appropriate neurosurgical procedure growth in the most current year.*
- *Is less than historical total neurosurgical growth in the last year.*
- *Does not include any growth associated with incremental vascular volumes estimated by PH surgeons.*
- *Is less than the 2012-2017 average population CAGR for the North Carolina county defined Hybrid OR service area residents, ages 65+ (3.79%).*
- *Is less than the 2012-2017 average population CAGR for the North Carolina county defined Hybrid OR service area residents, ages 55+ (3.22%).*
- *Is less than all of the above, any of which would be appropriate to project future utilization for the proposed equipment in the hybrid OR.*

*For “other” specialty surgical ICD-9 surgical procedure code case volume, PH determined that it would be reasonable to hold volume constant at CY 2012 annual volume. That determination is realistic and in fact conservative because it:*

- *Does not include any growth associated with incremental vascular volumes estimated by PH surgeons.*
- *Is less than the Advisory Board projected thoracic surgery growth rates.*
- *Is less than the 2012-2017 average population CAGR for the North Carolina county defined Hybrid OR service area residents, ages 65+ (3.79%).*
- *Is less than the 2012-2017 average population CAGR for the North Carolina county defined Hybrid OR service area residents, ages 55+ (3.22%).*
- *Is less than all of the above, any of which would be appropriate to project future utilization for the proposed equipment in the hybrid OR.*

#### *Step 4: Project Surgical Volume Appropriate for Hybrid OR*

*Presbyterian Hospital multiplied the CY 2012 vascular ICD-9 procedure code case volume (Step 2) by an annual growth rate of 1.8% (Step 3) through CY 2016 to project vascular surgical volume appropriate for the hybrid OR. As discussed in Step 3, CY 2012 neurosurgical and other surgical specialty volumes were held constant at CY 2012 annualized volumes. The three future volumes were combined to project future volume appropriate for the hybrid OR, as shown in the following table.*

**Presbyterian Hospital  
 Projected Surgical Volume Appropriate for Hybrid OR**

	<b>2012 Estimated</b>	<b>Interim Year 2013</b>	<b>PY 1 CY 2014</b>	<b>PY 2 CY 2015</b>	<b>PY 3 CY 2016</b>
<i>Vascular Cases Appropriate for Hybrid OR</i>	343	349	356	362	368
<i>Neuro Cases Appropriate for Hybrid OR</i>	511	511	511	511	511
<i>Other Specialty Cases Appropriate for Hybrid OR</i>	336	336	336	336	336
<i>Total Projected Surgical Cases Appropriate for the Hybrid OR</i>			1,203	1,209	1,216

*Presbyterian Hospital expects that the equipment will be installed and the hybrid OR will open on January 1, 2014.*

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

*It is important to note that the hybrid OR does not have capacity to perform 100% of appropriate surgical cases. Due to capacity constraints, PH reasonably believes that 70% of appropriate surgical cases will be performed in the hybrid OR by the third year of operations.*

**Presbyterian Hospital  
 Projected Utilization of Hybrid OR**

	<b>PY 1 CY 2014</b>	<b>PY 2 CY 2015</b>	<b>PY 3 CY 2016</b>
<i>Cases Appropriate for Hybrid OR</i>	1,203	1,209	1,216
<i>Percent of Appropriate Cases to be Performed in Hybrid OR</i>	50%	60%	70%
<i>Other Specialty Cases Appropriate for Hybrid OR</i>	601	725	851

*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.*

*Based upon discussion with the Presbyterian Hospital Surgical Services operations team, the capacity of the hybrid OR will be 2,600 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.*

***Presbyterian Hospital  
 Projected Utilization of Hybrid OR***

	<b><i>PY 1 CY 2014</i></b>	<b><i>PY 2 CY 2015</i></b>	<b><i>PY 3 CY 2016</i></b>
<i>Total Projected Cases</i>	601	725	851
<i>Weighted Cases using Average Case Time = 3 Hrs</i>	1,804	2,176	2,553
<i>Hybrid OR needed at 2,600 Hours/Year</i>	0.69	0.84	0.98

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

The applicant adequately demonstrated the need to develop a hybrid OR that will “*deliver the enhanced ability to efficiently perform minimally invasive procedures and open surgery with the imaging support and surgical tools that the surgeon and surgical team require*” and “*allow PH’s vascular surgeons and neurosurgeons to perform advanced hybrid therapies – combinations of scope-based, conventional, and less invasive surgical procedures – and streamline care for patients who need multiple procedures as part of their treatment.*”

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

- 1) The applicant does not propose to increase the number of ORs as part of this project;
- 2) 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
- 3) Use of the advanced hybrid therapies within the hybrid OR will enable PH’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 identified the population to be served and demonstrated the need the population has for the project. The applicant adequately demonstrated the extent to which the medically underserved will be served as discussed in Section VI of the application. See Criterion 13 for the analysis of the extent to which the medically underserved will have access to the proposed services which is incorporated hereby as if set forth fully herein. Based on the foregoing, 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.

CA

In Section III.3, pages 58 - 59, the applicant describes the alternatives considered, including:

1. maintaining the status quo,
2. relocating an existing angiography unit to the proposed hybrid operating room, and
3. acquiring the proposed Siemens Artis Zeego Angiography imaging system to place in an existing PH OR.

The status quo, not developing a hybrid OR, was rejected because quality, patient safety, efficiency, and the needs of surgeons, staff, and patients make continuing the status quo an unacceptable alternative. Using an existing angiography unit was rejected because the existing equipment would not have the features and functions of the Siemens Artis Zeego Angiography imaging system which is specifically designed for use in an operating room.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria and thus, is approvable. An application that is not approvable would not be an effective alternative.

The applicant adequately demonstrates that the proposed alternative is the most effective alternative to meet the needs for the proposed project. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Presbyterian Hospital shall materially comply with all representations made in its certificate of need application and the supplemental information provided. In those instances where representations conflict, Presbyterian Hospital shall materially comply with the last-made representation.**
- 2. Presbyterian Hospital shall acquire no more than one specialized fixed C-arm angiography system to be installed in an existing operating room.**
- 3. Presbyterian Hospital 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. Upon completion of this project (develop a hybrid OR), Project I.D. #F-8040-08 (relocate 7 shared ORs from Presbyterian Orthopedic Hospital to PH), and**

**Project I.D. #F-8765-11 (POH replacement), Presbyterian Hospital shall be licensed for no more than 41 operating rooms, including 3 open heart surgery, 3 dedicated C-Section, 6 dedicated ambulatory surgery operating rooms and 29 shared operating rooms.**

- 5. Presbyterian Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and which would otherwise require a certificate of need.**
  - 6. Prior to issuance of the certificate of need, Presbyterian Hospital 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 Section VIII, page 106, the applicant states the total capital cost of the project will be \$2,680,265, including \$1,885,026 for the Siemens Artis Zeego Angiography Imaging System and \$197,871 to renovate the existing OR. Other major equipment cost includes \$265,837 for the surgical lights, camera, booms, video router, wall cameras and cabling; and \$19,403 for the endoscope. In Section IX, page 115, the applicant states, *"The project does not involve start-up and initial operating expenses because Presbyterian Hospital is an existing, ongoing operation."* In Section II.2(a), page 16, the applicant further states, *"No incremental expansion of these ancillary and support services will be required to support the operation of the new angiography unit in an existing Presbyterian Hospital OR, which will become the Hybrid OR."*

In Section VIII.3, page 107, the applicant states that the project will be funded with the accumulated reserves of its parent, Novant Health, Inc. in the amount of \$2,680,865, the total cost of the project. Exhibit 5 contains a July 11, 2012 letter signed by the Senior Vice President, Operational Finance for Novant Health, Inc. which states:

*"This letter will serve to confirm that Novant Health will be funding the capital cost of \$2,680,265 for the proposed new medical equipment to create a hybrid OR in an existing licensed PH operating room. There are no start-up and working capital needs as defined in CON Application Section IX, as PH 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 of the application 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 of the application also contains a July 16, 2012 letter from Presbyterian Hospital Senior Vice President/Chief Operating Officer stating that PH is committed to receiving and using 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 PH operating room.

The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project, for the entire medical system, Novant Health, Inc., Presbyterian Hospital 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 Presbyterian Hospital. 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. See Criterion (3) for the discussion of utilization projections which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues, and 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 to create a hybrid OR in an existing OR. The proposal will not result in the development of an additional OR. Instead, an existing OR will be modified by installing specialized equipment for the performance of certain vascular and neurological procedures. The applicant has no existing hybrid ORs. The applicant does not propose any new services. The proposed equipment will be used to perform procedures currently being performed but in a more efficient and effective manner. The specialized fixed C-arm angiography system, to be located in an existing OR, will allow PH to perform open surgical procedures as well as image guided endovascular procedures in the same operating room.

The applicant adequately demonstrates the need to acquire the proposed specialized angiography system to create a hybrid OR in an existing OR. See the discussion in Criterion (3) which is incorporated hereby as if fully set forth herein. Therefore, the applicant adequately demonstrated that the proposal would not result in an unnecessary

duplication of existing and approved services. 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(a), page 93, the applicant states, “*There is no hybrid OR such as the one proposed in this Application currently in operation at PH. Thus, there is no current staffing to be provided.*” In Section VII.1(b), pages 93, the applicant provides the projected staffing during the second full fiscal year for the hospital’s hybrid OR, as illustrated in the table below.

**Projected Full-Time Equivalents (FTEs)  
CY 2015**

Certified Nurse Anesthetist	1.0
Anesthesia Technician	0.5
OR Assistant	0.5
Surgical Technologist	2.0
Registered Nurse	2.0
Radiology Technologist	1.0
<b>Total FTEs</b>	<b>7.0</b>

In Section VII.3(a), page 96, the applicant states:

*“The proposed Hybrid OR will not add any new FTEs, as existing Presbyterian Hospital staff will be utilized to staff the Hybrid OR with all the necessary expertise (vascular, neurological, surgical nurses, surgical technologist, OR Assistants, anesthesia technologist and CRNAs).*

...

*In addition, the creation of the Hybrid OR will not result in an increase in the number of operating rooms at Presbyterian Hospital, 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 96 and VII.6(a), page 98, the applicant discusses its recruitment and staff retention plan, including its salaries and benefits practices and its relationships with area nursing schools and allied health profession programs. In Section VII.8(a), pages 100 and 101, the applicant states Dr. Sidney Fletcher (Emergency Medicine) is President of the Medical Staff and the clinical Department Heads relevant to this project are: Dr. Joe

Ducey (Anesthesiology), Dr. David Voellinger (General Surgery), Dr. Mark Smith (Neurological Surgery), and Dr. Lance Diehl (Vascular Surgery). In Section VII.7(c), page 100, the applicant states, “*Physicians and surgeons expected to use the PH hybrid OR are and will continue to be members in good standing of the Presbyterian Hospital medical staff with privileges to practice at PH.*” Exhibit 11 provides letters of support from these physicians and surgeons and documents their active status on the PH medical staff. The applicant demonstrated 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 currently provides vascular and neurosurgical 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, Presbyterian Hospital, has on its campus in Charlotte, all ancillary and support services to support hospital operations, including the proposed a [sic] Hybrid OR, that will serve both vascular and neurosurgical patients, as well as other surgical specialties (including but not limited to) urological, oncologic, pediatric, and thoracic surgeries.*

...

*Clinical and non-clinical ancillary and support services that exist currently at Presbyterian Hospital 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)*

*Presbyterian Hospital 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 PH hybrid OR.”*

See Exhibit 3 of the application for a copy of a 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 and others for the proposed hybrid OR. The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would 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 90 - 91, the applicant provides the payor mix during Calendar Year 2011, its last full fiscal year, for the entire hospital, the main hospital surgery program ORs, and for the cases appropriate to have been performed in the hybrid OR as illustrated in the table below:

**Presbyterian Hospital Payor Mix  
 Percent of Total Utilization CY2011**

	Entire Facility Patients	Main Hospital Surgery ORs Cases	Appropriate Hybrid OR Cases
Self Pay/Indigent/Charity	12.64 %	2.74%	2.41%
Medicare/Medicare Managed Care	35.55 %	25.92%	55.83%
Medicaid	18.20%	19.01%	4.55%
Commercial Insurance	1.21%	0.82%	0.83%
Managed Care	29.88%	49.42%	34.23%
Other(Other Gov. /Worker Comp)	2.52%	2.09%	2.15%
Total	100.0%	100.0%	100.0%

In Section VI.2, page 79, the applicant states:

*“It is the policy of all the Novant Health facilities and programs, including PH, 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 PH and the surgeons and physicians who will support the PH 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 PH conforms and will continue to conform to all requirements of 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 October 16, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available. Mecklenburg and Union County comprise 69 percent of the projected patient origin for the proposed service.

	<b>Total # of Medicaid Eligibles as % of Total Population</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population</b>	<b>% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)</b>
Mecklenburg County	15.0%	2.3%	20.1%
Union County	11.0%	1.6%	18.0%
Statewide	17.0%	3.5%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the 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 (Mecklenburg County percentage was 44.1% and Union County was 46.7% for those age 20 and younger) and 31.6% for those age 21 and older (Mecklenburg County percentage was 30.7% and Union County was 30.7% 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 NCOSBM website provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. 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 demonstrated that medically underserved populations currently have adequate access to the services offered at Presbyterian Hospital. 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. Presbyterian Hospital far exceeded its requirements for delivering uncompensated care pursuant to that program and its regulations. Presbyterian Hospital exceeded the Hill-Burton quota in 1982.” ... “As required by the former Hill-Burton program, the Presbyterian Hospital has far exceeded its requirements for delivering uncompensated care pursuant to that program and its regulations. FMC, PH and all Novant acute care and other 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.”*

PH maintains that Novant's Charity Care policies, included in Exhibit 6, are among the most generous in North Carolina. The applicant provided \$81,524,533 in Charity Care in CY 2011. This amounts to 14.8% of Net Revenue for CY2011. The applicant projects 15.9% of Net Revenue in Charity Care in the proposed Hybrid OR. Exhibit 6 also 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.”*

There have been no patient civil rights access complaints in the last five years. A complaint was filed in July 2007 alleging discrimination in violation of Section 504 of the Rehabilitation Act. The Office of Civil Rights investigated and determined that PH 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) and VI.15(a), pages 91 - 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 in the table below:

**Presbyterian Hospital Payor Mix  
Percent of Total Utilization CY2015**

	Entire Facility Patients	Proposed Hybrid OR Cases
Self Pay/Indigent/Charity	12.64 %	2.41%
Medicare/Medicare Managed Care	35.55 %	55.83%
Medicaid	18.20%	4.55%
Commercial Insurance	1.21%	0.83%
Managed Care	29.88%	34.23%
Other(Other Gov, /Worker Comp)	2.52%	2.15%
Total	100.0%	100.0%

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

The applicant demonstrated 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 87, the applicant states:

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

- *Physician referral by a PH medical staff member to an [sic] PH surgeon credentialed to practice in the hybrid OR;*
- *Physician referral and inpatient admission by an [sic] PH hospitalist physician or by another admitting physician with privileges on the PH medical staff;*
- *Referral by the patient’s primary care physician to a surgeon who is a member of the PH medical staff with privileges to practice in the PH hybrid OR;*
- *Referral to PH by physicians who practice at other Novant acute care hospitals;*
- *Patients presenting in the PH Emergency Department, who following assessment and triage are assigned to and [sic] PH surgeon with privileges to practice in the PH hybrid OR; and*
- *Physicians who are not on the PH medical staff by referral to member of the PH medical staff with privileges to practice in the PH hybrid OR.”*

The applicant adequately demonstrated it offers a 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:

*“Presbyterian Hospital will continue to serve as an educational site [sic] will benefit local healthcare professional training programs. Presbyterian Hospital and its proposed Hybrid OR for vascular, neurosurgical and other specialized surgical 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.”*

The applicant states it has existing clinical education agreements with the following health professional training programs in Mecklenburg and surrounding counties, including, but not limited to:

- Cabarrus College
- Catawba Valley Community College
- Central Piedmont Community College
- Davidson College

- Duke University
- ECPI University
- Gaston College
- Guilford Technical Community College
- Kings College
- Pfeiffer University
- Queens University
- Rowan-Cabarrus Community College
- Stanly Community College
- University of North Carolina
- Wingate University
- York Technical College

Exhibit 10 contains a comprehensive list of educational institutions with which Novant Health has established educational arrangements. 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 with 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

In Section V.7, pages 72 – 77, the applicant explains how the proposed hybrid OR will foster competition by promoting cost effectiveness, quality and access to the proposed services. See also Sections II, III, and VI. 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 will enhance competition and have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- 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 PH to perform open surgical procedures as well as image guided endovascular procedures in the same operating room, thus enhancing competition by

providing safe, high quality services in a more efficient manner to meet the needs of surgeons, staff and patients.

- The applicant adequately demonstrates the need to acquire the proposed specialized angiography system to create a hybrid OR in an existing OR. The proposal is a cost-effective alternative to meet the need to have cutting edge technology at Presbyterian Hospital. In Section III.6(b), page 63, the applicant states,

*“The purpose of the proposed project for a hybrid OR at PH in Charlotte is to provide more technologically advanced and sophisticated surgical care to existing PH patients, and to meet the needs of PH medical staff members for state-of-the-art equipment. Thus, that need cannot be met by another provider. ... The project is necessary to accommodate current and future patient demand at PH.”*

- The applicant has and will continue to provide quality services. In Section V.7, page 73, 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 [RPE]*
- b. Moving toward a Payer Neutral Revenue (PNR) System*

...

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

- *Safer and higher quality*
- *More patient-focused*
- *More integrated*
- *More affordable”*

The NC Hospital Quality Performance Reports for the six months ending 12/31/2011 show Presbyterian Hospital is above the North Carolina average or in the Top 10% of North Carolina Hospitals on the Surgical Care measures. In 2011, Presbyterian Hospital was named one of the 50 “Best Hospitals” in America by Becker’s Hospital Review.

- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.2, page 79, the applicant states:

*“It is the policy of all the Novant Health facilities and programs, including PH, 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.”*

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

Presbyterian Hospital 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 12, PH lists numerous awards, recognitions and certifications that address the provision of quality care. The NC Hospital Quality Performance Reports for the six months ending 12/31/2011 show Presbyterian Hospital is above the North Carolina average or in the Top 10% of North Carolina Hospitals on the Surgical Care measures. In 2011, Presbyterian Hospital was named one of the 50 “Best Hospitals” in America by Becker’s Hospital Review.

According to the files in the Acute and Home Care Licensure and Certification Section, PH was surveyed on June 7-9, 2011 as part of a complaint investigation. The survey resulted in the identification of an immediate jeopardy (IJ) and several condition-level deficiencies. The hospital was placed on a 23-day termination tract by CMS. A follow-up survey was conducted August 1-4, 2011, and the IJ was removed and the 23-day termination tract was halted. However, condition-level deficiencies were cited under Physical Environment based upon the Life Safety Report of Survey. Also, Governing Body remained out of compliance, and several standard-level deficiencies were cited. As of a January 6, 2012 survey, Life Safety deficiencies were still uncorrected and the facility was granted a waiver by CMS. As of October 18, 2012, the facility is in compliance with all other Conditions of Participation. 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 .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- PH 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 28, 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 hybrid OR. The applicant states the proposed service area includes Mecklenburg, Union, Gaston, Cabarrus, Lincoln, Anson, Iredell, Stanly, Rowan, Cleveland, and Catawba counties in North Carolina, and York, Chesterfield, Lancaster and Chester counties in South Carolina.

**Historical Patient Origin for Cases PH Designated as Appropriate for Hybrid OR**

County	Vascular 2010-2012	Neurosurgical 2010-2012	Other 2010-2012	Combined 2010-2012	Three Yr Avg
Mecklenburg	336	691	770	1797	57.58%
Union	77	177	103	357	11.44%
York, SC	13	131	32	176	5.64%
Gaston	12	98	35	145	4.65%
Cabarrus	7	87	13	107	3.43%
Lincoln	4	56	7	67	2.15%
Anson	11	21	23	55	1.76%
Iredell	7	42	2	51	1.63%
Stanly	5	38	3	46	1.47%
Chesterfield, SC	11	13	21	45	1.44%
Rowan	10	32	0	42	1.35%
Lancaster, SC	4	30	6	40	1.28%
Cleveland	7	21	3	31	0.99%
Catawba	2	20	2	24	0.77%
Chester, SC	0	10	2	12	0.38%
Total Defined Service Area	506	1467	1022	2995	95.96%
Other Counties	10	98	18	126	4.04%
Totals	516	1565	1040	3121	100.00%

The table shows that the identified counties represent over 95% of the 2010-2012 vascular, neurosurgical, and other cases identified by the Presbyterian Hospital Surgical Department and respective surgeons supporting the project to be performed in the hybrid OR. The applicant maintains that the proposed patient origin is also consistent with PH's tertiary services patient origin.

(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 28, the applicant describes its experience in providing care to the patients to be served by the proposed project. The applicant states, *“Presbyterian Hospital has a long history of providing vascular, neurosurgical, and other surgical services to patients in the defined service area who will benefit from the proposed equipment.”*

PH surgical department representatives identified cases by ICD-9 procedure code for patients with surgeries that would be clinically appropriate to be performed in the hybrid OR using the proposed equipment. Based on the identified cases, PH presents the following data to illustrate its experience in the last four calendar years providing care to patients in each surgical specialty that will be served by the proposed major medical equipment.

**PH Historical Surgical Volume Appropriate for Hybrid OR**

	2009	2010	2011	2012 (Jan-May Annualized)
Vascular Cases	334	285	336	343
Neurosurgical Cases	624	565	491	511
Other Specialty Cases	380	323	382	336
Total	1,338	1,173	1,209	1,190

On page 29, the applicant states:

*“At present, cases shown in the above table are performed in existing PH 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 Siemens Artis Zeego Multi-axis 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- Exhibit 12 of the application contains a floor plan of the second floor surgical suites where the hybrid OR will be created with the acquisition and installation of the proposed equipment. The applicant provided clarifying information which adequately identified the locations of the above areas.
- (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 30, the applicant states, *“Please see Exhibit 3 for a letter from Laura MacFadden, Novant Health, Senior Director, Design and Construction, documenting that PH meets or exceeds the appropriate building codes and federal, state, and local manufacture’s [sic] standards for the Siemens Artis Zeego Multi-axis 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- In Section II, page 30, the applicant states:

*“Presbyterian Hospital reviewed the principle diagnosis code for patients with the ICD-9 procedure codes reflected in the previous table. Projected patients by principle diagnosis are included in Exhibit 2, Table 6.”*

Exhibit 2, Table 6 identifies the number of 2011 surgical cases appropriate for the hybrid OR classified by diagnosis. The following table condenses the historical data provided in Table 6 and identifies the top five diagnosis codes for each surgical type.

**Table 6. 2011 Principal Diagnosis Codes (Condensed to Top Five)**

Code	Vascular	Percent	Code	Neuro	Percent	Code	Other	Percent
99673	76	23%	72210	235	48%	40391	140	37%
43310	34	10%	72402	51	10%	99673	71	19%
44021	32	10%	75612	33	7%	40390	25	7%
9961	20	6%	7384	29	6%	5920	18	5%
44022	19	6%	7213	26	5%	44022	10	3%
Other	155	46%	Other	117	24%	Other	118	31%
Total	336	100%	Total	491	100%	Total	382	100%

It is reasonable to assume future use of the service classified by diagnosis will mirror the historical. Cases should be interpreted as patients, per the applicant in Section II, page 27, *“For purposes of this Application, the terms “patient” and “cases” are used interchangeably. In addition, “one case” equals “one procedure” in the proposed hybrid OR.”* The following table illustrates projected cases in Project Year 1.

**PY 1 Projected Patients Classified by Diagnosis Code (Top Five)**

Code	Vascular	Percent	Code	Neuro	Percent	Code	Other	Percent
99673	40	23%	72210	122	48%	40391	62	37%

43310	18	10%	72402	26	10%	99673	31	19%
44021	17	10%	75612	17	7%	40390	11	7%
9961	11	6%	7384	15	6%	5920	8	5%
44022	10	6%	7213	14	5%	44022	4	3%
Other	82	46%	Other	61	24%	Other	52	31%
<b>Total</b>	<b>178</b>	<b>100%</b>	<b>Total</b>	<b>255</b>	<b>100%</b>	<b>Total</b>	<b>168</b>	<b>100%</b>

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

-C- In Section II, page 31, 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:

**Projected Patient Origin for Hybrid OR**

<b>County</b>	<b>PY 1</b>	<b>PY 2</b>	<b>PY3</b>
Mecklenburg	346	417	489
Union	69	83	97
York, SC	34	41	48
Gaston	28	34	39
Cabarrus	21	25	29
Lincoln	13	16	18
Anson	11	13	15
Iredell	10	12	14
Stanly	9	11	13
Chesterfield, SC	9	11	12
Rowan	8	10	12
Lancaster, SC	8	9	11
Cleveland	6	7	8
Catawba	5	6	7
Chester, SC	2	3	3
Other NC	16	19	22
Other SC	5	6	7
All Other	4	5	6
<b>Total</b>	<b>601</b>	<b>725</b>	<b>851</b>

(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- PH has no existing hybrid ORs. In Section II, page 31, the applicant provides the maximum number of procedures that the proposed hybrid OR is capable of performing. The applicant states:

*“The vascular, neurosurgical and other surgical procedures identified in Exhibit 2, Tables 2, 3, and 4 are performed in existing operating rooms at Presbyterian Hospital. Below is the methodology PH is assuming related to the maximum number of procedures the proposed hybrid OR is capable of performing:*

*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 32, the applicant states that PH does not have an existing hybrid OR with a Siemens Artis Zeego Angiography System and provides the following projected quarterly utilization for the proposed hybrid OR during the first three Project Years.

**Presbyterian Hospital  
 Projected Quarterly Utilization in Hybrid OR**

	Q1	Q2	Q3	Q4
PY 1 CY 2014	150	150	150	150
PY 2 CY 2015	181	181	181	181
PY 3 CY 2016	213	213	213	213

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

-C- The applicant provides the assumptions and methodology used in Section III.1.(a) and III.1.(b), pages 36-54 and Exhibit 2, Tables 1-7. Detailed Steps 1 through 5 for projected utilization begin on page 47.

- (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, “*PH is not proposing to acquire new major medical technology as defined by 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 16, the applicant states,

*“Please see the response to Section II.2(a) and Exhibit 3, which provides detailed responses about ancillary and support services at PH in Charlotte.*

*An analysis of clinical services currently involved in caring for vascular and neurosurgical patients requiring hybrid OR appropriate procedures revealed these patients use a host of services at PH. 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.*

*PH 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”.*

Exhibit 3 contains a letter from PH’s Senior VP and COO confirming the above services are currently available and will continue to be available for the proposed hybrid OR.

### **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 34, the applicant states,

*“... Presbyterian Hospital’s hybrid OR staff will work with the PH Radiology Department to assure that qualified personnel are available to operate the Siemens Artis Zeego Multi-axis Angiography System.”*

The letter in Exhibit 3 from PH’s VP and COO documents PH employs and will continue to employ trained and qualified clinical staff and trained technical staff and support personnel 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 34, the applicant states,

*“Presbyterian Hospital’s surgeons 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, Siemens, the equipment vendor, will provide additional training regarding the specifics of the Artis Zeego Multi-axis Angiography System in the hybrid OR.”*

See the letter from PH's VP and COO for documentation of the physicians and surgeons relevant residency training, formal continuing medical education courses, and prior on-the-job experience with similar medical equipment. The vendor quote in Exhibit 4, application pages 207 and 208 documents additional vendor training on the proposed equipment.

- (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 her letter in Exhibit 3, PH VP and COO states,

*“....the PH staff that operates the proposed Artis Zeego Angiography System in the PH 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.”*