Comments in Opposition from Novant Health, Inc.
Regarding Duke University Health System d/b/a Raleigh Hospital
CON Application for Two Additional Shared Use Operating Rooms at
Duke Raleigh Hospital (Project I.D. # J-8467-10)
Submitted February 15, 2010 for March 1, 2010 Review

In accordance with N.C.G.S. Section 131E-185(a1)(1), Novant Health, Inc. submits the following comments regarding the CON Application of Duke University Health System d/b/a Raleigh Hospital for Two Additional Shared Use Inpatient/Outpatient Operating Rooms at Duke Raleigh Hospital (Project I.D. #J-8467-10).

I. Introduction

The following five CON applications were submitted in response to the need determination identified in the *2010 State Medical Facilities Plan* (*2010 SMFP*) for three surgical operating rooms in Wake County:

- J-8467-10: Duke University Health System d/b/a Raleigh Hospital for Two Additional Shared Use Surgical Operating Rooms
- J-8463-10: WakeMed for Three Additional Shared Use Surgical Operating Rooms at WakeMed Cary Hospital
- J-8468-10: Rex Hospital, Inc. d/b/a Rex Healthcare for Two Outpatient Surgical Operating Rooms in a Hospital-Based Ambulatory Surgery Center at Rex Healthcare of Holly Springs
- J-8469-10: Rex Hospital, Inc. d/b/a Rex Healthcare for One Additional Operating Room at Rex Hospital
- J-8471-10: Novant Health's Holly Springs Surgery Center for a Freestanding Ambulatory Surgery Center with Three Outpatient Surgical Operating Rooms

II. Duke Raleigh Hospital's Proposal

Duke Raleigh Hospital (DRH) seeks approval to renovate and expand its existing hospital facility in Raleigh, zip code 27619, and to add two shared surgical operating rooms[1] that will be used for inpatient surgery[2], with a total project cost of $8,700,000.

The project involves the following renovation and expansion of the surgical services and facilities at DRH:

- Construction of a two-level addition to the Surgery Department totaling 5,084 square feet. That addition will be the site of the proposed additional two shared surgical operating rooms and support space.
- Renovation of 6,982 square feet in the Surgery Department.

[1] CON Application J-8467-10, page 3
[2] CON Application J-8467-10, page 12

- Expansion of Preoperative Suite to add six new patient bays.
- Renovation of the Post Anesthesia Care Unit to add two additional patient care areas.
- Renovation and expansion of Central Sterile Reprocessing area.[3]

If approved, DRH will increase its surgical operating room inventory from 13 to 15 shared surgical operating rooms.

DRH states that "[w]hat's innovative about this project is the focus on subspecialty inpatient surgery."[4] It proposes "the development of an environment that is equipped to support a substantial increase in inpatient surgery."[5] DRH expects "the demand for inpatient procedures to increase much faster [than the need and demand for ambulatory procedures]."[6]

As will be discussed in detail below, DRH failed to disclose circumstances that jeopardize its ability to sustain current surgical volume and attain projected surgical volume. Those circumstances render unreasonable its assumptions and methodology, and result in overstated projections. Overstated projections are the basis for future revenue, and do not validate a proposed capital expenditure of $8,700,000.

III. CON Statutory Review Criteria

The following comments are submitted based upon the CON Review Criteria found at N.C.G.S.131E-183. While some issues impact multiple Criteria, they are discussed under the most relevant review Criteria and referenced in others to which they apply.

G.S. 131E-183 (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.

A. *SMFP* Policy GEN-3 – Basic Principles

As discussed in detail in the context of Criterion (3) below, DRH failed to adequately demonstrate the need for the project, and therefore failed to document how its projected volumes incorporate the Basic Principles in meeting the need identified in the *2010*

[3] CON Application J-8467-10, page 7
[4] CON Application J-8467-10, page 11
[5] CON Application J-8467-10, page 7
[6] CON Application J-8467-10, page 11

SMFP for new ORs in Wake County. Consequently, the DRH Application is not conforming to Policy Gen-3, and does not conform to Criterion (1).

In addition, the plain language of "SMFP Policy GEN-3: Basic Principles" requires that: *"A certificate of need applicant applying to develop or offer a new institutional health service for with there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan, as well as addressing the needs of all the residents in the service area. (Emphasis added)*

DRH's response to CON Application Question III.4, pertaining to applicable SMFP need determinations and policies is scant and does not address all the mandatory elements of SMFP Policy GEN-3 above. First, DRH is applying for 2 new ORs which are the subject of a need determination for Wake County in the 2010 SMFP. Thus, SMFP Policy GEN-3 is clearly applicable to the project proposed by DRH. Second, SMFP Policy GEN-3 mandates that the applicant "shall demonstrate" how the project promotes safety, quality of care, equitable access, and value. DRH's response on CON Application page 29 includes only three bullet points and no substantive discussion. Third, SMFP Policy GEN-3 mandates that the applicant "shall document" plans for access to care for patients with limited financial resources and the available capacity. DRH's response to CON Application Question III.2 and the CON Application exhibits do not address this. Fourth, SMFP Policy GEN-3 requires the applicant to document how its projected volumes incorporate these concepts in meeting the need identified in the SMPF. Again, DRH fails to fully address this requirement. Thus, DRH has failed to provide sufficient narrative responses and documentation in its CON Application exhibits to demonstrate conformity with the most crucial SMFP Policy and thus, is non-conforming with Criterion (1).

B. Operating Room Need Methodology – Results in Significantly Overstated Surgical Volume

As discussed below in detail in the context of Criterion (3), projected DRH surgical utilization is unsubstantiated, unreasonable, and overstated, and cannot be used to justify DRH's total operating rooms in Wake County. Therefore, the DRH Application is non-conforming to Criterion (1).

G.S. 131E-183 (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.

The proposed project is non-conforming to Criterion (3) because it overstates a need at DRH for expanded surgical services. As such, DRH fails to justify a need for 15 shared surgical operating rooms at DRH, two of which are proposed in the DRH Application.

A. DRH Historical Surgical Volume

1. Underutilized Surgical Operating Room Inventory at DRH

DRH presents its historical surgical utilization on pages 17 (CON Application Section II) and 27 (CON Application Section III) of the DRH Application, as shown in the following table. DRH, however, fails to disclose that its surgical operating room inventory has been historically underutilized during FY 2007 and FY 2008 as reflected in the following table. Note that Duke Raleigh Hospital utilizes a July to June Fiscal Year as noted on its Annual Hospital Licensure Renewal Application; therefore all references in this document to FY are for July to June timeframe.

Duke Raleigh Hospital
Surgical Utilization: July 2006 – June 2009

Surgical Cases	FY 2007	FY 2008	FY 2009
Inpt	2,177	2,346	3,004
% Change		*7.8%*	*28.0%*
Outpt	9,134	9,138	10,817
% Change		*0.0%*	*18.4%*
Total	11,311	11,484	13,821
Inpt Weighted	6,531	7,038	9,012
Outpt Weighted	13,701	13,707	16,226
Total Weighted	20,232	20,745	25,238
ORs needed at 1,872	10.8	11.1	13.5
Licensed ORs	13.0	13.0	13.0
OR Surplus/Deficit	**-2.2**	**-1.9**	**0.5**

Source: DRH Application, page 27
Note: Deficits appear as positive number; surpluses as negative numbers

As a result of double-digit growth in FY 2009, DRH's historic surgical operating surplus has been eliminated, as shown in the previous table. DRH does not provide any documentation or discussion regarding the significant increase in surgical volume from 2008 to 2009. Furthermore one year's significant growth does not reflect a trend.

2. DRH Lost 17 Surgeons Associated with Raleigh Surgical Group and Wake Surgical Specialists Which Will Impact Future Surgical Volume

Competing CON Applications submitted by Rex Hospital (CON Applications J-8468-10 and J-8469-10) fill in the blanks left by the DRH Application. According to Rex's CON Applications, on **August 1, 2009**, Raleigh Surgical Group and Wake Surgical Specialists joined Rex Healthcare, adding "**17 world-class surgeons to Rex Healthcare's employed medical staff**. The merged group is called Rex Surgical Specialists and is employed by Rex Physicians, LLC."[7] **[Emphasis added.]** At pages 90-91 of Rex's Holly Spring ASC CON Application, also filed on 2/15/2010, it states: *"While Raleigh Surgical Group previously performed surgery exclusively at Rex, Wake Surgical Specialists previously performed surgery at Rex and at other facilities....Wake Surgical Specialists...performed 326 inpatient surgical cases and 1,696 outpatient surgical cases from April 2008 to March 2009 at Duke Raleigh Hospital (2,022 cases in total.)*

A loss of the surgeons associated with Wake Surgical Specialists should have been acknowledged by DRH in its Application. The Agency should not have learned of those circumstances through a competing application.

According to Rex's CON Applications, "Wake Surgical Specialists performed 326 inpatient surgical cases and 1,696 outpatient surgical cases from April 2008 to March 2009 at DRH (2,022 cases in total)."[8] Rex provided the following table to show Wake Surgical Specialists cases at DRH.

Wake Surgical Specialists Cases at Duke Raleigh Hospital
April 2007 – March 2009

Time Period	Cases
April 2007 to March 2008	1,397
April 2008- March 2009	2,022
Percent Growth	44.7%

Source: Rex Hospital CON Applications J-8468-10 and J-8469-10, pages 91-92, citing Thomson Reuters

Rex explains that "[t]he impetus behind some of this 44.7 percent growth in cases at Duke Raleigh was the addition of another Wake Surgical Specialists surgeon during this time frame. This group also added another surgeon just prior to joining Rex [...]."[9]

Rex did quantify the surgical volume it expects will shift from Wake Surgical Specialists to Rex in FY 2010 – FY 2015, as shown in the following table.

[7] Rex Hospital CON Applications J-8468-10 and J-8469-10, pages 83 & 90-91
[8] Rex Hospital CON Applications J-8468-10 and J-8469-10, page 91
[9] Rex Hospital CON Applications J-8468-10 and J-8469-10, page 91, FN 18

Projected Future Wake Surgical Specialists
Surgical Cases Shifted from DRH to Rex

Federal Fiscal Year	Inpatient	Outpatient	Total
2010	326	1,696	2,022
2011	332	1,768	2,100
2012	332	1,843	2,181
2013	338	1,921	2,265
2014	344	2,002	2,352
2015	350	2,087	2,444
CAGR	1.8%	4.2%	3.9%

Source: Rex Hospital CON Applications J-8468-10 and J-8469-10, pages 92-94

It is reasonable to assume that the Wake Surgical Specialists surgical volume shown in the previous table would have been performed at DRH, had those surgeons not joined Rex. Those cases therefore represent significant lost surgical volume to DRH.

The magnitude of the loss to DRH of surgeons associated with Wake Surgical Specialists joining Rex as employed surgeons is significant both in terms of current volume on which to base projections, and the projections themselves. Consequently, it is reasonable to assume the following:

- DRH surgical volume will decline by at least the number of cases performed annually by the surgeons associated with Wake Surgical Specialists.
- DRH annual surgical volume will be negatively affected until replacement surgeons are performing surgical cases at DRH.
- DRH has a lower surgical volume on which to base projections for its proposed inpatient surgery expansion, including the addition of 2 new ORs.
- DRH has a lower rate of growth for surgical cases, which reflects the extent of lower utilization.
- DRH projected FY 2010 through FY 2015 annual surgical volume must be adjusted downward to reflect a lower base volume and lower growth rate.

DRH's failure to incorporate the aforementioned assumptions into its projections renders the DRH Application incomplete at best, and at worst misleading. In either scenario, the DRH Application should be denied based on non-conformity with Review Criterion (3).

B. DRH Projected Surgical Volume Is Overstated and Unreasonable

1. DRH Projections are Dependent on Recruiting 14 New Surgeons

DRH cites its "recruitment of 14 additional surgeons" as the fourth factor that "drive[s]" the "need for the renovation and expansion of surgical services of DRH."[10] However, on

[10] CON Application J-8467-10, pages 27-28 and 12

page 28, DRH states that "[w]ithout additional rooms, it will prove difficult to recruit the additional surgeons proposed on page 28 of the DRH Application because schedules for the existing ORs are virtually full, and the hospital has very little block time to offer."

Therefore, DRH does not have 14 additional surgeons on its medical staff performing additional surgical cases and may not be able to recruit them as stated above. On page 12 of the DRH application, DRH predicts that it will successfully recruit 4 new surgeons in who will begin performing surgery in 2011 or 2012; 5 more surgeons who will begin performing surgery in 2012; and 3 additional surgeons who will begin performing surgery in 2013 Without at least some of these 14 additional surgeons in place prior the projected 2011 opening date for the two new ORs and performing cases at DRH, there is an insufficient "fourth factor driving need for the proposed project." The need for DRH to recruit surgeons is even more immediate given DRH's loss in August 2009 of the surgeons associated with Wake Surgical Specialists. Based on the timing of the surgeon recruiting plan set forth on page 12 of the DRH CON Application, it appears there will be at least a two-year gap between the loss of the Wake Surgical Specialist surgeons and cases and the recruitment of four to six new surgeons expected to start performing cases in 2011 and 2012. This gap does not appear to allow sufficient time for the new surgeons to build up there surgical case volumes in a manner that supports the projected future DRH OR cases volumes to support 15 ORs (13 existing and 2 new ORs).

DRH quantifies its "recruitment plan" on page 12 of the DRH Application, as shown in the following table.

Duke Raleigh Hospital
Subspecialty Surgeon Recruitment Plan: 2011 - 2015

Recruitment Plan	**Number of Additional Surgeons FY 11 – FY 15**						
Specialty		Start Date	2011	2012	2013	2014	2015
Gynecology Oncology	1	2011	1.0	1.0	1.0	1.0	1.0
Surgical Oncology	1	2011		1.0	1.0	1.0	1.0
Thoracic Oncology	1	2012		1.0	1.0	1.0	1.0
Vascular Surgeon	2	2012		2.0	2.0	2.0	2.0
Orthopedics	1	2013			10.0	1.0	1.0
Neurosurgery	1	2013			1.0	1.0	1.0
General Surgery (Breast/Colorectal)	3	2011 & 2012	2.0	3.0	3.0	3.0	3.0
ENT	1	2013			1.0	1.0	1.0
Urology	3	2011 & 2012	2.0	3.0	3.0	3.0	3.0
Total	14		6	11	14	14	14

Source: CON Application J-8467-10, page 12

DRH's projections are inextricably linked to its successful "recruitment of 14 additional subspecialty surgeons." No details are provided, however, about how and from where an

additional 14 physicians will be recruited. It is uncertain whether DRH will be successful in recruiting the number, specialty mix, and by the dates set forth in the previous table. Future recruitment is an unreasonable assumption on which to base the majority of DRH's future surgical volume, which serves to justify the need for two more ORs.

Equally importantly, reasonable future surgical volume requires DRH to have a written commitment from each surgeon to perform a specific number of inpatient and outpatient cases per year at DRH, and the type of cases each has committed to perform. DRH has no such written commitments. Written commitments are impossible when none of the "14 additional subspecialty surgeons" have become members of DRH's medical staff.

2. DRH does not Provide a Methodology to Substantiate its Interim and Projected Surgical Volume

DRH fails to provide a response to Section III.1.(b), which requires each applicant to "provide statistical data that substantiates the existence of an unmet need for each project component and proposed services identified in Section II.1." In addition, DRH's in response to the Questions in Section IV.1 (a)-(d) are incomplete. These four questions require the applicant to provide the following.

- Question IV.1(a)—two full fiscal years of historical utilization/volumes, for the two years prior to the CON application filing date.
- Question IV.1(b)—projected utilization for the period beginning when the CON Application is submitting and ending when the project is complete (open for business).
- Question IV.1(c)—projected annual OR case utilization for the first three full fiscal years after the completion of the project (Project Years 1-2-3).
- Question IV`(d)—all assumptions and the specific methodology used for the projected OR case utilization in the CON Application.

In response to these questions in CON Application Section IV, DRH refers the Agency to a CON Application Exhibit IV.1. Neither DRH CON Application Section IV responses nor Exhibit IV.1 contain any narrative explanation of the assumptions (base year data, growth rates, use rates, population growth, inmigration, etc) used in the utilization projections or any explanation of the method used to project future DRH future OR case volumes.

Furthermore, DRH has **not** provided a specific step-by-step methodology used to project future utilization of surgical operating rooms.

Table IV.1 contains the following table showing projected surgical volume at DRH.

Duke Raleigh Hospital
Surgical Utilization

Surgical Cases	Interim Year: FY 2010*	Interim Year: FY 2011	Interim Year: FY 2012	PY 1: FY 2013	PY 2: FY 2014	PY 3: FY 2015
Inpt	3,442	3,561	4,003	4,356	4,704	5,062
Outpt	11,239	11,649	12,231	12,973	13,819	14,473
Total	14,681	15,210	16,234	17,329	18,523	19,535

Source: Exhibit IV.1 pages 252-253
**There is a discrepancy between the FY 2010 volume reported on page 252 (FY 2010 = 3,442 inpatient cases & 11,239 outpatient cases) and reported on page 21 (FY 2010 = 3,609 inpatient cases and 11,246 outpatient cases). The latter volume is higher than the former.*

DRH provides absolutely no analysis or explanation to substantiate the utilization in the previous table.

The following table reveals the growth rates that underlie DRH's projected interim and future surgical volume.

Duke Raleigh Hospital – Current and Projected Surgical Utilization

Surgical Cases	FY 2009	Interim Year: FY 2010*	Interim Year: FY 2011	Interim Year: FY 2012	PY 1: FY 2013	PY 2: FY 2014	PY 3: FY 2015	CAGR 2009-2015
Inpt	3,004	3,442	3,561	4,003	4,356	4,704	5,062	9.1%
% Change		14.6%	*3.5%*	*12.4%*	*8.8%*	*8.0%*	*7.6%*	
Outpt	10,817	11,239	11,649	12,231	12,973	13,819	14,473	5.0%
% Change		*3.9%*	*3.6%*	*5.0%*	*6.1%*	*6.5%*	*4.7%*	
Total	13,821	14,681	15,210	16,234	17,329	18,523	19,535	5.9%
% Change		*6.2%*	*3.6%*	*6.7%*	*6.7%*	*6.9%*	*5.5%*	

Source: Exhibit IV.1 pages 252-253
**There is a discrepancy between the FY 2010 volume reported on page 252 and reported on page 21 The latter volume is higher than the former.*

The previous table shows that DRH projects inpatient surgical volume to increase an aggregate of 68.5%[11] outpatient surgical volume to increase by an aggregate of 33.8%[12] and a total surgical volume by an aggregate of 41.3%[13] between July 2009 and June 2015. It is quite unreasonable for DRH to project that level of growth in view of the recent departure of the Wake Surgical Specialists surgeons and the untested surgeon recruiting plan.

The DRH Application is silent on the assumptions it made in selecting the various annual growth rates it applied to determine interim and projected utilization, as shown in the previous table. Thus, DRH failed to respond to CON Application Question IV.1(d) and

[11] Calculation: (5062 – 3004)/3004 = 2058/3004 = 68.5%
[12] Calculation: (14473 – 10817)/10817 = 3656/108179 = 33.8%
[13] Calculation: (19535 -13821)/13821 = 5714/13821 = 41.3%

the CON OR Regulation performance standard provision at 10A NCAC.14C.2103(g). The applicant failed to explain the assumptions used to project the quantitative need for the ORs.

DRH was neither conservative nor reasonable in its projections. It is highly unreasonable for DRH to project a need for surgical operating room in view of its recent loss of the Wake Surgical Specialist surgeons and present and future surgical volume performed by those surgeons, as well as the surgeon recruiting plan that has yet to be implemented.

3. There Are Insufficient Surgeon Letters to Support DRH's Large Future OR Case Volume Projections

DRH states that the proposed renovation and expansion of the DRH surgical program, including two new operating rooms, is to support the expansion of inpatient surgical services, especially in the surgical specialties of Neurosurgery, Oncologic Surgery, Vascular Surgery, and Urologic Surgery. See DRH CON Application at pages 7, 16 and 29. DRH CON Application Exhibit V.3 includes only ten surgeon support letters from the following surgical specialists: 1 Gynecologist; 2 ENTs; 2 Ophthalmologists; 2 Neurosurgeons; 1 Thoracic Surgeon; and 2 Orthopedic Surgeons. These surgeon letters of support are insufficient for two reasons:

- DRH states it is planning two grow four types of inpatient surgery (neurosurgery, oncologic, vascular, & urologic), and yet there are no surgeon letters of support from three of the four inpatient surgical specialists—urology, vascular surgery, and oncologic surgery.
- DRH provides only ten surgeon letters of support which is insufficient to support and justify the increase in surgical cases from 14,681 surgical cases in FY 2010 to 19,535 surgical cases in FY 2015.

C. DRH Projected Acute Care Bed Volume

So confident is DRH in its surgical projections that it "[...] expect[s] to increase the utilization of the Hospital's [existing inventory of] acute care beds."[14] On page 253, DRH provides the following table showing actual and projected discharges and patient days.

[14] Page 253 of CON Application J-8467-10

Duke Raleigh Hospital
Acute Care Utilization: July 2008 – June 2015

	Discharges	Patient Days
FY 2008 (actual)	5,304	24,625
FY 2009 (actual)	6,263	28,201
FY 2010 (projected)	6,993	30,424
FY 2011 (projected)	7,189	31,276
FY 2012 (projected)	7,448	32,402
FY 2013 (projected)	7,716	33,568
FY 2014 (projected)	7,993	34,777
FY 2015 (projected)	8,281	36,029

Source: CON Application J-8467-10, page 253

DRH fails to disclose the methodology used to project acute care bed utilization. The DRH Application is silent on the assumptions it made in selecting the various annual growth rates it applied to determine interim and projected inpatient utilization, as shown in the following table.

Duke Raleigh Hospital
Projected Acute Care Bed Utilization

Acute Care	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	CAGR 2009-2015
Discharges	6,263	6,993	7,189	7,448	7,716	7,993	8,281	4.8%
% Change		*11.7%*	*2.8%*	*3.6%*	*3.6%*	*3.6%*	*3.6%*	
Patient Days	28,102	30,424	31,276	32,402	33,568	34,777	36,029	4.2%
% Change		*8.3%*	*2.8%*	*3.6%*	*3.6%*	*3.6%*	*3.6%*	
ALOS	4.49	4.35	4.35	4.35	4.35	4.35	4.35	
Licensed Beds	186	186	186	186	186	186	186	
ADC	77.0	83.4	85.7	88.8	92.0	95.3	98.7	
Occupancy Rate	41.4%	44.8%	46.1%	47.7%	49.4%	51.2%	53.1%	
Bed Surplus/Deficit	-78	-69	-66	-62	-57	-53	-48	

Source: Exhibit IV.1, page 253
Note: Deficits appear as positive number; surpluses as negative numbers

DRH also fails to disclose that the projected expansion of surgical services and facilities will not eliminate its historical and projected double digit acute care bed surplus, as shown in the previous table.

G.S. 131E-183 (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.

DRH discusses two alternatives on pages 29-30 in Section III of the DRH CON Application. DRH discusses only two alternatives: (1) status quo; (2) build a

freestanding surgery center. DHSR fails to discuss the alternative of doing the surgical services renovation and expansion with only the 13 existing DRH ORs and without adding any new ORs at this time. This might make sense in light of the recent departure of the Wake Surgical Specialists surgeons and their 1000s of cases per year, especially since recruiting for replacement surgeons has not been accomplished yet. DHSR also fails to discuss the alternative of adding less than two new ORs. Again, in light of the departure of the Wake Surgical Specialists Surgeons and cases, it would be reasonable to focus on a more modest expansion of the DRH surgical program until there was more concrete evidence that the proposed DRH surgeon recruiting program would be effective. Since DRH could expand and renovate its surgical program without adding any new ORs, the project proposed in DRH's 2/15/2010 CON application is not least costly alternative. The Application is non-conforming to Criterion (4).

G.S. 131E-183 (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.

It is not possible for the Agency to determine either the immediate or long term financial feasibility of the proposed DRH project to expand and renovate surgical services and add two new operating rooms. First, the applicant identifies the start of Project Year 1 (the opening date for the expanded surgical services at DHR) as August 1, 2011. See DHR CON Application Section XII responses at CON Application page 76. Based on this response, the first three project years would be:

1. 8/1/2011 – 7/31/2012
2. 8/1/2012 – 7/31/2013
3. 8/1/2013 – 7/31/2014

Second, in CON Application Section IV and the related Exhibit IV.1, the applicant projects surgical case volumes for the first three project years, identified as:

1. FY 2013: July 1, 2012 – June 30, 2013
2. FY 2014: July 1, 2013 – June 30, 2014
3. FY 2015: July 1, 2014 – June 30, 2015

Third, the applicant also prepared CON ProForma Form C Surgical Component financial projections, "Statement of Revenue and Expense" for the FY 2013 to FY 2015 time period, July 1, 2012 through June 30, 2015.

Fourth, the projected surgical case volumes for the first three years of operation (Project Years 1-2-3) are in July to June years starting on July 1, 2012 and ending on June 30, 2015; however, in CON Application Section XII, the applicant stated that the project would become operational on August 1, 2011. August 1, 2011 is eleven months prior to

the initial date of July 1, 2012 for which the applicant has projected future volumes for the first three years of operation. The operational date defined in CON Application Section XII, must be consistent with the timeframes used by the applicant in CON Application Section IV for the future surgical case volume projections and also consistent with the CON ProForma future financial projections for the first three years of operation. That is not the case with the DRH CON application.

Fifth, given this discrepancy and inconsistencies in the time period definitions it is impossible for the Agency to determine the financial feasibility of the project proposed by DRH.

In addition, in DHR's CON ProForma Form C projected Statement of Revenues and Expenses for DRH Surgical Renovation and Expansion, the expense line item labeled "Professional and Purch Services-Surgical," "Drugs and Supplies-Surgical Services," and "Non-Medical Supplies Surgical Services," are not identified for the future years (FY 2011, FY2012, FY 2013, etc), when the surgical expansion becomes operational. It appears that significant future expenses are not included in the operating expenses of the proposed project.

Given all of the above, it will be impossible for the Agency to determine with any certainty the immediate and long-term financial feasibility of the DHR surgical project. Thus, DHR should be found non-conforming with Criterion (5).

G.S. 131E-183 (6)

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

DRH does not indicate that 86% of all existing and approved surgical operating rooms in Wake County are within 8 miles/10 minutes of DRH, as shown in the following table.

Surgical Operating Room Inventory of
Existing and Approved Wake County Surgical Providers

Existing and Approved Wake County Surgical Provider	Operating Room Inventory	To: 3400 Wake Forest Road, Raleigh, NC 27609
Duke Health Raleigh	13	0 miles/0 minutes
WakeMed	26*	4 miles/6 minutes
Blue Ridge Surgery Center	6	5.4 miles/6 minutes
Rex Raleigh Campus	24**	5.8 miles/7 minutes
WakeMed North Healthplex	4***	6.7 miles/10 minutes
Orthopedic Surgery Center Raleigh	4	7.7 miles/9 minutes
Rex Wakefield	3	4.2 miles/8 minutes
Subtotal	*80*	
WakeMed Cary	9	14 miles/17 minutes
Rex Surgery Center of Cary	4	15.1 miles/19 minutes
TOTAL	93	

Source: 2010 LRAs; Mapquest.com
**Includes WakeMed Raleigh Surgery Center, which has been approved for 8 ambulatory surgery operating rooms. WakeMed total does not include 3 C-section rooms*
***Does not include 3 C-section rooms*
****Does not include 1 C-section room*

A map included as Attachment 1 illustrates the proximity of DRH to Wake County surgical providers. Of the total of 93 surgical operating rooms in Wake County, 86% (80/93) are within 8 miles/10 minutes of DRH.

DRH does not discuss the reasons that its proposed project will not result in unnecessary duplication of existing or approved health care services – in this case surgical operating rooms. If the Agency were to approve an additional two shared surgical operating rooms at DRH, 86% (82/95) of all surgical operating rooms in Wake County will continue to be located within 8 miles/10 minutes of DRH.

The DRH Application should be denied because it does not conform to Criterion (6).

G.S. 131E-183 (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.

When compared to the to the cost to implement the new Wake County ORs proposed by Novant's Holly Springs Surgery Center and by Rex's Holly Springs Surgery Center, the Construction Cost Per Square Foot is higher for the DRH two new ORs plus surgical

expansion/renovation. The comparative Construction Cost per Square Foot for DRH and the other four competing applications is listed below:

Construction Cost Per SF

- DRH for 2 New ORs: $360/SF
- Novant's Holly Springs Surgery Center for 3 new ORs: $246/SF
- Rex's Hospital-Based Holly Springs ASC for 2 new ORs: $339/SF
- Rex Hospital for 1 new OR: $570/SF
- WakeMed Cary for 3 new ORs in the hospital: $567/SF

Furthermore, DRH could have chosen to renovate and expand the DHSR surgical suite with the existing 13 ORs and without the addition of 2 new ORs. This might make sense in light of the recent departure of the Wake Surgical Specialists surgeons and their 1000s of cases per year, especially since recruiting for replacement surgeons has not been accomplished yet. If that option had been chosen, DRH's ability to move forward with the project to accommodate projected inpatient surgical growth would not have been subject to the delays potentially associated with this competitive review for new Wake County ORs. Thus, cost associated with DRH's project to expand and add two ORs is not the "most reasonable alternative" in terms of "cost, design, and means of construction."

G.S. 131E-183 (13)

The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and members of the 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 identified in the State Health Plan as deserving of priority.

In Section VI (Question 8(a)) of the DRH CON application, DRH provides its current Charity Care dollars and Charity care as a percent of Net Revenue. DRH specifies that its Charity Care does not include Bad Debt dollars. See DRH CON application at page 45. However, in the DRH response to Question VI.8(b), DRH fails to provide any dollar amount for current DRH Bad Debt or Bad Debt as a percent of DRH Net Revenue. In addition, in response to CON Application Question VI.8(d), DRH also fails to provide DRH Project Year 2 projected Bad Debt information. Charity Care and Bad Debt are a measure of a provider's access for medically underserved populations as identified in Statutory Review Criterion (13). DRH as provided incomplete information and should be found non-conforming with Criterion (13).

In addition, the comparison below of DRH's Charity Care policy, as well as other indicators of access for medically underserved populations shows that DRH provides less comprehensive access for the medically underserved populations than is proposed by Novant's Holly Springs Surgery Center. This is measured by a comparison of the Charity Care policies, Medicare access, Medicaid access, and Bad Debt and Charity Care

as a percent of Net Revenue. This information in included in CON Application Section VI of each application and in the CON Application exhibits.

	Duke Health Raleigh (2 Inpt ORs)	**Novant's Holly Springs Surgery Center (3 ORs)**
Charity Care Policy	200% of Federal Poverty Level	300% of Federal Poverty Level
Family of 4 Household Annual Income Qualifying for Full Charity Care ($0 Owed)	$44,100	$66,150
PY2: ASC Medicare Percent of Payor Mix	60.9%	31.08%
PY2: ASC Medicaid Percent of Payor Mix	7.2%	9.12%
PY 2: ASC Self-Pay Percent of Payor Mix	3.5%	6.97%
PY 2: ASC Charity Care as % of Net Revenue	15.3%	12.82%
PY2: ASC Bad Debt as % of Net Revenue	N/A	2.8%

Based on the comparison above, DRH provides less access to the medically underserved as measured by the Charity Care policy, Medicaid and Self-Pay payor mix percents for Project Year 2, and by the Bad Debt percentage. DRH's proposal is comparatively inferior on these access measures when compared to Novant's Holly Springs Surgery Center project.

IV. CON Criteria and Standards for Operating Room – 10A NCAC 14C .2100

The proposed project is non-conforming to the Criteria and Standards for Operating Rooms as follows:

10A NCAC 14C .2103 Performance Standards

10A NCAC 14C .2103(a)

DRH did not provide a response to 10A NCAC 14C .2103(a), which requires each applicant to confirm that "[i]n projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year."

10A NCAC 14C .2103(b)(1)(A) and (c)(1)(A)

As discussed in detail in the context of Criterion (3), DRH based its projections on unreasonable assumptions, which result in overstated projections. Overstated projections have been used to demonstrate a need for the proposed two additional shared surgical

operating rooms. DRH has not demonstrated a need for the proposed total of 15 shared surgical operating rooms. As a result, DRH has not shown that its projections conform to the performance standard set forth in 10A NCAC 14C.2103(b)(1(A) and .2103(c)(1)(A).

10A NCAC 14C .2103(g)

DRH referenced Exhibit IV.1 and "the response to Section III.1." in response to 10A NCAC 14.2103(g), which requires each applicant to "document the assumptions and provide data supporting the methodology used for each projection in this Rule."

As discussed in detail in the context of Criterion (3) above, DRH neither documented assumptions nor provided a methodology for projecting future surgical volume. DRH provided a mere two pages of text in response to Section III.1.(a) and (b) (pages 27-28) in which it briefly describes the qualitative need factors for the proposed project. DRH does not respond separately to Question III.1(a) which directs the applicant to describe the "qualitative need" for the project and to Question III.1(b), which directs the applicant to demonstrate the "quantitative need" for the project. DRH fails to provide specific or coherent information to demonstrate the quantitative need for its project. In Table IV.1., DRH simply provided historical, interim, and projected surgical data. Completely missing from the DRH Application is a step-by-step methodology, assumptions, and details to substantiate the unmet need for the proposed two additional shared surgical operating rooms and total surgical operating room inventory at DRH. Both the applicable CON OR regulations (10A NCAC 14C.2103(g)) and CON Application Question IV.1(d) require the applicant to provide "all assumptions and the specific methodology used for projected utilization." DHSR failed to provide this mandatory information which is crucial to the demonstration of the quantitative need for the project. If the quantitative need is not demonstrated by the applicant, then the application is not approvable.

Consequently, the DRH Application should be denied for failure to conform to the Criteria and Standards for Operating Rooms and for failure to conform with Statutory Review Criterion (3).

Conclusion

The CON Application submitted by Duke Raleigh Hospital fails to conform to key Criterion reflected in G.S. 131E-183. The project fails to document the need for the proposed two additional shared surgical operating rooms at DRH.

DRH projects 41.3%[15] growth in total surgical procedures between July 2009 and June 2015. This growth is unsubstantiated as DRH fails to provide required assumptions

For all of the above reasons, the Application is non-conforming to the Review Criteria for a New Institutional Health Service, and the Application must be denied.

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[15]Calculation: (19535 -13821)/13821 = 5714/13821 = 41.3%

Attachment 1