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MFPB

August 15, 2014

VIA HAND DELIVERY

Christopher Ullrich, MD, Chairman
North Carolina State Health Coordinating Council
c/o Division of Health Service Regulation
Medical Facilities Planning Branch
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Comments Opposing Petition Filed by Rex Healthcare for an Adjusted Need Determination for One Additional of Cardiac Catheterization Equipment in Wake County

Dear Dr. Ullrich and Members of the State Health Coordinating Council:

WakeMed appreciates the opportunity to comment on the petition filed by Rex Healthcare for an adjusted need determination for one additional unit of cardiac catheterization equipment for Wake County in the 2015 State Medical Facilities Plan (SMFP). For the reasons outlined below, WakeMed believes this petition should be denied.

Rex provides a number of arguments regarding the merits of its petition, and provides examples of circumstances where the State Health Coordinating Council approved adjusted need determinations for cardiac catheterization and other major medical equipment regulated in the SMFP. However, none of these arguments are compelling. There are recent instances, not included in the Rex petition, which argue against an adjusted need determination.

Rex filed a petition in Spring 2014 seeking a change in the SMFP need determination methodology for fixed cardiac catheterization equipment; this petition was denied. WakeMed submitted comments in opposition to Rex's earlier petition, which are also relevant to the current petition under consideration. These comments are provided in Attachment 1.

Cardiac Catheterization Volumes at Wake County Hospitals

On page 2 of its petition, Rex references a 23 percent growth in Wake County's total population from 2006-2014, as well as its own growth in cardiac catheterization volume, as being factors that support the need for additional cardiac catheterization equipment. While Rex's cardiac cath lab volume has increased since 2010, total cardiac catheterization utilization at Wake County hospitals has declined during that time. Please see the following table.

Table 1
Diagnostic-Equivalent Cardiac Catheterization Volumes at Wake County Hospitals
2010-2013

Facility	2010	2011	2012	2013	Percent Change 2010-13	CAGR, 2010-13
Duke Raleigh Hospital	967	701	366	447	–53.8%	–22.7%
Rex Hospital	3,002	3,132	3,875	5,029	67.5%	18.8%
WakeMed Cary Hospital	382	325	282	222	–41.9%	–16.5%
WakeMed Raleigh Campus	12,618	12,130	10,535	8,570	–32.1%	–12.1%
Total All Hospitals	16,969	16,288	15,058	14,268	–15.9%	–5.6%
Total Excluding Rex	13,967	13,156	11,183	9,239	–33.9%	–12.9%

Source: 2011-2014 License Renewal Applications

Among Wake County facilities, overall diagnostic-equivalent cardiac catheterization volume *declined* 15.9 percent, by over 2,700 cases, from 2010-2013. When Rex is excluded from the calculation, the total volume at the remaining providers declined a dramatic 33.9 percent, by over 4,700 cases. The increase in Rex's volume has been more than offset by the decreases in volume at other hospitals. Therefore, there is actually a *negative* correlation between population growth in Wake County and cardiac catheterization volumes at Wake County hospitals, evidence that overall demand is declining.

The declines in cardiac catheterization utilization in Wake County and in North Carolina are also being experienced nationally, and are projected to continue. The Advisory Board Company projects that inpatient cardiac cath procedure volumes will decrease 22 percent nationally from 2012-2017, and that outpatient cardiac caths will decline 7 percent. Percutaneous coronary intervention volumes are projected to decline 15 percent over the same period.[1]

Cardiologists May Practice at Multiple Hospitals

Rex noted its recent affiliation with physicians of Wake Heart and Vascular Associates, and that group's subsequent absorption into North Carolina Heart & Vascular (NCHV), as being the chief driver of recent growth in its cardiac catheterization volume, as volume has been shifted from other providers to Rex. NCHV is one of the largest cardiovascular medical practices in North Carolina and according to its web site has 16 total office locations, including eight offices in Wake County. NCHV also has an office at WakeMed Raleigh Campus.

WakeMed's petition requesting no adjusted need determination for fixed cardiac catheterization equipment for Wake County in the 2015 SMFP pointed out that many of the physicians performing cardiac catheterization procedures at Rex also have practice privileges at

[1] Source: *Cardiovascular Market Trends for 2014*, The Advisory Board Company, Cardiovascular Roundtable & Service Line Strategy Advisor, published March 10, 2014, accessed at: http://www.advisory.com/Research/Service-Line-Strategy-Advisor/Resources/2014/Cardiovascular-Market-Trends, 3/19/2014.

WakeMed Raleigh Campus. A closer look at NCHV's medical staff indicates that 14 of their 31 physicians have privileges at both Rex and WakeMed Raleigh, 7 have privileges only at Rex, 4 only at WakeMed Raleigh, and 6 at neither facility. Please see the table below. Because 14 of the 21 NCHV physicians with privileges at Rex can also practice at WakeMed Raleigh, Rex's argument that physicians cannot provide timely care to patients due to lack of access to cardiac cath labs is misleading.

Table 2
N.C. Heart & Vascular Physicians' Practice Privileges

Facility	Number of Physicians
Rex Hospital Only	7
WakeMed Raleigh Campus Only	4
Both Rex and WakeMed Raleigh	14
Neither Rex Nor WakeMed Raleigh	6
Total	31

The table below shows the cardiology group/independent cardiologist practices with offices in Wake County, and the facilities where at least one of its physicians are on medical staff.

Table 3
Cardiology Group Practices/Independent Cardiologists with Privileges at Wake County Hospitals

Practice/Physician (listed alphabetically)	At Least One Physician with Privileges at?			
	Duke Raleigh	Rex	WakeMed Raleigh	WakeMed Cary
Boice-Willis Clinic			✓	
Capital Heart Associates	✓	✓	✓	✓
Carolina Cardiology			✓	
Carolina Children's Cardiology		✓	✓	✓
Carolina Heart Center	✓	✓	✓	
Cary Cardiology		✓	✓	✓
Duke Cardiology of Raleigh	✓	✓		
Duke Medicine-Cardiology		✓		
Glenndale Moore, MD			✓	✓
Millenia Cardiovascular	✓		✓	
N.C. Heart & Vascular	✓	✓	✓	✓
Peak Cardiology		✓		✓
Piedmont Cardiology		✓	✓	✓
Premier Cardiology	✓	✓	✓	
Rafael Moreschi, MD		✓		✓
Raleigh Cardiology			✓	✓
Rex Heart & Vascular		✓		
UNC Heart & Vascular		✓		
WakeMed Cardiovascular			✓	✓

Source: Hospital web sites

The SHCC denied a petition filed in 2013 by Iredell Health System for an adjusted need determination for fixed cardiac catheterization equipment in Iredell County in part because two other providers of cardiac catheterization located in Iredell County were in close proximity to Iredell Memorial Hospital (including one with 5 miles), and that local cardiologists could utilize these facilities to perform their cases. Please see additional discussion below. The circumstances in Wake County are similar to that of Iredell County, in that all four acute care hospitals in the county offer cardiac catheterization services, and many cardiologists based in Wake County practice at multiple sites. Given the distribution of cardiology practices and acute care hospitals within Wake County – Rex Hospital is located within 10 road miles and less than 15 minutes' driving time from Duke Raleigh Hospital, WakeMed Cary Hospital, and WakeMed Raleigh Campus -- the notion that patients in need of cardiac catheterization cannot receive care in a timely manner is specious. Table 3 demonstrates that there is little practice exclusivity among cardiology groups based in Wake County. Fourteen of the 19 cardiology groups/independent cardiology physicians in Wake County have privileges at more than one facility.

Other Highly Utilized Providers of Cardiac Catheterization

On page 4, the Rex petition compares its volume to that of other highly utilized providers of cardiac catheterization: New Hanover Regional and Cape Fear Valley Medical Center. Despite Cape Fear Valley's recent trend of high cardiac catheterization utilization – above 80 percent of the State's definition of capacity for the last three years – it has not triggered, nor have they requested, a need determination for an additional unit of cardiac cath equipment. New Hanover Regional has been utilized above 80 percent each year from 2010-2013 and has generated a need determination on two separate occasions, yet it has petitioned to have both need determinations removed. Please see the following table.

Table 4
Cardiac Catheterization Equipment Utilization at Cape Fear Valley Medical Center and New Hanover Regional Medical Center, 2010-2013

		2010		2011		2012		2013	
Facility	Cath Lab Inventory	Weighted Cath Procedures	Percent Util.	Weighted Cath Procedures	Percent Util.	Weighted Cath Procedures	Percent Util.	Weighted Cath Procedures	Percent Util.
Cape Fear Valley	3	3,405	76%	3,800	84%	4,005	89%	3,906	87%
New Hanover Regional	5	6,641	89%	6,599	88%	7,175	96%	6,459	86%

Percent Utilization calculation: Weighted Cath Procedures ÷ (Cath Lab Inventory x 1500)
Source: 2011-2013 SMFPs, Proposed 2014 SMFP

Thus, while there are other highly utilized providers of cardiac catheterization in the state, neither has sought to capitalize on its utilization to obtain additional equipment. Rex, on the other hand, had a lower utilization in 2013 than either Cape Fear Valley or New Hanover

Regional, and would not have generated a need for an additional cardiac cath machine even if it were the only provider in Wake County.

Cardiac Catheterization Equipment Not Analogous to Linear Accelerator Equipment

On page 11, Rex describes the similarities between its cardiac catheterization utilization and the radiation therapy utilization at Duke Raleigh Hospital, which successfully petitioned the SHCC in 2013 for an adjusted need determination for one additional linear accelerator in Service Area 20. Rex quoted former SHCC member Dr. Dennis Clements, who, in recommending approval of Duke Raleigh's petition, said:

> *"Most of these are cancer patients, and you get standardized on one machine you have to stay on that machine. You have maybe ten, twenty maybe more procedures on that machine. The machine tends to be associated with a hospital, often with oncologists in that hospital."*[2]

Rex applies this logic to cardiac catheterization equipment:

> *"Rex believes the cardiac catheterization services and their physicions are similarly associated with one hospital and that capacity is not interchangeable as the SHCC determined in the case of Duke Raleigh."*

Dr. Clements' statement is pertinent, because it makes an important distinction between cancer care and cardiac care. Radiation therapy treatments are typically administered in a series of doses over several weeks, and it is important to receive those treatments with the same machine and staff at a single facility where a plan of care, with many specific treatment points identified, has been developed by an oncologist and other clinical and support staff. Cardiac catheterization is *episodic* – that is, most patients are diagnosed and treated only once for a specific occurrence of coronary blockage(s). Patients do not return multiple times over the course of several weeks to continue their care. Thus, Rex's assertion that cardiac catheterization equipment is comparable to linear accelerator equipment is not true, particularly given the differences in type of care, and because cardiologists may treat patients at two or more hospitals.

Coordination of Care

On page 9, Rex extols the benefits of its electronic medical record in coordinating care between physicians and hospital:

> *"Hospitals and physicians are working together with the benefit of information technology to delivery coordinated services to patients. At Rex, patients see their cardiologist in the adjacent medical office building and receive their ancillary tests such*

[2] Excerpted from discussion at the October 2, 2013 meeting of the State Health Coordinating Council. Referenced on page 12 of the Rex petition.

> *as X-ray, Echo, and EKGs in the hospital. All of that data, including information from their referring primary care physician is captured in Rex's electronic medical record which is available to physicians.*

The scenario Rex describes is commonplace at most hospitals that offer comprehensive cardiac services, particularly as these hospitals continue to develop and implement integrated electronic medical records, including WakeMed and Duke. Later on page 9, Rex attempts to explain why its own electronic medical record is unique:

> *"While other healthcare systems in the region have electronic medical records or allow the cardiologist to bring the patient's medical record from a different facility, these workarounds cannot achieve the level of integration (and the resulting patient benefits) with UNC/Rex Healthcare."*

It is not clear what point Rex is trying to make in the passage above. All three major healthcare systems based in the Triangle area, UNC/Rex, Duke, and WakeMed, recently implemented, or are in the process of implementing, the Epic Electronic Health Record system. As long as hospitals continue to offer open medical staffs, there will be opportunities to share appropriate clinical information between providers when necessary.

Recent Petitions Regarding Adjustments to Fixed Cardiac Catheterization Equipment Need Determinations

In the last three years there have been four petitions requesting adjustments to fixed cardiac catheterization need determinations that are particularly relevant to the substance of the Rex petition.

<u>Iredell Health System – 2011</u>

In 2011, Iredell Health System petitioned for the addition of one unit of fixed cardiac catheterization based on the fact that its existing unit had exceeded the 80 percent utilization threshold for a need determination. However, two other hospitals in the service area had excess capacity so no need determination was generated.

The SHCC denied Iredell's request. The Technology and Equipment Committee recommended denial based on an Agency Report that explained that the petition had used data from a partial fiscal year not yet completed and not consistent with the methodology. In addition, it pointed out that the interventional cardiologists practicing at Iredell also have privileges at one of the other hospitals located only five miles away. Please see Attachment 2 for the Agency Report. Contrary to their argument, the chart on page 15 of the Rex petition specific to Iredell County shows that volume has increased at the nearby underutilized facilities and that Iredell Health System is no longer generating a need.

New Hanover Regional Medical Center – 2011

A second petition also received in 2011 came from New Hanover Regional Medical Center, requesting that a need determination of one unit of fixed cardiac catheterization equipment for New Hanover County be *removed* from the Proposed 2012 SMFP. The petition explained that Wilmington Heart Center, a facility located in the county, was not currently operating, but that it could restart. In addition, NHRMC pointed out that the utilization of cardiac catheterization equipment had been gradually falling and was expected to continue to do so.

The Agency Report recommended approval of the petition. The Technology and Equipment Committee concurred, and the SHCC approved the deletion. Please see Attachment 3 for the Agency Report.

New Hanover Regional Medical Center – 2013

In 2013, New Hanover Regional Medical Center again petitioned the SHCC to *remove* a need determination of one unit of fixed cardiac catheterization equipment for New Hanover County shown in the Proposed 2014 SMFP. The petition explained that the hospital's cardiac catheterization labs were open ten hours a day, five days a week, year-round. The five units of equipment that the hospital operates are therefore available approximately 13,000 hours per year [calculation: 10 hours per day x 5 days per week x 52 weeks per year x 5 units = 13,000]. The petition further stated that the average case time for both diagnostic and therapeutic catheterizations at its facility was approximately one hour each and, as a result, NHRMC considered its catheterization labs were only utilized at 55 percent, even though the methodology used in the SMFP indicated that they were over 95 percent of capacity. The SHCC approved the petition with both the Agency Report (please see Attachment 4) and the Technology and Equipment Committee recommending the action.

Southeastern Regional Medical Center – 2012

Southeastern (SRMC) filed a petition in 2012 for an adjusted need determination for one unit of fixed cardiac catheterization equipment in Robeson County. At the time of the petition, SRMC had one unit of cardiac cath equipment and its volume was approaching the threshold that would allow it to add capacity, but due to numeric rounding it did not trigger a need determination. The Agency Report (contained in Attachment 5) which recommended approval of the petition noted that SRMC is located in a rural county with a high incidence of heart disease, and that SRMC was the only open heart surgery provider in North Carolina with one cardiac cath lab. The SHCC approved the petition based on the recommendations of the Agency and the Technology & Equipment Committee.

Unlike Rex, SRMC is the only provider of cardiac catheterization in its county. Robeson County is rural, socioeconomically disadvantaged, and has one of the state's highest rates of coronary artery disease. In contrast, Wake County is urban, and has been named "North Carolina's Healthiest County" five years in a row by the County Health Rankings and Roadmaps program, a collaboration between the University of Wisconsin Population Health Institute and the Robert

Wood Johnson Foundation. Wake County also has four acute care hospitals that offer cardiac catheterization services. Thus, while Rex and SRMC both have well-utilized cardiac cath programs, the comparisons end there in terms of local demographics and access to services.

SMFP Need Methodology for Cardiac Catheterization Equipment

The petition filed by New Hanover Regional in 2013 is particularly compelling, because it runs counter to the SMFP's need methodology for cardiac catheterization equipment. New Hanover argued successfully that the capacity thresholds in the current need methodology are too low.

The current need methodology for fixed cardiac catheterization equipment was adopted in 2000 and first used in the 2001 SMFP. It was approved using mostly data from the 1990s, during a time when utilization was rising and the SHCC was concerned about staying ahead of the curve and meeting demand. The data contained in WakeMed's comments to Rex's petition filed in Spring 2014 pointed out those trends have reversed. Cardiac catheterization utilization is now falling in all regions of the state. In addition, actual practice demonstrates that the methodology's definition of "capacity" may be understated.

The defined capacity of 1,500 procedures per year, with a weight of 1.00 for diagnostic and 1.75 for therapeutic procedures (in a facility that operates its labs eight hours a day, five days a week, 50 weeks a year or 2,000 hours per year) computes to 1 hour 20 minutes for a diagnostic procedure[3] and 2 hours 20 minutes for a therapeutic procedure[4]. The 2013 NHRMC petition estimated average procedure time to be 1 hour. Other sources also suggest that cardiac cath procedures take much less time that the current methodology assumes. Several internet sites give estimated times as follows:

- American Heart Association – The procedure lasts about an hour;
- Cleveland Clinic – The cardiac catheterization procedure itself generally takes 30 minutes, but the preparation and recovery time add several hours to your appointment time;
- www.cathlabdigest.com – Start to finish, a routine left heart catheterization should take no more than 30 minutes. Add 15 to 20 minutes for a right heart catheterization.

Considering that a need for additional capacity is triggered when average utilization reaches 80 percent, or 1,200 procedures per unit per year, these results suggest that defined capacity should be re-evaluated. First, It is unlikely that cardiac catheterization equipment at most hospitals, with the exception of very low-volume programs, is idle for a full two weeks each year. Likewise, busy interventional cardiology programs are capable of operating more than eight hours per day, to accommodate emergencies and "add-on" cases. In its 2013 petition, New Hanover Regional stated that its cardiac catheterization labs are open 10 hours per day, 5 days a week, 52 weeks (or 260 days) a year, for a total of 2,600 hours per unit per year. Like most hospitals with Code STEMI response teams, WakeMed Raleigh Campus operates cardiac

[3] Calculation: 2000 hours per year ÷ 1500 procedures per year = 1.33 hours, or 1 hour 20 minutes per procedure.
[4] Assuming a diagnostic catheterization takes 1 hour 20 minutes, or 1.33 hours, a therapeutic procedure would take 2 hours 20 minutes [Calculation: 1.33 hours per case x 1.75 weighted = 2.33 hours, or 2 hours 20 minutes per procedure].

cath labs 24/7/365 to treat patients who present to the emergency department with an acute myocardial infarction.

Rex Petition Does Not Enhance Safety and Quality, Access or Value

The Proposed 2015 SMFP shows Wake County with a surplus of 5.11 units of fixed cardiac catheterization equipment. Rex's petition seeks to add to this surplus, which would only serve to duplicate existing resources. Approval of the petition would not have any tangible effect on safety and quality, access or value.

Safety and Quality

Rex speaks of the need to ensure safety and quality for cardiac catheterization services yet the emergency patients described on page 20, who may require interventional treatment within 90 minutes of arrival at the hospital, can be accommodated into a daily schedule. High-volume cardiac catheterization programs make scheduling allowances to handle emergency cases that may present, much as their counterparts in the operating room suite must sometimes make adjustments for emergencies. Emergent cases can be treated in a cardiac cath lab within the 90-minute window.

Delays that result from emergencies happen occasionally in all busy cardiac catheterization programs where late-day procedures are scheduled; the patient would likely need an overnight stay regardless of whether there was a delay. Because Rex provided no statistical or anecdotal information to quantify the extent to which this is a problem, it is impossible to assess whether this is present or potential issue. There is no way to determine whether Rex has an unusually high number of delays or how often they cause problems for patients. Adding cardiac cath capacity will not obviate the occurrence of emergency patients requiring cardiac catheterization.

On page 21, Rex describes potential "disruptions in the continuity of care" if patients and physicians access care at another facility. Given that many Wake County-based cardiologists have practice privileges at multiple facilities, this is not likely to be an issue for many patients.

Access

Despite Rex's assertions, the petition contained no data or anecdotal evidence to demonstrate that access to cardiac catheterization equipment would be enhanced if it were approved. On page 21, Rex discusses the need to improve access for its main cardiology group:

> *"...North Carolina Heart and Vascular, the cardiology physician practice at Rex Hospital see patients in 19 offices in ten counties. Increasing these physicians' access to cardiac catheterization capacity will in turn broaden the access for these patients across a broad region, including areas where no cardiac catheterization capacity exists or is only pravided an a diagnastic basis."*

Because physicians at N.C. Heart & Vascular have access to cardiac catheterization labs at multiple Wake County hospitals, as shown in Tables 3 and 4 above, the Rex petition is more about the desire to continue to shift procedures between hospitals than about improving access for patients.

Value

Rex believes that its petition "promotes value", but in an era where population health management, cost containment and accountable care are being actively promoted, continued development of excess capacity in a service area does little to add value and only increases costs to our community as a whole.

Summary

Approval of the Rex petition would only serve to exacerbate the growing surplus of fixed cardiac catheterization equipment in Wake County. An additional cardiac cath lab in Wake County would do nothing to contain costs, improve access, or enhance quality. All health systems should work more closely to coordinate care and invest in services that meet an unmet need.

Thank you for your consideration of these comments. If you have questions or require additional information, please do not hesitate to contact Stan Taylor at 919-350-8108.

Very respectfully,

Donald R. Gintzig
President & CEO

Attachment 1

WakeMed Comments Regarding Rex Healthcare Petition Filed in Spring 2014

WakeMed
WakeMed Health & Hospitals
3000 New Bern Avenue
Raleigh, North Carolina 27610
919-350-8000

March 21, 2014

VIA ELECTRONIC MAIL

Mr. Jerry Parks, Chairman
North Carolina State Health Coordinating Council
c/o Division of Health Service Regulation
Medical Facilities Planning Branch
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Comments Opposing Petition Filed by Rex Healthcare to Change the Cardiac Catheterization Need Determination Methodology

Dear Mr. Parks and Members of the State Health Coordinating Council:

WakeMed appreciates the opportunity to comment on the petition filed by Rex Healthcare to change the Cardiac Catheterization Need Determination Methodology for the 2015 State Medical Facilities Plan (SMFP). For the reasons outlined below, WakeMed believes this petition should be denied.

Rex seeks to impose significant changes to the Cardiac Catheterization Need Determination Methodology, particularly in Steps 5 and 6, and adds a section for "Qualified Applicants" that would exclude any facility from applying from a need determination in its service area that does not perform at least 1,200 diagnostic-equivalent procedures per unit of equipment.

This request *is* at best premature, and at worst may never be needed. Cardiac catheterization volume trends are declining, and this petition would unnecessarily modify the methodology.

Cardiac Catheterization Volumes Declining

Based on information provided in annual License Renewal Applications, the number of cardiac catheterization procedures has been declining in recent years both statewide and in Wake County. In 2009, a total of 114,740 weighted, diagnostic-equivalent cardiac catheterization procedures[1] were performed in North Carolina facilities. In 2013, total volume had declined to 108,486, a 5.5 percent *decrease*. Total diagnostic-equivalent cardiac catheterizations have decreased statewide each year since peaking in 2010. Please see Attachment 1. Based on 2013 utilization, no cardiac catheterization equipment service area in the state will generate need for additional cardiac cath equipment in the 2015 SMFP.

Among Wake County facilities, diagnostic-equivalent cardiac catheterization volume *declined* 14.5 percent from 2009-2013. Mirroring the statewide trend, total cardiac catheterization procedures have also decreased each year since 2010. Please see the following table.

[1] Diagnostic cardiac catheterizations weighted at 1.00, interventional cardiac catheterizations weighted at 1.75, pediatric cardiac catheterizations weighted at 2.00.

Table 1
Diagnostic-Equivalent Cardiac Catheterization Volumes at Wake County Facilities
2009-2013

Facility	2009	2010	2011	2012	2013	Percent Change 2009-13	CAGR 2009-13
Duke Raleigh Hospital	770	967	701	366	447	-41.9%	-12.7%
Rex Hospital	3,489	3,002	3,132	3,875	5,029	44.1%	9.6%
WakeMed Cary Hospital	325	382	325	282	222	-31.7%	-8.3%
WakeMed Raleigh Campus	12,108	12,618	12,130	10,535	8,570	-29.2%	-9.1%
Total	16,692	16,969	16,288	15,058	14,268	-14.5%	-3.8%

Source: 2010-2014 License Renewal Applications

Wake County's hospitals operate a total of 17 units of fixed cardiac catheterization equipment. Based on 2013 utilization, the aggregate Wake County Service Area need is for 11.89 units, a surplus of 5 units when rounded to the nearest whole number. Please see the following table.

Table 2
2013 Cardiac Catheterization Equipment Inventory and Need in Wake County Service Area

Facility	Planning Inventory	2013 Diagnostic-Equivalent Procedures	Utilization Based on 1,200 Procs/Unit	Procedures Per Unit	Units Required at 80% Utilization
Duke Raleigh Hospital	3	447	10%	149.0	0.37
Rex Hospital	4	5,029	84%	1257.3	4.19
WakeMed Cary Hospital	1	222	15%	222.0	0.19
WakeMed Raleigh Campus	9	8,570	63%	952.2	7.14
Total	17	14,268	56%	839.3	11.89

Source: 2014 License Renewal Applications

The declines in cardiac catheterization utilization in Wake County and in North Carolina are also being experienced nationally, and are projected to continue. The Advisory Board Company projects that inpatient cardiac cath procedure volumes will decrease 22 percent nationally from 2012-2017, and that outpatient cardiac caths will decline 7 percent. Percutaneous coronary intervention volumes are projected to decline 15 percent over the same period.[2]

Rex Healthcare's Cardiac Catheterization Equipment Can Absorb Additional Volume

While Rex's 2013 utilization suggests that it currently needs 4.19 units of cardiac catheterization equipment, this equates to 83.8 percent utilization, based on capacity of 1,500 weighted diagnostic-equivalent procedures per unit [calculation: 5,029 diagnostic-equivalent procedures ÷ (1,500 x 4) = 0.838]. This is the first year Rex's cardiac catheterization equipment utilization has exceeded its

[2] Source: *Cardiovascular Market Trends for 2014*, The Advisory Board Company, Cardiovascular Roundtable & Service Line Strategy Advisor, published March 10, 2014, accessed at: http://www.advisory.com/Research/Service-Line-Strategy-Advisor/Resources/2014/Cardiovascular-Market-Trends, 3/19/2014.

planning inventory since 2006, and is its highest diagnostic-equivalent procedure volume since 2004. Please see the following table.

Table 3
Rex Hospital Cardiac Catheterization Utilization, 2004-2013

Year	Cardiac Cath Planning Inventory	Weighted Cardiac Cath Procedures	Units Required at 80% Utilization[3]	Percent Utilization[4]	Cath Procedures Per Unit
2004	3	4,206	3.51	93.5%	1,402
2005	3	3,897	3.25	86.6%	1,299
2006	3	4,015	3.35	89.2%	1,338
2007	3	3,557	2.96	79.0%	1,186
2008	3	3,581	2.98	79.6%	1,194
2009	4	3,489	2.91	58.2%	872
2010	4	3,002	2.50	50.0%	751
2011	4	3,132	2.61	52.2%	783
2012	4	3,875	3.23	64.6%	969
2013	4	5,029	4.19	83.8%	1,257

Sources: 2006-2013 SMFPs, 2014 License Renewal Application

Rex has operated at higher utilization in prior years, and has indicated that it could do so with its current inventory of cardiac cath equipment. In its response to comments filed during the 2011 Wake County Acute Care Bed CON Review, Rex indicated that its cardiac catheterization lab utilization could be extended well beyond its current utilization. As evidenced in the passage below, Rex acknowledges that it believes it can operate its cardiac catheterization equipment well above the 80 percent threshold:

> *Moreover, Rex is currently taking immediate steps to increase its cardiac cath capacity by implementing its approved fourth cardiac cath on an interim basis in administrative space and by extending cath lab hours to 9 pm. These actions will allow Rex to achieve greater cath capacity than WakeMed has assumed at an earlier date. While WakeMed contends that 1,500 procedures per lab is the maximum capacity, its historic experience as well as that of other providers suggests that cath labs can operate well above that level:*

Year	*Facility*	*Weighted Procedures*	*Current Cath Lab Inventory*	*Weighted Procedures per Lab*
2008	*High Point Regional*	*8,443*	*4*	*2,110*
2008	*New Hanover Regional*	*6,421*	*3*	*2,140*
2007	*Frye Regional*	*5,727*	*3*	*1,909*
2007	*New Hanover Regional*	*6,189*	*3*	*2,063*
2006	*Frye Regional*	*5,353*	*3*	*1,784*
2006	*New Hanover Regional*	*5,975*	*3*	*1,991*
2005	*WakeMed*	*11,984*	*7*	*1,712*
2005	*Frye Regional*	*4,593*	*2*	*2,296*

[3] Calculation: [Weighted cardiac cath procedures ÷ 1,200].
[4] Calculation: [Weighted cardiac cath procedures ÷ (Cardiac cath planning inventory x 1,500)].

Source: 2007 to 2010 SMFPs

In addition, WakeMed has projected or exhibited greater than 100 percent utilization of similar assets in prior CON applications. In the 2010 WakeMed Cary OR Application (Project ID# J-8463-10), WakeMed Raleigh projected, on page 68, to provide 31,319 surgical hours in 2015 with 13 ORs or over 100 capacity as defined in the SMFP (103 percent = 31,319 ÷ 9 hours per day ÷ 260 days per year ÷ 13 ORs).

Table II.31
WakeMed Raleigh Campus
Surgery Hours and Operating Rooms Needed, FYs 2013-2015
Excluding Cases Performed in Dedicated Open Heart ORs, Trauma Cases, and Cases Performed in Dedicated C-Section Rooms

Fiscal Year	IP Cases *(from Table II.27)*	IP Hours *(Cases x 3.0)*	OP Cases *(from Table II.27)*	OP Hours *(Cases x 1.5)*	Total Cases	Total Hours	ORs Needed *(Total Hrs ÷ 1872)*	Current Surgical OR Inventory[12]	OR Surplus/ (Deficit)
2013	7,774	23,321	3,658	5,487	11,432	28,808	15.4	13	(2.4)
2014	8,109	24,327	3,816	5,724	11,925	30,051	16.1	13	(3.1)
2015	8,451	25,353	3,977	5,966	12,428	31,319	16.7	13	(3.7)

See page 68.

Similarly, in its 2007 application to add one cardiac cath unit (Project ID# J-8018-07), WakeMed stated that had been operating its cardiac cath equipment above 100 percent of capacity for four years:

> ***Cardiac Catheterization Utilization at WakeMed Raleigh Campus Using Data from Hospital License Renewal Application***
>
> *Counting only the diagnostic and interventional cardiac catheterization procedures recognized in the annual Hospital License Renewal Application, utilization of cardiac catheterization equipment at WakeMed Raleigh Campus has been consistently high in recent years. WakeMed Raleigh Campus's cardiac catheterization diagnostic-equivalent procedure utilization was above 95% of capacity as defined by the State since 2000, and was over 100% capacity from 2000-2004. Please see the following table.*
>
> *See page 45.*

Given that there is significant evidence that other providers have exceeded the maximum capacity that WakeMed assumes and maintained that level of utilization over time, Rex believes it too can provide more than 1,500 diagnostic equivolent procedures per lab, if necessary. Rex recognizes that this is not ideal, but as the historic utilization of other providers shown above demonstrates, it can be achieved and will be achieved in order to treat Rex's patients. If Rex

> *operates at such a high level of utilization, then a need for additional cardiac cath labs in Wake County would be generated and Rex would apply to develop those resources.*[5]

[emphasis added]

Please see Attachment 2 for the pages referenced above.

In a deposition taken during the Contested Case that followed the Wake County Acute Care Bed Review, a consultant for Rex Healthcare provided his opinions regarding "capacity" of cardiac catheterization equipment:

> Page 113
> And this approach is taken for--in three different iterations. The next is Pages 228580 and 228581 with the distinguishing factor being the capacity of a cath lab. In this--the next page you'll see on Page--in Table 5 Column C, we've identified the capacity of a cath lab to be 1,712. And that is referenced in the Agency--references the Agency file on Page 854, which is our response to comments. And that is actually what WakeMed has achieved in 2005. So WakeMed in 2005 provided 1,712 caths per lab. Using that analysis, we show the occupancy rates below average. There's not much distinguishing factors between that.
>
> Page 114
> The final analysis uses the cath capacity--I'm sorry, the capacity of a cath lab from Frye Regional in the same year that we are discussing for WakeMed, 2,296 caths per lab.[6]

[emphasis added]

Please see Attachment 3 for the pages referenced above.

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[5] Excerpted from "Response to Comments on Rex Hospital's CON Applications to Develop Additional Acute Care Beds in Wake County (Project Nos. J-8667-11, J-8669-11 and J-8670-11)", submitted to Certificate of Need Section June 20, 2011, pages 15-16.

[6] Excerpted from the deposition of Nathan Marvelle, March 6, 2012, pages 113-114, in Case Nos. 11 DHR 12727, 11 DHR 12794, 11 DHR 12795 and 11 DHR 11796, filed at the Office of Administrative Hearings.

This testimony, along with comments made by Rex during the 2011 Wake County Acute Care Bed CON Review, makes it apparent that Rex believes the capacity of a cardiac catheterization lab may be 1,712-2,296 procedures per unit. It is clear that Rex believes it can operate its cardiac cath equipment well above the State's definition of capacity (1,200 diagnostic-equivalent procedures). Modification of the SMFP's Cardiac Catheterization Need Determination Methodology when Rex has been utilized above 80 percent for only one year is premature and unnecessary.

Proposed Modification to Methodology Would Only Benefit Rex Healthcare

Petitions filed during the Spring for consideration for the next year's SMFP are typically reserved for requests that involve changes in policies or methodologies that may have a statewide effect, which the SHCC and its committees have the opportunity to consider during the planning year. Upon closer analysis of Rex Healthcare's proposed modifications to the Cardiac Catheterization Need Determination Methodology, it becomes apparent that Rex would be the only likely beneficiary of the changes. For counties with more than one provider of fixed cardiac catheterization, Rex was the only provider with utilization of greater than 1,200 procedures per unit (see Attachment 1). If adopted as proposed, Rex's modifications of the Cardiac Catheterization Need Determination Methodology would preclude all providers in Wake County, except Rex, from even applying for additional cardiac cath equipment.

Rex's assertion on page 5 that "it is unlikely that that many providers will generate a need in the near future" casts into doubt why this petition is being proposed in the first place. Over the last five years, only 4 units of fixed cardiac catheterization equipment have been allocated statewide in the annual SMFPs – only *one* of these allocations resulted from a need determination generated through the Cardiac Catheterization Need Determination Methodology (Craven/Jones/Pamlico Service Area - 2013 SMFP). In 2013, New Hanover Regional Medical Center filed a petition for an Adjusted Need Determination to eliminate the allocation of one unit of cardiac cath equipment for New Hanover County.

Approval of Petition Would Have Adverse Effects

The Rex petition represents an unnecessary modification to a need methodology that has served the State well in its current iteration. According to Rex on page 6, "[a] provider could operate above the utilization standards indefinitely and not be able to acquire additional capacity, if another provider in its community was sufficiently underutilized." Rex further contends that filing a petition for an adjusted need determination "would, at best, result in a one-time allocation and would fail to address the problematic aspects of the current methodology" and "would not address potential issues in other counties or issues that arise in future years" (page 7). These are precisely the circumstances that are typically addressed by petitions for adjusted need determination.

The proposed Step 6(a) would trigger a need determination in a service area in the next year's SMFP when a *single provider* calculates a deficit threshold of 0.1 or greater. There are inherent problems with this step. First, a provider need have only one year of sufficiently high utilization to trigger the need determination, regardless of their utilization in prior years. Second, the 0.1 deficit threshold is barely above 80 percent utilization, particularly if a provider has several cath labs. The current methodology sums the number of machines required for *all facilities* in a service area (rounding to the nearest whole number), then subtracts that number from the total planning inventory for the service area to determine number of units of cardiac catheterization equipment needed.

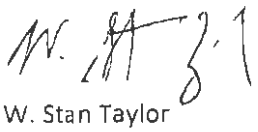
The proposed addition of "Qualified Applicants" effectively shuts out any potential applicant for a need allocation save for the provider that created the need determination. If adopted, this would create a form of inequity with "haves" and "have-nots" – essentially, providers with lower utilization would likely never generate sufficient volume to create a need determination of their own, and they would not be eligible to apply for the need determinations generated by other providers. The obvious by-product of this change would perpetuate underutilization of existing equipment and unnecessary duplication of resources.

The reality is that, given the trend of declining fixed cardiac catheterization equipment utilization locally and nationally, Rex's petition is unnecessary. Modification of the need methodology would have no impact on cost, quality or value. Physicians can and do perform procedures in more than one facility in a service area.

Summary

In conclusion, the Rex Healthcare petition would do little, if anything, to improve access to fixed cardiac catheterization in North Carolina. The petition is unnecessary, untimely, seeks to correct a problem that does not exist, and represents bad health policy. WakeMed respectfully requests that the petition be denied. Thank you for your consideration of these comments. If you have questions or require additional information, please call me at 919-350-8108.

Sincerely,



W. Stan Taylor
Vice President, Corporate Planning

ATTACHMENT 1

Diagnostic-Equivalent Cardiac Catheterization Procedures by Service Area and Facility
2009-2013
Includes Adult & Pediatric Diagnostic Cardiac Caths, Percutaneous Coronary Interventions
Sources: 2014 State Medical Facilities Plan (Tables 9S, 9T and 9V), 2014 License Renewal Applications on file at DHSR

Service Area	Facility	2009	2010	2011	2012	2013	Percent Change, 2009-13	CAGR, 2009-13	2013 Planning Inventory	2013 Units Req. at 80% Util.
Alamance	Alamance Regional Medical Ctr.	1,222	1,398	1,133	1,109	1,007	-17.6%	-4.7%	1	0.84
Buncombe/Graham/ Madison/Yancey	Mission Hospital	5,818	5,586	5,485	5,492	5,238	-10.0%	-2.6%	6	4.37
Burke	CMC-Blue Ridge	393	795	426	566	453	15.3%	3.6%	1	0.38
Cabarrus	CMC-NorthEast	2,067	2,238	2,414	2,172	2,103	1.7%	0.4%	2	1.75
Caldwell	Caldwell Memorial Hospital	331	190	91	169	323	-2.4%	-0.6%	1	0.27
Catawba	Catawba Valley Medical Ctr.	549	445	440	555	658	19.9%	4.6%	1	0.55
	Frye Regional Medical Ctr.	5,171	5,473	4,612	4,662	4,408	-14.8%	-3.9%	4	3.67
Total for Service Area		5,720	5,918	5,052	5,217	5,066	-11.4%	-3.0%	5	4
Cleveland	Cleveland Regional Medical Ctr.	396	333	305	194	305	-23.0%	-6.3%	1	0.25
Craven/Jones/ Pamlico	CarolinaEast Medical Ctr.	2,306	2,722	3,205	2,538	2,304	-0.1%	0.0%	3	1.92
Cumberland	Cape Fear Valley Medical Ctr.	3,558	3,405	3,800	4,005	3,906	9.8%	2.4%	3	3.26
Durham/Caswell	Duke Regional Hospital	1,164	1,046	1,015	958	834	-28.4%	-8.0%	2	0.70
	Duke University Hospital	6,696	7,451	7,232	7,366	6,739	0.6%	0.2%	7	5.62
Total for Service Area		7,860	8,497	8,247	8,324	7,573	-3.7%	-0.9%	9	6
Forsyth	North Carolina Baptist Hospital	3,376	3,129	3,268	3,176	3,361	-0.4%	-0.1%	5	2.80
	Novant Health Forsyth Medical Ctr.	5,667	5,101	4,550	4,511	4,612	-18.6%	-5.0%	8	3.84
Total for Service Area		9,043	8,230	7,818	7,687	7,973	-11.8%	-3.1%	13	7
Gaston	Caromont Regional Medical Ctr.	3,672	4,100	3,766	3,929	3,188	-13.2%	-3.5%	4	2.66

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2009-2013
Includes Adult & Pediatric Diagnostic Cardiac Caths, Percutaneous Coronary Interventions
Sources: 2014 State Medical Facilities Plan (Tables 9S, 9T and 9V), 2014 License Renewal Applications on file at DHSR

Service Area	Facility	2009	2010	2011	2012	2013	Percent Change, 2009-13	CAGR, 2009-13	2013 Planning Inventory	2013 Units Req. at 80% Util.
Guilford	Cardiovascular Diagnostic Ctr.	992	970	891	837	830	-16.3%	-4.4%	1	0.69
	Cone Health	5,044	5,261	5,793	5,701	5,245	4.0%	1.0%	7	4.37
	Greensboro Heart & Sleep Ctr. *[CLOSED]*	464	302	120	0	0	-100.0%	-100.0%	0	0.00
	High Point Regional Health	5,552	5,252	4,870	4,371	3,973	-28.4%	-8.0%	4	3.31
Total for Service Area		12,052	11,785	11,674	10,909	10,048	-16.6%	-4.4%	12	8
Halifax/Northampton	Halifax Regional Medical Ctr.	83	95	102	85	70	-15.7%	-4.2%	1	0.06
Haywood	MedWest Haywood	171	276	308	299	226	32.2%	7.2%	1	0.19
Henderson	Margaret Pardee Memorial Hosp.	165	168	158	91	102	-38.2%	-11.3%	1	0.09
Iredell	Davis Regional Medical Ctr.	258	153	432	407	441	70.9%	14.3%	1	0.37
	Iredell Memorial Hosp.	814	806	1,445	1,281	1,194	46.7%	10.1%	1	1.00
	Lake Norman Regional Medical Ctr.	126	77	23	44	53	-57.9%	-19.5%	1	0.04
Total for Service Area		1,198	1,036	1,900	1,732	1,688	40.9%	9.0%	3	1
Johnston	Johnston Memorial Hosp.	442	472	292	434	576	30.3%	6.8%	1	0.48
Lee	Central Carolina Hospital	0	0	0	0	186	NA	NA	1	0.16
Lenoir	Lenoir Memorial Hosp.	357	439	328	254	781	118.8%	21.6%	1	0.65
Mecklenburg	Carolinas Medical Center	7,657	7,281	7,302	5,929	6,478	-15.4%	-4.1%	7	5.40
	CMC-Mercy/Pineville	1,527	1,758	2,195	2,394	3,552	132.6%	23.5%	4	2.96
	CMC-University	153	121	68	87	39	-74.5%	-28.9%	1	0.03
	Novant Health Matthews Medical Ctr.	566	584	690	786	765	35.2%	7.8%	1	0.64
	Novant Health Presbyterian Medical Ctr.	3,967	4,289	3,638	3,770	3,447	-13.1%	-3.5%	4	2.87
Total for Service Area		13,870	14,033	13,893	12,966	14,281	3.0%	0.7%	17	12
Moore	FirstHealth Moore Regional Hosp.	6,331	6,243	4,723	5,238	5,340	-15.7%	-4.2%	5	4.45

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2009-2013
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Sources: 2014 State Medical Facilities Plan (Tables 9S, 9T and 9V), 2014 License Renewal Applications on file at DHSR

Service Area	Facility	2009	2010	2011	2012	2013	Percent Change, 2009-13	CAGR, 2009-13	2013 Planning Inventory	2013 Units Req. at 80% Util.
Nash	Nash General Hospital	754	709	1,434	1,495	1,334	76.9%	15.3%	2	1.11
New Hanover	New Hanover Regional Medical Ctr.	6,564	6,641	6,596	7,172	6,456	-1.6%	-0.4%	5	5.38
	Wilmington Heart Center *[CLOSED]*	977	916	386	0	0	-100.0%	-100.0%	0	0.00
Total for Service Area		7,541	7,557	6,982	7,172	6,456	-14.4%	-3.8%	5	5
Onslow	Onslow Memorial Hospital	45	16	17	1	0	-100.0%	-100.0%	1	0.00
Orange	UNC Hospitals	3,443	3,469	3,581	3,982	3,400	-1.2%	-0.3%	4	2.83
Pasquotank/Camden/ Currituck/Perquimans	Albemarle Hospital	860	789	791	964	922	7.2%	1.8%	1	0.77
Pitt	Vidant Medical Center	5,131	5,428	5,056	4,813	4,439	-13.5%	-3.6%	7	3.70
Randolph	Randolph Hospital	7	2	3	3	1	-85.7%	-38.5%	1	0.00
Robeson	Southeastern Regional Medical Ctr.	1,188	924	1,363	1,532	1,603	34.9%	7.8%	2	1.34
Rowan	Novant Health Rowan Medical Ctr.	701	629	724	719	634	-9.6%	-2.5%	1	0.53
Rutherford	Rutherford Regional Medical Ctr.	42	20	70	39	64	52.4%	11.1%	1	0.05
Scotland	Scotland Memorial Hospital	0	0	36	502	429	NA	NA	1	0.36
Stanly	Stanly Regional Medical Ctr.	29	23	7	0	0	-100.0%	-100.0%	1	0.00
Union	CMC-Union	379	489	536	411	264	-30.3%	-8.6%	1	0.22

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2009-2013
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Sources: 2014 State Medical Facilities Plan (Tables 9S, 9T and 9V), 2014 License Renewal Applications on file at DHSR

Service Area	Facility	2009	2010	2011	2012	2013	Percent Change, 2009-13	CAGR, 2009-13	2013 Planning Inventory	2013 Units Req. at 80% Util.
Wake	Duke Raleigh Hospital	770	967	701	366	447	-41.9%	-12.7%	3	0.37
	Rex Hospital	3,489	3,002	3,132	3,875	5,029	44.1%	9.6%	4	4.19
	WakeMed	12,108	12,618	12,130	10,535	8,570	-29.2%	-8.3%	9	7.14
	WakeMed Cary Hospital	325	382	325	282	222	-31.7%	-9.1%	1	0.19
Total for Service Area		16,692	16,969	16,288	15,058	14,268	-14.5%	-3.8%	17	12
Watauga	Watauga Medical Center	99	28	11	238	768	675.8%	66.9%	1	0.64
Wayne	Wayne Memorial Hospital	362	258	237	229	649	79.3%	15.7%	1	0.54
Wilkes	Wilkes Regional Medical Ctr.	0	0	0	0	0	0.0%	0.0%	1	0.00
Wilson	Wilson Medical Center	412	361	429	682	518	25.7%	5.9%	1	0.43
TOTAL		**114,740**	**115,630**	**112,685**	**111,250**	**108,486**	**-5.5%**	**-1.4%**		

ATTACHMENT 2

Received 6/20/11
Public Hearing

Response to Comments on Rex Hospital's (Rex's) CON Applications to Develop Additional Acute Care Beds in Wake County (Project ID #s J-8667-11, J-8669-11, and J-8670-11)

Below, Rex has grouped comments submitted on its applications by issue, followed by Rex's response in italics. Please note that in some instances for the sake of brevity, Rex has produced only a portion of a comment; however, it is responding to each comment in its entirety.

CRITERION 3 ISSUES

RESPONSE TO COMMENTS REGARDING POPULATION TO BE SERVED

Comments:

On page 177 of its Application Rex states that they have "excluded" zip codes where some of the population is closer to Rex's existing hospital and to other acute care providers than to the proposed site. Following this logic, Rex also should have excluded zip code 27606 as 100% of the zip is closer to Rex's existing hospital AND to WakeMed Cary. Therefore, Rex's statement on page 178 that inclusion of portions of zip 27606 "is appropriate as the proposed hospital would be closer or more convenient for residents of the areas within ten miles than Rex or other acute care providers in the county," is incorrect.

The proposed Rex Hospital Holly Springs is not closer for residents of zip 27606 and Rex provides no discussion or documentation to support that traveling further for hospital or outpatient care at Rex Holly Springs would be more convenient for residents of zip 27606. Therefore, the population to be served is overstated which results in overstated volumes for all proposed inpatient and outpatient services at Rex Holly Springs.

Page 2 of Novant's Comments submitted on Rex Hospital Holly Springs.

> Rex's assumptions about patient origin for the Rex Holly Springs linear accelerator seem to suggest a change existing referral patterns and the capture substantial market share from existing providers by locating a satellite cancer center and linear accelerator at the proposed new hospital in Holly Springs. These assumptions are unsupported and unexplained in the Rex Holly Springs application. The 14-step Rex Holly Springs linear accelerator need method fails to take into consideration the context of the existing market and its referral patterns and the impact of a linear accelerator in Holly Springs on existing radiation therapy providers.

Page 9 of Novant's Comments submitted on Rex Hospital Holly Springs.

have historically accounted for over 62 percent of total caths at Rex. Likewise, for Wake Heart & Vascular Associates, approximately two-thirds of total caths are outpatient. WakeMed's summary analysis concludes that 46.6 percent of Wake Heart & Vascular Associates' cath procedures will be in excess of Rex's capacity; as such, even by WakeMed's analysis the majority (53.6 percent) of Wake Heart & Vascular Associates' cath procedures can shift. Given that outpatient cath is majority of total caths, Rex will have the capacity to treat Wake Heart & Vascular Associates' inpatient caths.

Moreover, Rex is currently taking immediate steps to increase its cardiac cath capacity by implementing its approved fourth cardiac cath on an interim basis in administrative space and by extending cath lab hours to 9 pm. These actions will allow Rex to achieve greater cath capacity than WakeMed has assumed at an earlier date. While WakeMed contends that 1,500 procedures per lab is the maximum capacity, its historic experience as well as that of other providers suggests that cath labs can operate well above that level:

Year	Facility	Weighted Procedures	Current Cath Lab Inventory	Weighted Procedures per Lab
2008	High Point Regional	8,443	4	2,110
2008	New Hanover Regional	6,421	3	2,140
2007	Frye Regional	5,727	3	1,909
2007	New Hanover Regional	6,189	3	2,063
2006	Frye Regional	5,353	3	1,784
2006	New Hanover Regional	5,975	3	1,991
2005	WakeMed	11,984	7	1,712
2005	Frye Regional	4,593	2	2,296

Source: 2007 to 2010 SMFPs.

In addition, WakeMed has projected or exhibited greater than 100 percent utilization of similar assets in prior CON applications. In the 2010 WakeMed Cary OR Application (Project ID# J-8463-10), WakeMed Raleigh projected, on page 68, to provide 31,319 surgical hours in 2015 with 13 ORs or over 100 percent of capacity as defined by the SMFP (103 percent = 31,319 ÷ 9 hours per day ÷ 260 days per year ÷ 13 ORs).

Table II.31 WakeMed Raleigh Campus Surgery Hours and Operating Rooms Needed, FYs 2013-2015 *Excluding Cases Performed In Dedicated Open Heart ORs, Trauma Cases, and Cases Performed In Dedicated C-Section Rooms*									
Fiscal Year	IP Cases *(from Table II.27)*	IP Hours *(Cases x 3.0)*	OP Cases *(from Table II.27)*	OP Hours *(Cases x 1.5)*	Total Cases	Total Hours	ORs Needed *(Total Hrs ÷ 1872)*	Current Surgical OR Inventory[12]	OR Surplus/ (Deficit)
2013	7,774	23,321	3,658	5,487	11,432	28,808	15.4	13	(2.4)
2014	8,109	24,327	3,816	5,724	11,925	30,051	16.1	13	(3.1)
2015	8,451	25,353	3,977	5,966	12,428	31,319	16.7	13	(3.7)

See *page 68.*

Similarly, in its 2007 application to add one cardiac cath unit (Project ID# J-8017-07), WakeMed stated that had been operating its cardiac cath equipment above 100 percent of capacity for four years:

Cardiac Catheterization Utilization at WakeMed Raleigh Campus Using Data from Hospital License Renewal Application

Counting only the diagnostic and interventional cardiac catheterization procedures recognized in the annual Hospital License Renewal Application, utilization of cardiac catheterization equipment at WakeMed Raleigh Campus has been consistently high in recent years. WakeMed Raleigh Campus's cardiac catheterization diagnostic-equivalent procedure utilization was above 95% of capacity as defined by the State since 2000, and was over 100% capacity from 2000-2004. Please see the following table.

See *page 45.*

Given that there is significant evidence that other providers have exceeded the maximum capacity that WakeMed assumes and maintained that level of utilization over time, Rex believes it too can provide more than 1,500 diagnostic equivalent procedures per lab, if necessary. Rex recognizes that this is not ideal, but as the historic utilization of other providers shown above demonstrates, it can be achieved and will be achieved in order to treat Rex's patients. If Rex operates at such a high level of utilization, then a need for additional cath labs in Wake County would be generated and Rex would apply to develop those resources.

Finally, WakeMed assumes that Rex will only have have four cath labs by 2017. Rex projects that the shift of Wake Heart & Vascular Associates' inpatient utilization will occur over several years. The population growth in Wake County in recent years has resulted in additional need determinations for inpatient beds, operating rooms, MRI units, and other health care services.

ATTACHMENT 3

STATE OF NORTH CAROLINA — IN THE OFFICE OF ADMINISTRATIVE HEARINGS

COUNTY OF WAKE

HOLLY SPRINGS HOSPITAL II, LLC, Petitioner,	)	
v.	)	11 DHR 12727
N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION, Respondent,	)	
and	)	
REX HOSPITAL, INC., HARNETT HEALTH SYSTEM, INC. and WAKEMED, Intervenors.	)	

(CAPTION CONTINUED ON NEXT PAGE)

DEPOSITION OF
NATHAN MARVELLE

TUESDAY, MARCH 6, 2012
2:02 P.M.

AT THE OFFICES OF
SMITH MOORE LEATHERWOOD LLP
300 NORTH GREENE STREET, SUITE 1400
GREENSBORO, NORTH CAROLINA

VOLUME I

scenario assumes that Wakefield is not developed, those days are also subtracted. And then you have revised ADCs, and the occupancy rate, per the Agency's decision, assuming all we've discussed, would be 79.3 percent.

And then, finally, the scenario where Rex is awarded no beds. Again, Wakefield days are taken out. Holly Springs days that I did, you know, the same scenario for Wakefield days are taken out. And the revised occupancy rate of 87.4 percent.

And this approach is taken for--in three different iterations. The next is Pages 228580 and 228581 with the distinguishing factor being the capacity of a cath lab. In this--the next page you'll see on Page--in Table 5 Column C, we've identified the capacity of a cath lab to be 1,712. And that is referenced in the Agency--references the Agency file on Page 854, which is our response to comments. And that is actually what WakeMed has achieved in 2005. So WakeMed in 2005 provided 1,712 caths per lab.

Using that analysis, we show the occupancy rates below average. There's not much distinguishing factors between that.

The final analysis uses the cath capacity--I'm sorry, the capacity of a cath lab from Frye Regional in the same year that we are discussing for WakeMed, 2,296 caths per lab. And that results in revised occupancy rates as shown.

And then just to point out one other thing, I have provided an excerpt of the State Medical Facilities Plan behind that and--behind these pages in the exhibit, which shows those providers and their cath utilization in that year.

Q. So is the bottom line in here in your opinion is that you believe that Rex has sufficient capacity to handle the cath volume attributable to the Wake Heart and Vascular doctors?

A. Yes, I mean, I think what I discussed in the response to comments in terms of, you know, our response to WakeMed that we--you know, that we could provide additional capacity, and also I think this--this deposition exhibit is responding to the premise that WakeMed has put forward that 1,500 is the maximum and that all days are associated, I think was responsive to certain points that they made and rebutting certain points. But, yes, I think in--in summary it says

Attachment 2

Agency Report – Iredell Health System

2011 Petition

Technology and Equipment Committee
Agency Report on
An Adjusted Need Determination Petition for
Shared Fixed Cardiac Catheterization Equipment at
Iredell Memorial Hospital
Proposed 2012 State Medical Facilities Plan

Petitioner:
Iredell Health System
557 Brookdale Drive
(P.O. Box 1828)
Statesville, NC 28677

Contact:
Ed Rush, President and CEO
704-873-5661

Request:

The Petitioner, Iredell Health System (IHS), requests an adjusted need determination for one shared fixed cardiac catheterization laboratory in Iredell County in a program that provides both diagnostic and therapeutic (interventional) cardiac catheterization. The Petition specifies that the certificate of need applicant for the shared fixed cardiac catheterization unit must use existing equipment and show evidence that therapeutic catheterization procedures have been provided for the past 12 months.

Background Information:

The "Proposed 2012 State Medical Facilities Plan (SMFP)" provides two need determination methodologies for cardiac catheterization equipment. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment, and Methodology Two is the need determination methodology for shared fixed cardiac catheterization equipment. Application of these methodologies to utilization data in the "Proposed 2012 SMFP" does not generate a need determination for fixed cardiac catheterization equipment or for shared fixed cardiac catheterization equipment in Iredell County.

Shared fixed cardiac catheterization equipment is defined in the SMFP as "fixed equipment that is used to perform both cardiac catheterization procedures and angiography procedures." In practice, Methodology Two applies to cardiac catheterization service areas that do not offer fixed cardiac catheterization equipment, as stated:

"For cardiac catheterization equipment service areas in which a unit of fixed cardiac catheterization equipment is not located, need exists for one shared cardiac catheterization equipment (i.e. fixed equipment that is used to perform both cardiac catheterization procedures and angiography procedures) when:

a. *The number of cardiac catheterization procedures as defined in 10A NCAC 14C .1601 (5) performed at any mobile site in the cardiac catheterization service area exceeds 240 (300 procedures X 80 percent) procedures per year for eight hours per week the mobile*

equipment is operated at the site during the 12 month period reflected in the 2010 Hospital License Renewal Application or the 2010 Registration and Inventory of Cardiac Catheterization Equipment on file with the North Carolina Division of Health Service Regulation; and

b. *No other fixed or mobile cardiac catheterization service is provided within the same cardiac catheterization equipment service area."*

Methodology Two, as it is written, does not apply to Iredell County which has three operational fixed cardiac catheterization labs: one each at Iredell Memorial Hospital (IMH), Davis Regional Medical Center (DRMC), and Lake Norman Regional Medical Center (LNRMC). An example of the applicability of Methodology Two is the adjusted need determination for a shared fixed cardiac catheterization lab in Lee County in the "2011 SMFP". Prior to the adjusted need determination approval, Lee County did not have a fixed unit, but county residents received mobile cardiac catheterization services at Central Carolina Hospital.

Iredell Memorial Hospital's Grandfathered, Fixed Cardiac Catheterization Equipment

Iredell Memorial Hospital acquired one fixed cardiac catheterization laboratory in 1989, prior to the equipment being regulated under the state's certificate of need (CON) law. The hospital performed only diagnostic cardiac catheterization services until 2008, when therapeutic (i.e., interventional) cardiac catheterizations were initiated. Because IMH's fixed unit is grandfathered under CON law, therapeutic procedures can be performed without the hospital having open heart surgery capability, as currently required in CON Rule 10A NCAC 14C .1604(a), as follows: *"If the applicant proposes to perform therapeutic cardiac catheterization procedures, the applicant shall demonstrate that open heart surgery services are provided within the same facility."*

The Petitioner supports its adjusted need determination request based on 1,440 diagnostic equivalent procedures performed on IMH's grandfathered fixed cardiac catheterization unit during the 12 month period of July 2010 to June 2011. At this utilization, IHS states that its fixed unit is averaging 96% of capacity, and would trigger the need for a second fixed cardiac catheterization unit in Iredell County if Davis Regional Medical Center's one fixed cardiac catheterization unit and Lake Norman Regional Medical Center's one shared fixed cardiac catheterization unit were not underutilized.

Iredell Health System states it responded to its service area's cardiac mortality rate by developing a comprehensive cardiac care program. For clarification, however, the program is not a comprehensive cardiac care program by CON definition[1], because the hospital does not provide open heart surgery services, which is a separately regulated service under CON statute. IHS's program offers a coordinated continuum of care from primary care in the hospital's supported community health center, to certified preventive and rehabilitation programs and full time dedicated catheterization laboratory staff. The Petitioner states it has now reached limits on its response capability because the one fixed

[1] CON Rule 10A NCAC 14C .1601(8) states: "Comprehensive cardiac services program' means a cardiac services program which provides the full range of clinical services associated with the treatment of cardiovascular disease including community outreach, emergency treatment of cardiovascular illnesses, non-invasive diagnostic imaging modalities, diagnostic and therapeutic cardiac catheterization procedures, open heart surgery and cardiac rehabilitation services. Community outreach and cardiac rehabilitation services shall be provided by the applicant or through arrangements with other agencies and facilities located in the same city. All other components of a comprehensive cardiac services program shall be provided within a single facility."

cardiac catheterization laboratory is currently operating over capacity and into the evening/night. Further, the Petitioner states:

"If the special need is not approved, some patients will be forced out of the service area to get comparable quality care, unless Iredell Health System finds enough mobile unit capacity to fill the gap. Even so, extended use of mobile equipment is not a good solution. Other hospitals in the county do not have the staff to provide comparable service, or the policies to provide comparable charity care. Hence, referring physicians and patients will have only the out-of-county solution if Iredell Memorial cannot respond. Out-of-county care is not only stressful at the time of the procedure, it often results in breaks in care coordination; transition breaks in pharmaceutical regimens; and patient imposed breaks in follow up."

Iredell Memorial Hospital's Dedicated Electrophysiology (EP)/Angiography Equipment

In 2005, IMH received CON approval to acquire a second fixed unit of cardiac catheterization equipment to be used as a dedicated EP/angiography laboratory. The standard CON condition restricts IMH from performing cardiac catheterization procedures on the dedicated equipment, as follows:

"Iredell Memorial Hospital, Inc. shall not perform any cardiac catheterization procedures, as defined in 10A NCAC 14C.1601(5), with the cardiac catheterization equipment in the angiography and electrophysiology laboratory, which shall be used for angiography and electrophysiology procedures."

In effect, the Petitioner seeks to remove the CON condition on Iredell Memorial Hospital's dedicated EP/angiography laboratory to gain additional capacity to perform diagnostic cardiac catheterization procedures. The Petitioner concludes that the shared use of its EP/angiography laboratory for performing additional diagnostic cardiac catheterizations is the best alternative for managing increased demand for cardiac catheterization services, and would be a "high value solution" because additional cardiac catheterization equipment would not have to be purchased.

Analysis:

Iredell Health System's request relies on current cardiac catheterization utilization performed after the "Proposed 2012 SMFP" FY 2010 reporting period (October 1, 2009 to September 30, 2010). For that period (FY 2010), IMH reported 806 diagnostic equivalent procedures, and the number of cardiac therapeutic procedures performed (108) actually declined from the previous year (139 procedures). At 806 diagnostic equivalent procedures, IHS's one fixed cardiac catheterization equipment operated at only 54% of capacity and generated a need for only 0.67 units of fixed equipment. As shown in the table below, the combined cardiac catheterization utilization performed on all three fixed cardiac catheterization units in Iredell County generated a need for only one fixed unit (0.86) in FY 2010.

Iredell County Fixed Cardiac Catheterization Utilization - FY 2010

Hospital	Number of Fixed Cardiac Catheterization Units	Diagnostic Cardiac Procedures	Therapeutic of Interventional (PCTA) Procedures	Diagnostic Equivalent Procedures	Fixed Cardiac Catheterization Equipment Needed at 80% Capacity
IMH	1	617	108	806	0.67
DRMC*	1	153	--	153	0.13
LNRMC**	1	77	--	77	0.06
Iredell County	3	847	108	1036	0.86

*DRMC operates one fixed unit of cardiac catheterization equipment (grandfathered)
**LNRMC operates one shared fixed cardiac catheterization unit

Iredell Health System states its current, July 2010 to June 2011 cardiac catheterization utilization of 1,440 diagnostic equivalents would trigger a county need determination for a second fixed unit, except for underutilization of DRMC's fixed unit and LNRMC's shared fixed unit. However, even at 1,440 diagnostic equivalents, a second fixed unit of cardiac catheterization equipment would not be generated at IMH under the standard SMFP methodology for fixed units (Methodology One), which divides the number of diagnostic equivalent procedures by an 80% capacity of one fixed unit (1,200 procedures). At 80% capacity, IHS would still show a need for only one fixed unit [1,440/1,200 = 1.21]. Furthermore, data provided by IHS to support its petition is from July 2010 to June 30, 2011, which does not correspond to the data used by the "Proposed 2012 SMFP." Rather, the petition data relies on IMH cardiac catheterization utilization performed 9 months after the 2012 SMFP's reporting period, which should be used to determine the need for additional fixed cardiac catheterization equipment in next year's 2013 SMFP.

Iredell Memorial Hospital credits its recent increase in cardiac catheterization procedures on the practice of nine cardiologists, including two interventionist cardiologists who recently joined the medical staff. However, the same physicians also have privileges and practice at DRMC which is located less than five miles from IMH in Statesville. According to comments submitted by DRMC, it began to perform interventional cardiac catheterizations in January 2011, and recently experienced a significant increase in cardiac catheterization procedures. Similar to the increased utilization discussed in IHS's petition, DRMC states its increased utilization occurred after the "Proposed 2012 SMFP" reporting period. Iredell Health System does not discuss the effect of DRMC's new interventional cardiac program on the number of interventional cardiac procedures projected to be performed at IMH, or the combined effect of increased cardiac catheterization utilization at both IMH and DRMC, which could trigger a county need determination for additional fixed cardiac catheterization equipment in the future.

In comments by LNRMC, the hospital discusses the intent behind the SHCC's development of the standard need methodology for shared fixed cardiac catheterization equipment (Methodology Two), which LNRMC states was in response to a petition it submitted. LNRMC states Methodology Two was intended to provide a mechanism for mobile cardiac catheterization service area sites (without a fixed unit of cardiac catheterization equipment), to qualify for a shared fixed unit. In other words, the shared fixed methodology is meant to provide a way for mobile sites to develop or convert to fixed units, "without sacrificing the State standards for high utilization of expensive equipment" [Comments by LNRMC on IHS's petition]. Further, LNRMC states its shared fixed unit is not underutilized, as it performed 77 diagnostic cardiac catheterizations and a total of 2,775 angiography procedures in FY 2010, compared to zero (0) angiography procedures and zero (0) electrophysiology procedures

reported by Iredell Memorial Hospital for its dedicated EP/angiography equipment for the same time period [2011 Hospital Licensure Renewal Application].

The Petitioner states IMH's "under used" EP/angiography laboratory utilization is currently growing (306 procedures) with the addition of a new interventional radiologist and another physician who performs vascular angiography. However, the Petitioner did not discuss how the angiography equipment would provide sufficient capacity for performing both an additional number of diagnostic cardiac catheterization procedures, and an increasing number of angiography procedures.

With regard to access by the medically underserved population, G. Cecil Sheps Center data for Acute General Hospital Admissions by All Payers for FY 2009 showed IMH reported no uninsured patients, while DRMC reported 6.8% and LNRMC reported 3.6%. In regard to Medicaid, IMH ranked 3rd among the three hospitals in the percentage of Medicaid patients served. When outpatient surgery patients are considered, IMH showed no uninsured patients served, and for the number of uninsured emergency room patients, IMH also showed no uninsured patients, while the number of uninsured emergency room patients served at DRMC and LNRMC exceeded 20% at each facility.

The Petitioner does not request a revision of either Methodology One or Methodology Two, because IHS does not find the results of the methodologies' respective applications to be "inappropriate." Instead, IHS seeks to "conservatively" expand cardiac catheterization capacity at its own facility through means other than the standard need determination for fixed cardiac catheterization equipment. However, this request would benefit only one of three facilities in the Iredell County service area.

Further, approval of this request would not prevent the "adverse effect on providers and consumers" IHS claims would occur if its petition is denied. Specifically, the Petitioner states that before IMH started performing therapeutic cardiac catheterization procedures in 2008, "cardiac catheterization use in the county was low because referring physicians did not want to subject their patients to the risk of being transferred out mid-procedure for a therapeutic intervention. Nor did they want to subject patients to the extra costs associated with two hospital admissions for cardiac catheterization, one for diagnosis and another for interventional therapy. Consequently, most of Iredell Health System's primary service area residents traveled an hour or more to Winston-Salem, Charlotte, or Hickory, or they deferred care. High heart attack rates in the area testify to the amount of deferred care." However, even if IMH's existing EP/angiography cardiac catheterization laboratory was approved for use as a shared fixed cardiac catheterization laboratory, it would perform only diagnostic cardiac catheterization procedures, because CON Rule 10A NCAC 14C .1604(a) would prevent therapeutic procedures from being performed without open heart services at the hospital. Therefore, if a patient undergoing a diagnostic cardiac catheterization procedure on IMH's shared fixed equipment needed a therapeutic intervention "mid-procedure," the patient would still have to be transferred out or wait until IMH's fixed cardiac catheterization equipment was available.

Agency Recommendation:

In seeking an adjusted need determination, the rule of thumb is for a petitioner to provide compelling evidence that "unique or special attributes" of a service area or facility exist that differ from those determined by the annual SMFP's standard need methodology. The standard methodology for "fixed cardiac catheterization equipment" (Methodology One) shows no need for additional equipment in Iredell County. Methodology Two, for "shared fixed cardiac catheterization equipment," is based on circumstances that do not exist in Iredell County, and also shows no need for additional

equipment. The Petitioner bases its need on IMH's recent cardiac catheterization utilization, which covers a time span for which comparable data from other providers is not yet available, thereby limiting an analysis of the true impact on the total population of Iredell County. While a petitioner may request an adjustment to either of the two standard need determination methodologies, Iredell Health System's requested need adjustment for a shared fixed cardiac catheterization laboratory is contrary to Methodology Two and is unsupported by reasonable data. The basic question for the SMFP each year is whether there is sufficient capacity in a given service area to meet the needs of service area residents. Based on utilization data from the standard reporting period for existing fixed cardiac catheterization equipment in Iredell County, the current equipment capacity is sufficient. As IMH's more recent cardiac catheterization utilization may fluctuate over time, it should be compared to data from all providers for the same time period in future SMFPs. Therefore, based on the above analysis, and in support of the standard methodologies for cardiac catheterization equipment, the Agency recommends denial of the petition.

Attachment 3

Agency Report – New Hanover Regional Medical Center 2011 Petition

Technology and Equipment Committee
Agency Report on
An Adjusted Need Determination Petition for
Fixed Cardiac Catheterization Equipment in
New Hanover County
Proposed 2012 State Medical Facilities Plan

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Request:

New Hanover Regional Medical Center (NHRMC) requests an adjusted need determination to remove the need for one additional fixed cardiac catheterization laboratory in New Hanover County, as shown in the "Proposed 2012 State Medical Facilities Plan (SMFP)."

Background Information:

New Hanover Regional Medical Center is one of two providers that offered fixed cardiac catheterization services in New Hanover County during FY 2010. New Hanover Regional Medical Center had a total of five fixed cardiac catheterization laboratories and Wilmington Medical Center had one fixed unit of cardiac catheterization equipment, for a total of six units of fixed cardiac catheterization equipment in New Hanover County during that time.

Using the standard need determination methodology for fixed cardiac catheterization equipment, Methodology One in the "Proposed 2012 SMFP", a need determination for one additional fixed unit of cardiac catheterization equipment was generated in New Hanover County, driven by NHRMC's cardiac catheterization utilization (7,065 diagnostic equivalent procedures). This utilization level indicated a need for 5.89 fixed units based on five fixed units operating at 80% capacity.[1] Wilmington Heart Center showed a need for only 0.76 units of fixed equipment, based on 916 diagnostic-equivalent procedures. In total, cardiac catheterization utilization in New Hanover County resulted in a need determination for 7 fixed units of cardiac catheterization equipment [5.89 + 0.76 = 6.65].

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[1] "The North Carolina State Health Coordinating Council defines capacity of an item of cardiac catheterization equipment as 1,500 diagnostic-equivalent procedures per year, with the trigger of need at 80 percent of capacity" (Proposed 2012 SMFP).

However, NHRMC notified the Agency in July of an error in the number of therapeutic cardiac catheterizations reported by the hospital in its 2011 Hospital License Renewal Application. New Hanover Regional submitted corrected data which reduced its number of therapeutic cardiac catheterizations from 2,446 procedures to 2,204 procedures. Because the SMFP values one therapeutic cardiac catheterization procedure at 1.75 diagnostic equivalents, and one diagnostic cardiac catheterization procedure at one diagnostic equivalent procedure, NHRMC's total diagnostic equivalents were 6,641 procedures, instead of 7,065 procedures as shown in the "Proposed 2012 SMFP". This change would have eliminatcd the need for an additional unit of fixed cardiac catheterization in the county, because it reduced the number of fixed units needed at NHRMC to 5.53, and the county need to 6 units of fixed cardiac catheterization equipment [5.53 + 0.76 = 6.29].

However, during the "Proposed 2012 SMFP" comment period, the Agency learned that Duke LifePoint, which acquired Wilmington Heart Center's fixed cardiac catheterization unit in early 2011, had ceased operations in May and was converting the equipment to a mobile unit for use outside of New Hanover County[2]. In keeping with the language of Methodology One, the inventory of fixed cardiac catheterization equipment should include existing equipment in operation "immediately prior to publication of the annual State Medical Facilities Plan." Conversely, equipment no longer in operation, should be excluded from the inventory in the annual plan. By revising the proposed plan to exclude Wilmington Heart Center's fixed cardiac catheterization unit, New Hanover County again shows a need for one additional fixed cardiac catheterization unit based on 5 fixed units and a need for 6.3 fixed cardiac catheterization units [5.53+ 0.76 = 6.3 -5 fixed units =1.3 fixed units needed].

New Hanover Regional Medical Center asserts that an adverse effect on providers and consumers will occur without an adjustment to the county need determination. The Petitioner cites research from the Health Care Advisory Board that projects inpatient cardiac catheterization services will experience a 5-year, 15% decrease and a 10-year, 20% decrease in volume. The Petitioner also notes the declining numbers of diagnostic cardiac catheterizations reported in past State Medical Facilities Plan since 2005.

Analysis:

The September 2011 issue of "Consumer Reports" includes an article on the overuse of angioplasty nationally, as follows:

"*Overuse of angioplasty has made national headlines this past year, with the Department of Justice and Senate Finance Committee investigating incidences in which hospitals subjected hundreds of patients to needless procedures.*

But recent research suggests that the problem is not isolated to a few overzealous practitioners. Only half of procedures that used angioplasty to open narrowed arteries in nonemergency situations were clearly appropriate, according to a study of almost 500,000 cases published in July 2011 in the Journal of the American Medical Association. The researchers also uncovered wide variation among hospitals; the rate of clearly inappropriate procedures varied from less than 6 percent at some to greater than 16 percent at others."

[2] At this writing, the Agency does not know if the DLP mobile cardiac catheterization unit will be taken out of the state or to another county within the state.

The table below shows an historical downward trend in numbers of total diagnostic equivalent cardiac catheterization procedures performed throughout North Carolina since 2005, and a relatively flat increase in the number of angioplasty (PTCA) therapeutic procedures performed during that time.

Statewide Trend in Numbers of Fixed Cardiac Catheterization Procedures

Fixed Cardiac Catheterization Procedures	2005	2010	Percent Change
Diagnostic	84,662	64,856	-23.4
Therapeutic or Interventional	28,659	28,968	1.1
Total Diagnostic Equivalent Procedures-NC	134,815	115,550	-14.3

In New Hanover County, the combined number of fixed diagnostic equivalent cardiac catheterization procedures by both providers increased by 5.4% from 2005 to 2010, while the number of total diagnostic equivalent procedures performed at NHRMC declined by 7.4%.

New Hanover County Trend in Numbers of Fixed Cardiac Catheterization Procedures

Fixed Cardiac Catheterization	2005	2010	Percent Change
NHRMC			
Diagnostic Procedures	3,943	2,784	-29.4%
Therapeutic Procedures	1,846	2,204	19.4%
Total Diagnostic Equivalents	7,173	6,641	-7.4%
Wilmington Heart Center			
Diagnostic Procedures*	NA	919	--
Therapeutic Procedures * **	NA	NA	-
Total Diagnostic Equivalents	7,173	7,560	5.4%

*Wilmington Heart Center did not perform fixed cardiac catheterizations until 2008.

**Wilmington Heart Center did not perform therapeutic cardiac catheterization procedures.

NHRMC received CON approval to acquire a fifth fixed cardiac catheterization laboratory unit, which was not yet developed as of July of this year. Therefore, the cardiac catheterization utilization reported in NHRMC's 2011 Hospital Licensure Renewal Application was performed on four fixed units in operation at that time. NHRMC is maximizing its use of existing fixed equipment and will be able to absorb additional cardiac catheterization volume that previously would have been performed at Wilmington Heart Center, when the hospital's fifth fixed unit becomes operational.

Agency Recommendation:

The Agency supports the standard methodology for fixed cardiac catheterization equipment in the "Proposed 2012 SMFP". However, in consideration of the above, the Agency has determined that New Hanover Regional Medical Center has demonstrated "unique" or "special attributes" which are not appropriately addressed by the standard methodology. The Agency recommends approval of the petition to adjust the projected need determination for an additional unit of fixed cardiac catheterization equipment to zero (0) in New Hanover County in the Final 2012 SMFP.

Attachment 4

Agency Report – New Hanover Regional Medical Center 2013 Petition

Technology and Equipment Committee
Agency Report
Adjusted Need Petition for
One Fixed Cardiac Catheterization Equipment in New Hanover County
Proposed 2014 State Medical Facilities Plan

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Request:
New Hanover Regional Medical Center (NHRC) requests an adjusted need determination to remove the need for one additional fixed cardiac catheterization laboratory in New Hanover County, as shown in the Proposed 2014 State Medical Facilities Plan (SMFP).

Background Information:
The Proposed 2014 State Medical Facilities Plan (SMFP) provides two standard need determination methodologies for cardiac catheterization equipment. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment, and Methodology Two is the need determination methodology for shared fixed cardiac catheterization equipment. Application of Methodology One to utilization data in the Proposed 2014 SMFP generates a need determination for one additional fixed unit of cardiac catheterization equipment in New Hanover County.

Chapter Two of the North Carolina Proposed 2014 SMFP allows persons to petition for an adjusted need determination in consideration of "unique or special attributes of a particular geographic area or institution...," if they believe their needs are not addressed by the standard methodology. NHRC has submitted a petition to adjust the need determination to eliminate duplication of health services in New Hanover County.

NHRMC is the only provider that offered fixed cardiac catheterization services in New Hanover County as reported for the Proposed 2014 SMFP. For this time, NHRMC had a total of five fixed cardiac catheterization laboratories in New Hanover County.

The need determination in New Hanover County is driven by NHRMC's cardiac catheterization utilization of 7,175 diagnostic equivalent procedures reported for the Proposed 2014 SMFP. Capacity for cardiac catheterization equipment is defined in the Proposed 2014 SMFP as 1,500 diagnostic equivalent procedures per year. Need for additional cardiac catheterization equipment is triggered when 80% capacity is reached (1,200 procedures). Taking the total weighted procedures (7,175) divided by 80% of capacity (1,200) of one unit determines the number of units of fixed cardiac catheterization equipment needed for the service area. The cardiac catheterization volume at NHRMC indicates a need for 5.98 fixed units for New Hanover County.

The petition states that the five cardiac catheterization units at NHRMC are in operation 10 hours per day, 5 days per week for 52 weeks per year. The petition further states that, due to extended hours of operation, an actual functioning annual capacity of 2,600 hours per unit or 13,000 total hours for the facility is realized. Using 7,175 diagnostic-equivalent procedures from the Proposed 2014 SMFP divided by their stated actual capacity of 13,000 (instead of the 7,500 used in the methodology) multiplied by 100, the petition calculates the actual utilization to be 55.2%. Utilizing the capacity stated by the petition, no need would be generated.

NHRMC further reports that a cardiac catheterization procedure at their facility actually takes approximately one hour to perform - whether it is diagnostic or interventional. The SMFP values one therapeutic cardiac catheterization procedure at 1.75 diagnostic equivalent procedure, and one diagnostic cardiac catheterization procedure at one diagnostic equivalent procedure, which causes the standard methodology to overstate the actual utilization, according to the petition.

The petition asserts that an adverse effect on providers and consumers will occur without an adjustment to the county need determination. NHRMC notes a relatively flat trend in the numbers of diagnostic cardiac catheterizations reported in past SMFPs since 2006 with the exception of one spike in volume in the Proposed 2014 SMFP due to the elimination of cardiac catheterization services at Wilmington Heart Center. The petition cites research from the Health Care Advisory Board that projects inpatient cardiac catheterization services will experience a five-year, 5% decrease in volume. As stated in the Proposed 2014 SMFP, fixed and mobile cardiac catheterization equipment and services shall only be approved for development on hospital sites. NHRMC manages the only two hospitals in New Hanover County and does not want to increase unnecessary capacity for cardiac catheterization. The addition of an additional piece of cardiac catheterization has the potential to negatively impact the cost of these services in New Hanover County.

Analysis/Implications:

The table that follows shows an historical downward trend in numbers of total diagnostic equivalent cardiac catheterization procedures performed throughout North Carolina since 2006, and a relatively flat increase in the number of Percutaneous Coronary Interventional (PCI) procedures performed during that time.

Statewide Trend in Numbers of Fixed Cardiac Catheterization Procedures

Fixed Cardiac Catheterization Procedures	2006	2012	Percent Change
Diagnostic	74,556	62,092	-16.71%
Therapeutic or Interventional	27,713	27,981	0.97%
Total Diagnostic Equivalent Procedures-NC	118,892	114,567	-3.6%

Source: 2006 SMFP and 2012 SMFP

The inventory as reported in the Proposed 2014 SMFP for NHRMC is five fixed cardiac catheterization laboratory units. The petition reports that one of the five units is used solely for interventional radiology procedures. Therefore, the diagnostic cardiac catheterization utilization data from NHRMC's 2013 Hospital Licensure Renewal Application used in the standard methodology for the Proposed 2014 SMFP was performed on only four fixed units in operation at that time. NHRMC is maximizing its use of existing fixed equipment.

Agency Recommendation:

The agency supports the standard methodology for fixed cardiac catheterization equipment in the Proposed 2014 SMFP. However, in consideration of the above, the agency recognizes that New Hanover Regional Medical Center has unique attributes, such as longer operating hours allowing greater capacity on the equipment currently in the county, as well as being the only potential provider of cardiac catheterization services. Given available information submitted by the August 16, 2013 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends approval of the petition to adjust the projected need determination for an additional unit of fixed cardiac catheterization equipment to zero (0) in New Hanover County in the Final 2014 SMFP.

Attachment 5

Agency Report – Southeastern Regional Medical Center 2012 Petition

Technology and Equipment Committee
Agency Report
Adjusted Need Determination Petition for Cardiac Catheterization Equipment for the Proposed 2013 State Medical Facilities Plan

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Request:
Southeastern Regional Medical Center (SRMC) requests an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Robeson County in the 2013 State Medical Facilities Plan (SMFP).

Background Information:
The Proposed 2013 State Medical Facilities Plan (SMFP) provides two standard need determination methodologies for cardiac catheterization equipment. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment and Methodology Two is the need determination methodology for shared fixed cardiac catheterization equipment for service areas in which a unit of fixed cardiac catheterization equipment is not located. Application of these methodologies to utilization data in the Proposed 2013 SMFP does not generate a need determination for fixed cardiac catheterization equipment in Robeson County.

In deference to the standard methodology, Chapter Two of the North Carolina Proposed 2013 SMFP allows persons to petition for an adjusted need determination in consideration of "...unique or special attributes of a particular geographic area or institution...," if they believe their needs are not appropriately addressed by the standard methodology. Southeastern Regional Medical Center (SRMC) has submitted a petition to adjust the need determination in order to add one fixed unit of cardiac catheterization equipment to meet patient safety, quality and access issues.

Analysis/Implications:
In 2001, a petition for an adjusted need determination for an open heart surgery program was approved for a joint venture from SRMC and Duke University Health System. In 2006, the program opened and began providing open heart surgery as well as interventional cardiac catheterization procedures at SMRC. The petitioner reports that at the time this program was approved, Robeson County's age-adjusted heart disease death rate was 358.3, the state's 7th highest death rate from disease. According to the petitioner, heart disease risk is higher among Native Americans. There is a high minority population of Native Americans residing in Robeson County. This project initially was approved due to the unique demographics and socioeconomic characteristics of Robeson County. Southeastern Regional Medical Center reports that Robeson's death rate from heart disease now places them as the 15th highest county death rate in North Carolina to illustrate the success of the program.

Currently SRMC is the only open heart provider in North Carolina with only one cardiac catheterization laboratory. The petitioner states that this presents issues of access, quality of care and safety for patients, and operational concerns.

Methodology One determines the number of units of fixed cardiac catheterization equipment required based upon the number of weighted cardiac catheterization procedures performed with consideration of a 1200 weighted procedure (80 percent of a capacity of 1500 weighted procedures) threshold. The number of units of fixed cardiac catheterization equipment needed in a service area is then determined by taking the calculated number of units of fixed cardiac catheterization equipment required and the number is subtracted from the total planning inventory for all facilities for the cardiac catheterization equipment service area. In the Proposed 2013 SMFP, this methodology does not generate a need determination for additional fixed cardiac catheterization equipment in Robeson County. With only one unit of fixed cardiac catheterization equipment, the need for the second unit would not be generated until the need for 1.5 units is calculated due to the rounding factor of the methodology. In other words, Robeson County must perform 600 procedures over the threshold of 1200 procedures before a need is generated. With only one piece of equipment, the entire burden of providing 120% of capacity falls on that one piece of cardiac catheterization equipment.

An added comment in the petition is that most other major medical equipment such as MRI scanners, PET scanners, lithotripters, gamma knives and linear accelerators are rarely used for emergency cases. Exceeding capacity in those cases may be an inconvenience but would not delay an emergency treatment. With cardiac catheterization equipment, the equipment is often utilized on an emergency basis to save the patient's life. If a patient arrives at the facility with a need for an emergency intervention, the optimal 90 minute "Door to Balloon" window recommended by the American College of Cardiology may be delayed when the single lab is in use. Further, the non-emergent patient may then be delayed with a potential for added length of stay days for that patient.

Agency Recommendation:
The Agency believes the unique circumstances support the need for a second unit of cardiac catheterization based on a sufficient demand for cardiac catheterization services, the

demographics of this county and the lack of backup for emergency cases for this open heart surgery provider. Therefore, given available information and comments submitted by the 8/17/12 deadline, and in consideration of factors discussed above, the Agency recommends that the petition for an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Robeson County be approved.