

Comment on WakeMed's Petition for Methodology Change for Cardiac Catheterization in 2016 State Medical Facilities Plan

COMMENTER

Rex Healthcare
4420 Lake Boone Trail
Raleigh, NC 27607

Erick Hawkins
System Vice President, Heart and Vascular Services
919-784-4586
Erick.Hawkins@unchealth.unc.edu

INTRODUCTION

Rex strongly disagrees with WakeMed's suggested changes to the cardiac catheterization methodology in the *State Medical Facilities Plan (SMFP)*. WakeMed's petition will not result in better healthcare planning in North Carolina; rather, it is a veiled attempt to preserve a competitive advantage against a competitor, Rex Healthcare (Rex). WakeMed's petition is frivolous, unsupported by the facts, and disingenuous. If WakeMed is truly concerned with reducing excess cardiac catheterization lab capacity, it could close up to three of its underutilized labs. The State Health Coordinating Council (SHCC) should deny the petition.

FAILURE TO IDENTIFY THE NEED FOR THE PROPOSED CHANGES

Cardiac catheterization is often provided as a life-saving emergency service. WakeMed has requested changes that will make it more difficult for providers to add cardiac catheterization capacity when needed. WakeMed argues that the assumed capacity of a catheterization lab should be increased and that the weighting of interventional procedures should be decreased. Both of these changes will raise the utilization target that hospitals must achieve so that the *SMFP* methodology will recognize that additional capacity is needed.

By increasing the utilization target for additional capacity, WakeMed's petition is increasing the risk that the citizens of North Carolina will have insufficient access to cardiac catheterization services. WakeMed states "*the number of cardiac catheterization procedures performed has been declining in recent years ... [which] has resulted in a substantial surplus of cardiac catheterization machines.*" However, this surplus is a result of declining utilization at some providers, not additional capacity generated by the *SMFP* methodology. WakeMed's petition will do nothing to address existing surplus capacity

in the state. Thus, WakeMed's petition appears to be a (bad) solution to a non-existent problem.

In fact, WakeMed's petition has the potential to be very harmful given recent changes in cardiac catheterization services in North Carolina. Four hospitals in North Carolina (Carteret General Hospital, Central Carolina Hospital, Johnston Health, and WakeMed Cary) were given permission in late 2014 to offer interventional cardiac catheterization procedures. This change will allow patients in Carteret, Johnston, and Lee counties to receive interventional procedures in their home counties for the first time. Additionally, there are several other existing hospitals that could add interventional catheterization services in the future. It is reasonable to expect that cath lab utilization at these providers will increase dramatically as the addition of interventional services will also bolster diagnostic utilization. These new interventional programs are working in coordination with comprehensive programs that offer open-heart surgery backup. WakeMed's petition would make it more difficult for these new interventional programs and their larger partners to add capacity when needed.

Adequate cath lab capacity enables providers to deliver safe, high-quality, accessible, and cost-effective services. Unlike other diagnostic or even interventional services, the unique qualities of cardiac catheterization make operating at high utilization difficult for the facility, for physicians, and most importantly, for patients.

Cardiac catheterization, particularly for patients presenting with ST-elevated myocardial infarction, or STEMI, is provided on an emergency basis to save patients' lives. When a hospital's labs are operating over capacity and a patient presents with a need for emergency intervention, the lack of an available lab can lengthen the time until that care is available. As the SHCC is no doubt aware, prolonged door-to-balloon or symptom-to-balloon times have been correlated with increased mortality after primary percutaneous coronary intervention (PCI). As a result, the American College of Cardiology has established as part of its "Door-to-Balloon" campaign (known as the "D2B Alliance") that patients should receive interventional treatment within fewer than 90 minutes from the time the patient arrives at the hospital. The Joint Commission has also adopted this parameter as a core quality measure. As part of this 90-minute guideline, the D2B Alliance advocates that the cath lab team be available to perform the procedure within 20 to 30 minutes of the patient's arrival at the hospital. When a provider is operating at nearly 100 percent of capacity, it is significantly more challenging to meet this lifesaving guideline. Given the parameters of the current methodology, it is possible for one or more providers in the service area to be operating at significant capacity constraints, while others have tremendous surpluses, resulting in an overall surplus in the service area. This service area surplus does not mitigate the challenges for a provider operating near its own capacity level, particularly when timely lifesaving treatment is needed.

High cath lab utilization has many other drawbacks such as unnecessary overnight patient stays, extended periods of fasting for patients, delays for physicians (and as a result, delays for their clinic patients), unnecessary staffing expenses to compensate for overtime, decreased employee satisfaction due to long hours, and higher maintenance expenses due to the consistent overuse of the equipment and overnight or weekend repairs.

Given the significant drawbacks of high utilization cath labs and the emergent, lifesaving nature of the service they provide, it does not make sense to make it more difficult for hospitals to add capacity when it is needed.

WAKE COUNTY BACKGROUND

Given that there is no healthcare planning rationale for WakeMed’s petition, Rex believes that WakeMed is requesting these changes in order to maintain control of cardiac catheterization capacity in Wake County. WakeMed does not want Rex to be able to add cardiac catheterization capacity for competitive reasons. WakeMed currently operates ten cardiac catheterization labs in Wake County (at WakeMed Raleigh and WakeMed Cary). Based on the current cardiac catheterization methodology in the SMFP, WakeMed’s 2014 utilization indicates that it has a surplus of 3.0 cardiac catheterization labs. By contrast, Rex has a deficit of 1.0 labs and provided more than 1,500 equivalent procedures per lab in 2014 which is the current SMFP-defined capacity. Rex has achieved this high utilization and has faced all of the negative impacts described above that face providers operating at high utilization.

Wake County Cardiac Catheterization Need

	<i>Current Inventory</i>	<i>2014 Diagnostic Procedures</i>	<i>2014 Therapeutic Procedures</i>	<i>2014 Procedures (Weighted Totals)</i>	<i>Machines Required Based on 80% Utilization</i>	<i>Deficit/ (Surplus)</i>
WakeMed Raleigh	9	3,687	2,563	8,172	6.8	(2.2)
WakeMed Cary	1	223	0	223	0.2	(0.8)
WakeMed Total	10	3,910	2,563	8,395	7.0	(3.0)
Rex Healthcare	4	3,050	1,689	6,006	5.0	1.0
Duke Raleigh	3	260	76	393	0.3	(2.7)

Source: 2015 Hospital License Renewal Applications.

As the 2014 data clearly shows, WakeMed’s cardiac catheterization labs are underutilized while Rex’s lab are over capacity. As a result, Rex patients and physicians face unnecessary delays for needed care. Due to its high cath lab utilization, Rex has no extra time during the day, and any emergency or delay can multiply, impacting the rest of the days’ patients, as well as staff and physicians. Inadequate cath lab capacity

hinders a hospital's ability to deliver safe, high-quality, accessible, and cost-effective services.

Last year, Rex Healthcare filed two petitions with the SHCC, a methodology change petition and a special need adjustment petition, seeking to address its capacity problems. Both petitions were denied. WakeMed also filed a comment¹ last year requesting that the SHCC not make an adjusted need determination for cardiac catheterization equipment in Wake County. The current petition is WakeMed's latest attempt to prevent Rex from adding capacity.

WakeMed disingenuously argues that its current petition will reduce unnecessary duplication and excess capacity. The data clearly shows that WakeMed possesses excess capacity. If WakeMed was truly concerned about excess capacity, it could relinquish the Certificate of Need for up to three units of its cardiac catheterization equipment.

WakeMed is not truly interested in reducing excess capacity. WakeMed is trying to prevent Rex from adding the capacity it needs. In order to do so, WakeMed's petition erroneously argues that there is a problem with the current methodology and provides unsupported arguments for its proposed changes. Please see the discussion below for Rex's analysis of WakeMed's petition.

NEW HANOVER REGIONAL MEDICAL CENTER'S PRIOR PETITIONS

WakeMed's petition states that there is a 'problem' with a cardiac catheterization methodology in the *State Medical Facilities Plan (SMFP)*. According to WakeMed, the evidence for this 'problem' is New Hanover Regional Medical Center's (NHRMC) 2013 petition to remove a need determination for additional capacity in its home county. As WakeMed is well aware, requests for the removal or reduction of need determinations are common and in most cases do not indicate that there is a problem with the methodology in question. Since 2010, there have been 13 petitions asking for the removal or reduction of a need determination:

1. 2014 Cape Fear Valley Health System - Removal of acute care bed need in Cumberland County.
2. 2014 Carolinas Healthcare System - Removal of MRI need in Lincoln County.
3. 2013 Cape Fear Valley Health System - Reduction of acute care bed need in Cumberland County.
4. 2013 NHRMC - Removal of cardiac catheterization need in New Hanover County.

¹ Given that WakeMed's petition from last year did not request any changes to the 2015 SMFP, the Agency stated that it did "not technically follow the standards of the petition process . . . [and] recommends that this request be considered a comment and not a petition."

5. 2013 Granville Vance District Health Department - Removal of home health agency in Granville County
6. 2012 Cape Fear Valley Health System - Removal of acute care bed need in Cumberland/Hoke service area.
7. 2012 Vidant Medical Center - Removal of acute care bed need in Pitt-Greene-Hyde service area.
8. 2011 Pitt County Memorial Hospital - Reduction of acute care bed need in Pitt-Greene-Hyde service area.
9. 2011 NHRMC - Removal of cardiac catheterization need in New Hanover County.
10. 2011 Personal Home Care of North Carolina - Reduction of home health agency need in Mecklenburg County.
11. 2010 Mission Hospital - Reduction of acute care bed need in Buncombe-Yancey-Madison service area.
12. 2010 Columbus Regional Healthcare System - Removal of operating room need in Columbus County.
13. 2010 Rowan Regional Medical Center - Removal of operating room need in Rowan County.

The *SMFP* process allows for petitions for adjustments to need determinations to be filed annually. WakeMed's incorrectly assumes that one petition for a removal of a need determination indicates that there is a problem in the methodology. There is no evidence that there are substantial problems with the current cardiac catheterization methodology. NHRMC is the only provider that has requested a removal of a need determination since 2010 and in that same time multiple providers have requested adjusted need determinations for additional units of catheterization equipment.

Moreover, NHRMC's petition does not claim that there is a problem with the methodology; rather, the petition argues that need determination should be removed because of NHRMC's unique circumstances (e.g. hours of operation, utilization trends, use of one lab for interventional radiology only). Contrary to WakeMed's assertions, NHRMC's petition does not state that the capacity thresholds in the plan were too low for planning purposes, but rather that the capacity thresholds were not accurate for the catheterization labs at NHRMC.

FAILURE TO INCLUDE RELEVANT DATA

WakeMed's petition fails to provide relevant data to support its statement that the *SMFP* overestimates case times for cardiac catheterization procedures. Notably, WakeMed does not provide its own case times. Instead, WakeMed provides a list of internet references which are vague and contradictory. This is puzzling. WakeMed certainly knows how long a cardiac catheterization procedure takes from its own

experience. Given the context of the petition, Rex can only surmise that the internet sources are misleading.

The internet sources listed are patient education websites and thus focus on the experience of the patient. For example, the first reference, from Cleveland Clinic, states “[t]he cardiac catheterization procedures itself generally takes 30 minutes, but the preparation and recovery time add several hours to your appointment time” (emphasis added). Because this information is presented to inform Cleveland Clinic’s patients, it is unclear how long the cardiac catheterization lab is occupied for one case, including room setup and turnover time which may occur when the patient is not in the room. It is understandable that patient education websites would not provide data that could help determine the capacity of a cardiac catheterization lab. As such, it is unreasonable for WakeMed to use this information as the basis for its petition.

In addition to failing to provide relevant data, the internet sources provided by WakeMed are inconsistent:

- Cleveland Clinic states that the procedure generally takes 30 minutes;
- Medline Plus states that a test may last 30 to 60 minutes;
- University of Pittsburgh Medical Center states that a complete cardiac cath usually last about an hour; and,
- The American Heart Association states that the procedure last about an hour.

Given their context, it is likely that none of these sources are including setup and turnover time in their figures. As such, WakeMed’s argument that “*the current SMFP methodology with its diagnostic-equivalent average case time of one hour twenty minutes is clearly out of step with widely accepted actual times*” is wrong. In fact, the one internet source that discusses room turnover, Cath Lab Digest, states that “*the time for room turnover should be no longer than the case time*” which suggests each of the case times provided by the internet sources could be doubled.

Finally, some of the internet sources appear to use the same language over and over; three of the sources use the phrase “*but the preparation and recovery time adds several hours*”. This pattern indicates that these internet sources are not independent, but are more likely one source modified and repeated.

Historically, the SHCC collects and reviews multiple years of data in order to arrive at meaningful methodology assumptions for the entire state (e.g. the operating room methodology, the acute care bed methodology, and the planned MRI methodology review). Patient education websites are a poor source of data for determining the capacity of a cardiac catheterization lab. Actual case time data from existing providers is much more useful. Rex’s own recent experience is that diagnostic catheterization case times (including setup and room turnover) are longer than the one hour and twenty

minutes calculated by WakeMed and that interventional case times vary widely and can take up to two or three hours. Rex’s experience may not be representative of hospitals across the state, but it is certainly a more reliable data source than WakeMed’s internet sources. The SHCC should reject WakeMed’s suggestion that it utilize unrelated internet sources as the basis for its decisions.

UNREASONABLE CARDIAC CATHETERIZATION CAPACITY

In addition to requesting decreased case time assumptions, WakeMed’s petition requests that the SHCC increase the assumed capacity of cath lab from 1,500 to 2,000 equivalents. This increase is simply not supported by actual data. From 2008 to 2013, no hospital in North Carolina provided 2,000 or more cardiac equivalents per catheterization lab. From 2003 to 2007, only four providers statewide achieved that level of utilization and in each case that hospital added additional cath lab capacity in subsequent years to ease its capacity constraints. Yet, since 2003 North Carolina has added 34 cath labs. Of course, not all of these labs were added to ease capacity constraints; some were added to provide services in counties without existing access. However, if WakeMed’s petition is to be believed, only four hospitals in North Carolina have been over capacity since 2003 and yet multiple providers, including WakeMed Raleigh added unneeded capacity. In light of the petition, WakeMed Raleigh’s experience is particularly instructive.

WakeMed Raleigh Cardiac Catheterization Lab Utilization

	2003	2004	2005	2006	2007	2008
Equivalent Procedures	10,772	11,709	11,984	11,698	11,657	12,312
Catheterization Labs	5	5	7	8	9	9
Equivalents per Lab	2,154	2,342	1,712	1,462	1,295	1,368

Source: Hospital License Renewal Applications and SMFPs.

As the table above indicates WakeMed Raleigh provided more than 2,000 cardiac equivalents in 2003 and 2004. WakeMed Raleigh added two labs in 2005 and added an additional lab in both 2006 and 2007 for a total of nine labs, which it still operates today. WakeMed Raleigh has not operated above 2,000 equivalents per lab since 2004, yet it has nearly doubled its capacity since that time.

As noted above, actual utilization data from cardiac catheterization providers in North Carolina suggest that WakeMed’s capacity assumption is unsupported. In addition, the healthcare planning experience in many other states also contradicts WakeMed’s petition. According to the National Conference of State Legislatures², 26 states with certificate of need programs, including North Carolina, regulate cardiac catheterization

² List of CON states that regulate cardiac catheterization can be found here: <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx>

services (note: many do not utilize specific assumptions for capacity and case times). Based on its research, Rex believes that the current assumptions in North Carolina’s *SMFP* are consistent with or more conservative (i.e. higher capacity and lower weighting) than other states. The table below provides a comparison of cardiac catheterization planning assumptions among several states as well as the assumptions requested in WakeMed’s petition.

Comparison of Cardiac Catheterization Planning Assumptions

	<i>North Carolina</i>	<i>WakeMed Petition</i>	<i>Alabama</i>	<i>Georgia</i>	<i>Hawaii</i>	<i>South Carolina</i>	<i>West Virginia</i>
Adult Diagnostic Weight	1.0	1.0	1.0	1.0	1.0	1.0	NA
Adult Interventional Weight	1.75	1.5	2.0	1.5	2.0	2.0	NA
Annual Capacity (in equivalents)	1,500	2,000	1,250	1,300	1,500	1,200	1,250

Source: See Exhibit 1.

WakeMed’s suggested capacity of 2,000 equivalents is the highest of all the states in the data above. Furthermore, WakeMed’s suggested adult interventional weight of 1.5 is the lowest of all the states, although it is equal to Georgia’s assumption. However, Georgia’s assumed capacity is 1,300 equivalents, which offsets the lower weighting (e.g. Rex’s cardiac catheterization need using Georgia’s capacity and weighting assumptions is a deficit of 1.4 units or 0.4 units greater than the deficit shown under the current *SMFP* methodology).

Rex has not done an exhaustive review of cardiac catheterization planning assumptions nationwide; however, it is clear from the data above that WakeMed’s petition provides aggressive assumptions, not supported by those of other states.

INCONSISTENCY WITH SMFP BASIC PRINCIPLES

Ultimately, WakeMed’s petition is inconsistent with the basic principles of the *SMFP*.

Safety and Quality

Quality and safety will be weakened by the approval of WakeMed’s petition, which will prevent the development of needed cardiac catheterization capacity. Without sufficient capacity, particularly for a service often provided on an emergent basis, like interventional cardiac catheterization, quality can suffer and patient care may not be optimal. Cardiac catheterization services must be available immediately for emergency patients who present to a hospital. These emergency situations often require a patient to be taken out of a room before the case is finished. Emergency patients inevitably

delay scheduled patients or cause rescheduling. The American College of Cardiology has established that patients should receive interventional treatment within fewer than 90 minutes from the time the patient arrives at the hospital. When a provider is operating at or above its capacity, it is more challenging to meet this lifesaving guideline.

If the demand for cardiac catheterization services at a facility exceeds its reasonable capacity, then any delays result in patients beginning their procedures late in the day, thus requiring a more expensive and inconvenient overnight stay, or waiting until a later scheduled time. Scheduled procedures, while not emergency cases, are needed to improve the health of these patients and the delays that may result from overcapacity equipment results in delays in their recovery and return to normal life. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment.

If patients and physicians are forced to access care at another facility which has available capacity, they may encounter disruptions in the continuity of care. Physicians and providers work every day to improve the systems of care which leverage information technology, multidisciplinary teams, and processes of care to deliver the right care at the right time to the right person. Electronic medical records allow physicians and staff to access all of the patient's records including relevant diagnostic tests that can provide vital information to guide the care of the patient. A facility under the control of another healthcare system cannot provide that same system of care to an unfamiliar physician and patient. As a result, safety and quality will be diminished if WakeMed's petition is approved.

Access

Access to vital services will be restricted by WakeMed's petition, which will prevent the development of needed cardiac catheterization capacity. As noted above, three hospitals in North Carolina recently were permitted to begin offering interventional catheterization services for the first time and more may add this service in the future. These hospitals are working with larger partners to increase access to a vital, life-saving service. WakeMed's petition would restrict the ability of these providers to add capacity as need grows over time.

Value

WakeMed's petition would also harm the value of healthcare services provided in North Carolina. As discussed above, overutilization of cardiac catheterization capacity sometimes results in expensive and inconvenient overnight stays for patients that could

have been discharged on the same day. Additional catheterization lab capacity, when needed, will ensure that patients—both inpatients and outpatients—receive care in a timely manner, enabling patients to be discharged within an appropriate timeframe, which will prevent unnecessary expenditures by the patients and payors. Delays in needed treatment or unanticipated overnight stays at the hospital add to healthcare expenditures. At Rex, high utilization necessitates that any routine maintenance occur overnight or on the weekends, which is more costly than if completed during work hours. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues, which increases cost. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment. Finally, hospitals cannot efficiently staff high utilization cath labs as staff must routinely work overtime, which decreases job satisfaction and adds unnecessary costs.

OTHER METHODOLOGY CHANGES FOR CONSIDERATION

As noted above, Rex filed a petition last year for changes to the cardiac catheterization methodology (see Exhibit 2). If the SHCC is interested in reviewing the cardiac catheterization methodology in order to improve the planning process, Rex believes that its prior petition provides several improvements to the current methodology:

- Rex requested that need be assessed for each hospital, or in the case of hospitals under common ownership in the same service area, to each group of hospitals. Need determinations would be granted once equipment is appropriately utilized irrespective of the utilization of other hospitals in the same service area.
- Rex proposed that the threshold for a need determination for additional units of equipment be lowered to a projected deficit of 0.1 (from the current 0.5 unit threshold).
- Rex proposed that only qualified applicants may apply for a certificate of need to acquire needed cardiac catheterization capacity. An applicant is a qualified if it is an existing hospital without fixed cardiac catheterization equipment, or if its existing cardiac catheterization equipment is operating at an average of 1,200 weighted procedures per unit of fixed cardiac catheterization equipment as reported in the current State Medical Facilities Plan under which the application is being reviewed.

If the SHCC is considering revising the cardiac catheterization methodology, Rex believes that its previously proposed change is needed in order to provide access to cardiac catheterization services, that it will not have adverse effects on providers or consumers, will not result in unnecessary duplication, and is consistent with the Basic Principles of the SMFP. Please see Rex's previously submitted petitions for extensive historical data from North Carolina providers and analysis which support these changes.

SUMMARY

In conclusion, Rex requests that the SHCC deny WakeMed's petition to change the cardiac catheterization need determination methodology. The proposed changes are unsupported by data, not needed, and inconsistent with the basic principles of the *SMFP*.

Thank you for your consideration.

Exhibit 1

Alabama

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
ALABAMA STATE HEALTH PLAN
2014-2017
ADMINISTRATIVE CODE

CHAPTER 410-2-3
SPECIALTY SERVICES

TABLE OF CONTENTS

410-2-3-.01	Introduction
410-2-3-.02	Neonatal Services
410-2-3-.03	Cardiac Services
410-2-3-.04	Oncology-Radiation Therapy Services
410-2-3-.05	End Stage Renal Disease Services
410-2-3-.06	Magnetic Resonance Imaging
410-2-3-.07	Extracorporeal Lithotresis
410-2-3-.08	New Technology
410-2-3-.09	Transplantation Services
410-2-3-.10	In Home Hospice Services
410-2-3-.11	Air Ambulance

410-2-3-.01 **Introduction.** This chapter of the *Alabama State Health Plan* reviews the status of certain specialty health care services and the need for additional services to address the problems cited in the Priorities section of the Plan. Specialty Services are separately identified for ease of reference and to highlight their importance in the overall planning and regulatory responsibilities. The health care system in Alabama should not be burdened by an unnecessary duplication of expensive services.

Author: Statewide Health Coordinating Council (SHCC)

Statutory Authority: Code of Ala. 1975, §22-21-260(4).

History: Effective May 18, 1993. **Amended:** Filed June 19, 1996; effective July 25, 1996. **Repealed and New Rule:** Filed October 18, 2004; effective November 22, 2004. **Amended (SHP Year Only):** Filed December 2 2014; effective January 6, 2015.

410-2-3-.02 **Neonatal Services.**

(1) Discussion

(a) A leading indicator of the health status of a state's citizens is the infant mortality rate. Alabama has one

highly likely that the role of cardiac catheterization will continue to evolve.

3. Fixed-based cardiac catheterization services are the only acceptable method for providing cardiac catheterization services to the people in Alabama.

4. For purposes of this section, a cardiac catheterization "procedure equivalent" is defined as a unit of measure which reflects the relative average length of time one patient spends in one session in a cardiac catheterization laboratory. One procedure equivalent equals 1.5 hours utilization time.

(b) Planning Policies

1. **Planning Policy. Diagnostic catheterizations shall be weighed as 1.0 equivalents, while therapeutic/interventional catheterizations (Percutaneous Transluminal Coronary Angioplasty (PTCA), directional coronary atherectomy, rotational coronary atherectomy, intracoronary stent deployment, and intracoronary fibrinolysis, cardiac valvuloplasty, and similarly complex therapeutic procedures) and pediatric catheterizations shall be weighed as 2.0 equivalents.** Electrophysiology shall be weighed as 3.0 equivalents for diagnostic and 4.0 equivalents for therapeutic procedures. For multi-purpose rooms, each special procedure which is not a cardiac catheterization procedure, performed in such rooms shall be weighed as one equivalent.

2. Planning Policy - New Institutional Service. New "fixed-based" cardiac catheterization services shall be approved only if the following conditions are met:

(i) Each facility in the county has performed at least 1,000 equivalent procedures per unit for the most recent year;

(ii) An applicant for diagnostic/therapeutic cardiac catheterization must project that the proposed service shall perform a minimum of 875 equivalent procedures (60% of capacity) annually within three years of initiation of services;

(iii) An applicant for diagnostic catheterization only must project that the proposed service shall perform a minimum of 750 procedures per room per year within three years of initiation of services;

(iv) At least two physicians, licensed in Alabama, with training and experience in cardiac catheterization shall provide coverage at the proposed facility.

3. Planning Policy - Expansion of Existing Service. Expansion of an existing cardiac catheterization service shall only be approved if:

(i) If an applicant has performed 1,000 equivalent procedures per unit (80% of capacity) for each of the past two years, the facility may apply for expansion of catheterization services regardless of the utilization of other facilities in the county;

(ii) Adult and pediatric procedures may be separated for those institutions with a dedicated pediatric catheterization lab in operation on the effective date of this section.

4. Planning Policy. Pediatric cardiac catheterization laboratories shall only be located in institutions with comprehensive pediatric services, pediatric cardiac surgery services, and a tertiary pediatric intensive care unit.

5. All cardiac catheterization services without open-heart surgical capability ("OSS") shall have written transfer agreements with an existing open-heart program located within 45 minutes by air or ground ambulance service door to door from the referring facility. Acute care hospitals providing diagnostic cardiac catheterization services may provide emergency interventional/therapeutic cardiac catheterization procedures. Notwithstanding anything in the State Health Plan to the contrary, an acute care hospital without on site open-heart surgery capability may provide elective percutaneous coronary intervention (PCI) if the following criteria are met:

(i) The hospital shall maintain twenty-four (24) hour, seven (7) day a week continuous coverage by at least one interventional cardiologist and catheterization laboratory team for primary PCI treatment of ST elevation myocardial infarction;

(ii) The hospital shall participate in a recognized national registry for cardiac catheterizations and PCI procedures, such as the National Cardiovascular Data Registry (NCDR);

(iii) The hospital shall obtain informed patient consent for all elective PCI procedures, including an informed consent process in which it is clearly stated that the hospital does not offer OSS, and which clearly states that the patient may request at any time to be transferred to a hospital with OSS to undergo the PCI procedure;

Georgia

111-2-2-.21 Specific Review Considerations for Adult Cardiac Catheterization Services.

(1) Applicability.

(a) For Certificate of Need (CON) purposes, Adult Cardiac Catheterization Services is classified as a specialized service and is defined as a new institutional health service which must be delivered in a permanently fixed location in either an acute care hospital or in a diagnostic, treatment, or rehabilitation center (DTRC). A certificate of need will be required prior to the establishment of a new or expanded adult cardiac catheterization service, if not exempt as provided by O.C.G.A. § 31-6-47(a)(21) and Rule 111-2-2-.03(23).

(b) If the service will be provided within a licensed acute care hospital, the hospital shall be the applicant.

(c) If cardiac catheterization services will be provided in a DTRC, the organizational entity that develops the service shall be the applicant.

(d) Seeking and receiving approval from the Department under the provisions of 111-2-2-.21(3)(f)3. shall neither be considered a new adult cardiac catheterization service nor an expanded service. Additionally, the issuance of such an approval shall not be construed to be anything other than a time-limited approval to participate in the particular medical research trial specified in 111-2-2-.21(3)(f)(3).

(2) Definitions.

(a) "Adjacent acute care hospital" means an acute care hospital which is physically connected to another acute care hospital in a manner that emergency transport of a patient by a stretcher or gurney can be achieved rapidly, conveniently, and effectively without the use of motorized vehicles.

(b) "Adult" means a person fifteen (15) years of age and over.

(c) "Authorized service" means an adult cardiac catheterization service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not yet become operational.

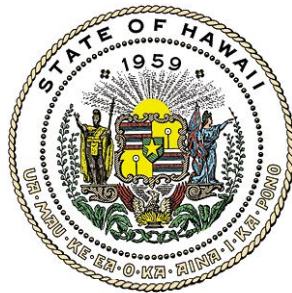
(d) "Capacity" means 1300 adult cardiac catheterization procedure equivalents per dedicated and multipurpose room per year. In the computation of the use rate (percent of capacity) of authorized adult cardiac catheterization rooms, each adult diagnostic cardiac catheterization and other cardiac catheterizations of similar complexity shall equal a 1.0 procedure equivalent, each coronary angioplasty procedure shall equal 1.5 procedure equivalents, and each electrophysiological (EP) study shall equal 2.0 procedure equivalents. If pediatric catheterizations are performed in a room in which adult cardiac catheterizations are performed, each pediatric procedure shall equal 2.0 procedure equivalents.

(e) "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

Hawaii



STATE OF HAWAII
HEALTH SERVICES
AND
FACILITIES PLAN



State Health Planning and Development Agency

	For expansion of existing units/services, the provider's utilization is an average of at least 720 treatments per year per unit.
Radiation Therapy Unit	For a new unit/service, the minimum annual utilization for each provider in the service area is 7,200 procedures per unit and the utilization of the new unit/service is projected to meet the minimum utilization rate by the third year of operation. For expansion of existing units/services, the provider's utilization is at least 8,600 procedures per year per unit.
Gamma Knife	For a new unit/service, the minimum annual utilization rate for each provider in the service area is 335 procedures per unit and the utilization of the new unit/service is projected to meet the minimum utilization rate by the third year of operation. For expansion of existing units/services, the provider's unit utilization rate is an average of at least 400 procedures per year per unit.
Adult Cardiac Catheterization Unit	For a new service/unit, the minimum annual utilization for each provider in the service area is 1,000 diagnostic-equivalent procedures per unit, and the utilization of the new unit/service is projected to meet the minimum utilization rate by the third year of operation. For expansion of existing units/services, the providers' annual utilization is an average of at least 1,200 diagnostic-equivalent procedures per unit per year. Maximum capacity of a cardiac catheterization unit is 1,500 diagnostic equivalent procedures per year per unit, based on 6 diagnostic equivalent procedures per day, 5 days a week for 50 weeks a year. Cardiac catheterization utilization shall be determined by counting all therapeutic, pediatric or electrophysiology procedures as two (2) diagnostic equivalents, and other procedures as one (1) diagnostic equivalent. For diagnostic catheterizations, only one (1) diagnostic procedure will be counted per patient visit in the cardiac catheterization unit regardless of the number of procedures performed.
Open Heart Surgery	For a new service, the minimum annual utilization for each provider in the service area is 350 adult or 130 pediatric open-heart operations per year, and the new unit/service is projected to meet a utilization rate of at least 200 adult or 100 pediatric open-heart operations in the third year of operation.
Freestanding Ambulatory Surgery Center (less than 24 hours stay)	A collaborative arrangement shall be made with an existing acute care hospital in the county. This collaboration shall, without limitation: <ul style="list-style-type: none"> a. Include a transfer agreement b. Commit to support all training and recruitment of health care personnel for the benefit of the area c. Commit to enhance the EMS and trauma care systems of the area by using the ASC, when necessary, for cases such as natural disaster or pandemic.
Medical/Surgical Bed	For new or additional SHPDA-approved medical/surgical beds, the minimum annual occupancy rate for each provider in the service area must be 75% based on the number of licensed medical/surgical beds.
Obstetric Bed	For new or additional SHPDA-approved OB beds, the minimum annual occupancy rate for each provider in the service area must be 75% based on the number of licensed OB beds.
Psychiatric Bed	For a new or additional SHPDA-approved psychiatric beds, the average annual occupancy rate for licensed beds for each service provider in the service area is at least 80% for adult (age 18 and over) programs and at

South Carolina

D H E C



PROMOTE PROTECT PROSPER

2012 – 2013

**SOUTH CAROLINA
HEALTH PLAN**

EFFECTIVE 11/9/12

services should meet full accreditation standards for The Joint Commission (TJC) or similar accrediting body.

Certificate of Need Standards

1. The capacity of a fixed cardiac catheterization laboratory shall be 1,200 diagnostic equivalents per year. Adult diagnostic catheterizations (ICD-9-CM Procedure Codes 37.21, 37.22 and 37.23) shall be weighted as 1.0 equivalents, while therapeutic catheterizations (ICD-9-CM Procedure Codes 00.66, 35.52, 35.96, 36.06, 36.07, 36.09, and 37.34) shall be weighted as 2.0 equivalents. For pediatric and adult congenital cath labs, diagnostic caths shall be weighted as 2.0 equivalents, therapeutic caths shall be weighted as 3.0 equivalents, electrophysiology (EP) studies shall be weighted as 2.0 equivalents, and biopsies performed after heart transplants shall be weighted as 1.0 equivalents. The capacity of mobile cardiac catheterization labs will be calculated based on the number of days of operation per week.
2. The service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes one way automobile travel time; for comprehensive cardiac catheterization laboratories the service area is all facilities within 60 minutes one way automobile travel time; a pediatric cardiac program should serve a population encompassing at least 30,000 births per year, or roughly two million people.

Diagnostic and Mobile Catheterization Services

3. New diagnostic cardiac catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed at a minimum of 500 diagnostic cardiac catheterization procedures per laboratory during the most recent year;
4. An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.
5. Expansion of an existing diagnostic cardiac catheterization service shall only be approved if the service has operated at a minimum use rate of 80% of capacity (i.e. 960 equivalents per laboratory) for each of the past two years and can project a minimum of 500 procedures per year on the additional equipment within three years of its implementation.
6. An applicant for a mobile diagnostic catheterization laboratory must be able to project a minimum of 100 diagnostic equivalents annually for each day of the week that the mobile lab is located at the applicant's facility by the end of the third year following initiation of the service, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory (i.e. an applicant wishing to have a mobile cath lab 2 days per week must project a minimum of

West Virginia

**CARDIAC CATHETERIZATION
STANDARDS**

I. DEFINITIONS

A. Cardiac Catheterization Procedure: Any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, as applicable, performed on a patient during a single session in a Cardiac Catheterization laboratory or a multi purpose special radiological room. Cardiac Catheterization is a medical diagnostic or therapeutic procedure during which a catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart.

B. Cardiac Surgery: Surgery on the heart or major blood vessels of the heart including both open and closed heart surgery.

C. Dedicated Cardiac Catheterization Laboratories: Laboratories exclusively dedicated to cardiac procedures.

D. Diagnostic Cardiac Catheterization: Diagnostic Cardiac Catheterization is a classification of invasive procedures in which a slender tube is passed into a peripheral vein or artery, through the blood vessels, and into the heart. These procedures permit study of the heart chambers and the arteries supplying the heart to diagnose illness or

disease. Facilities that do not have Open Heart Surgery capabilities may perform Diagnostic Cardiac Catheterization procedures on carefully screened patients. High-risk patients are referred to facilities capable of caring for more complicated patients. The capacity of a Diagnostic Cardiac Catheterization laboratory is 1,250 cases per year, based on five procedures per day for 250 days.

E. Freestanding Laboratory: A Cardiac Catheterization laboratory which is not on the campus of an acute care facility.

F. Medical Transport Time: The time from when the referring facility initiates contact with the receiving facility which provides primary and elective PCI regarding the transfer of a patient with the diagnosis of ST segment elevation or new left bundle branch block to the time the patient arrives at the receiving facility, including the actual transport time.

G. Mobile Cardiac Catheterization Laboratory: A Cardiac Catheterization laboratory used for diagnostic procedures and which typically travels between two or more acute care facilities.

H. Non-Dedicated Cardiac Catheterization Laboratories: Laboratories that provide, but are not limited to, cardiac procedures. A Non-Dedicated Cardiac Catheterization laboratory must also have the ability to perform radiological arteriography.

Exhibit 2

PETITION

Petition for Change to Cardiac Catheterization Need Determination Methodology

PETITIONER

Rex Healthcare
4420 Lake Boone Trail
Raleigh, NC 27607

Erick Hawkins
System Vice President, Heart and Vascular Services
919-784-4586
Erick.Hawkins@rexhealth.com

STATEMENT OF THE PROPOSED CHANGE

Rex Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to change the Cardiac Catheterization Need Determination Methodology in *2015 State Medical Facilities Plan (2015 SMFP)*. Specifically, Rex requests that the threshold for additional cardiac catheterization equipment be applied to each hospital, or in the case of hospitals under common ownership in the same service area, to each group of hospitals. Need determinations would be granted once equipment is appropriately utilized irrespective of the utilization of other hospitals in the same service area. Rex proposes the following changes to Chapter 9: Cardiac Catheterization Need Determination Methodology, Methodology 1:

Step 5: ~~Sum the number of units of fixed cardiac catheterization equipment required for all facilities in the same cardiac catheterization equipment service area as calculated in Step 4. (NOTE: The sum is rounded to the nearest whole number.)~~

Subtract the total planning inventory for each facility from the number of units of fixed cardiac catheterization equipment required as calculated in Step 4. The difference is the surplus or deficit of units of fixed cardiac catheterization equipment. *(Note: Deficits will appear as positive numbers; surpluses, as negative numbers.)*

Step 6: ~~Subtract the number of units of fixed cardiac catheterization equipment required in each cardiac catheterization equipment service area from the total planning inventory for each cardiac catheterization equipment service area. The difference is the number of units of fixed cardiac catheterization equipment needed.~~

Petition: Cardiac Catheterization Need Determination Methodology

Rex Healthcare

Page 2 of 9

The number of units of fixed cardiac catheterization equipment needed in a service area is determined as follows:

- a) The threshold for a need determination for additional units of fixed cardiac catheterization equipment is a projected deficit of 0.1 or more units as calculated in Step 5.
- b) The threshold is applied individually to each hospital, and a need determination is generated irrespective of surpluses at other hospitals in the service area, unless there are other hospitals in the service area under common ownership.
- c) If two or more hospitals in the same service area are under common ownership, the surpluses and deficits for those hospitals are totaled as calculated in Step 5. The threshold for a need determination for hospitals under common ownership in the same service area is a total projected deficit of 0.1 or more.
- d) The projected need determinations of all facilities and owners in the service area will be summed to determine the total number of units of fixed cardiac catheterization equipment needed in the service area.

Qualified Applicants

Any qualified applicant may apply for a certificate of need to acquire needed cardiac catheterization capacity. An applicant is a qualified if it is an existing hospital without fixed cardiac catheterization equipment, or if its existing cardiac catheterization equipment is operating at an average of 1,200 weighted procedures per unit of fixed cardiac catheterization equipment as reported in the current State Medical Facilities Plan under which the application is being reviewed.

Based on Rex's review of the 2014 Hospital License Renewal Applications and Inventory of Medical Equipment Forms, the proposed change will result in an additional need determination in Wake County for the 2015 *SMFP*. Please see Attachment 1 for detailed tables comparing the results of the current methodology and the proposed methodology. As discussed below, Rex believes the proposed change is needed in order to provide access to cardiac catheterization services, that it will not have adverse effects on providers or consumers, will not result in unnecessary duplication, and is consistent with the Basic Principles of the *SMFP*.

BACKGROUND

The various methodologies in the *SMFP* generally consider need based either on the entire service area or each individual provider. The current cardiac catheterization methodology determines need based on the entire service area, and as a result, individual providers may have a significant deficit, but no need is determined to exist in the area because of the surplus at other providers. The idea of ensuring that additional capacity is not prematurely allocated is central to the goal of suppressing unnecessary duplication, a central tenet of the CON statute. This approach may be reasonable for certain services, particularly those for which the service is merely one adjunct to the overall diagnostic process and treatment plan. For example, a patient needing an MRI scan to support a diagnosis may choose an MRI provider separate from his physician or hospital, without it negatively impacting his diagnosis or treatment, particularly on an outpatient basis, as the vast majority of MRI scans are provided. Other services, however, are much more central to the overall process of diagnosis and treatment, require a physician present to perform the procedure, and may be performed more often on an inpatient basis than other procedures. Such is the case for cardiac catheterization services. The cardiologist is central to the diagnosis and treatment, as he or she is directly involved with performing the procedure on the patient. Since that physician has been chosen by the patient to provide his or her care, the notion of the physician referring the patient to a physician at another facility, just because there may be more capacity available there, is extraordinarily unlikely. Although cardiologists may be privileged at multiple hospitals, they typically choose a single facility at which to perform most of their procedural work. The utilization of a particular facility is thus driven primarily by physician and patient preference, not the deficit or surplus at a facility. Therefore, a facility-specific methodology for cardiac catheterization is more appropriate than a service area-based methodology.

As noted above, other methodologies within the *SMFP* use a facility-specific approach, consistent with the proposed change, including the methodologies for acute care beds and PET scanners. In contrast, the existing fixed cardiac catheterization need determination methodology calculates projected need based on the aggregate need within each service area. However, since cardiac catheterization services are limited to hospital providers, and since most service areas include only one hospital, the vast majority of facilities have a need methodology that is, in essence, facility-based. Specifically, in the 39 cardiac catheterization service areas, all but seven (7) of them have only one fixed cardiac catheterization provider. In each of these service areas, the need methodology bases its calculation on the utilization of a single facility, and so the methodology is effectively facility-specific for the majority of state. In the remaining seven service areas in which there are two or more providers of fixed cardiac catheterization services, the need methodology calculates projected need based on the aggregate need of all providers in the service area. As such, the utilization of a single facility is subordinate to overall utilization. Please note, however, that the Durham/Caswell Service Area includes two hospitals under the common ownership of Duke University Health System; thus, as a result, the proposed methodology will have

Petition: Cardiac Catheterization Need Determination Methodology

Rex Healthcare

Page 4 of 9

no impact on this service area.¹ Therefore, only six (6) service areas will be affected by the proposed change in the methodology.

Rex believes that for services such as cardiac catheterization, a service area-based methodology can perpetuate imbalances between highly utilized and underutilized providers. Underutilized equipment offsets the need expressed by well-utilized equipment and prevents the creation of additional need determinations which would allow high utilization providers to acquire more capacity and operate at more appropriate utilization levels. Even some methodologies which determine need on a service area basis attempt to mitigate this imbalance by excluding chronically underutilized facilities. In order to ensure that underutilized providers cannot diminish the need of overutilized providers, Rex proposes that only providers operating their fixed cardiac catheterization equipment at appropriate utilization levels be qualified applicants for additional fixed capacity. By failing to adjust the methodology as proposed, well-utilized facilities may be forced to operate above appropriate utilization levels and may not be able to deliver optimal care consistent with the Basic Principles of the *SMFP*, as discussed below.

Similar to other methodologies, the cardiac catheterization need methodology considers the units of equipment needed by dividing the number of weighted procedures by some percentage of the total capacity of the equipment—in this case, 80 percent. For cardiac catheterization, the capacity is defined as 1,500 diagnostic-equivalent procedures, so 80 percent is 1,200 diagnostic-equivalent procedures. The cardiac catheterization methodology differs somewhat from other need methodologies for other types of services as it currently requires the number of units of equipment needed to be rounded to the nearest whole number. In other words, the need for a second unit of cardiac catheterization equipment is not generated until a need for 1.5 units is shown. Therefore, to trigger a need determination, the existing cardiac catheterization equipment in a county must actually perform 600 procedures over the stated threshold (1,200 procedures) (e.g., a need for at least 0.5 units of equipment is required to generate a need determination for one additional unit of equipment; $0.5 \times 1,200$ procedures = 600 procedures). As a result of this step, providers located in counties with only one piece of cardiac catheterization equipment are forced to perform 1,800 procedures per year, or 120 percent of defined capacity, before a need is triggered for additional equipment. Under the proposed facility-based methodology, each provider will be evaluated on its own and will be required to perform above capacity in order to generate a need. This burden on providers is due to the lack of a “tiering” approach for facilities/counties with less total capacity in the cardiac catheterization methodology, unlike the “tiered” approaches used in the acute care bed, operating room and MRI methodologies. As noted above, cardiac catheterization is a much different service than most of the other regulated services in the *SMFP* in that it is often used for emergency procedures. Most

¹ Under the proposed methodology change, if two or more hospitals in the same service area are under common ownership, their surplus or deficit of equipment is totaled and then evaluated against the threshold for a need determination. Please see the revised Step 6.c above for the specific language.

Petition: Cardiac Catheterization Need Determination Methodology

Rex Healthcare

Page 5 of 9

other equipment-based services, including MRI, PET, lithotripsy, gamma knife and linear accelerator treatments, are rarely, if ever used for emergency cases. Thus, with those services, when equipment reaches or exceeds capacity, patients may be inconvenienced, but rarely is emergency treatment potentially delayed as a result. Given these factors, Rex proposes that a need determination be generated when a provider reaches the capacity of its current equipment. In order to avoid potential issues related to rounding, as experienced relative to the home health methodology in recent years, Rex proposes that the threshold for a need determination for additional units of fixed cardiac catheterization equipment be defined as a projected deficit of 0.1 or more units.

Although Rex believes the proposed change is important, and though it will change the methodology statewide, it does not believe it will have a far-reaching impact. As the SHCC is aware, since 2003, cardiac catheterization volume has decreased statewide, although it does appear to have stabilized in recent years. Given this trend, it is unlikely that many providers will generate a need in the near future. However, Rex believes the methodology should evolve to reflect changes in healthcare, including the increasing alignment between physicians and hospitals in single systems of care, which has led to substantial shifts of patients among providers. Notably, Rex has experienced a substantial increase in its cardiac catheterization volume recently (more than 20 percent increase in weighted procedures in each of the last two years) due to its increased alignment with its cardiologists. In this context, the cardiac catheterization methodology must be more flexible in responding to the needs of specific facilities and the patients and physicians who choose to utilize them.

REASON FOR THE REQUESTED ADJUSTMENT

Rex believes that the cardiac catheterization methodology should determine need on a facility-specific basis, which would provide an equitable approach and only impact a minority of the hospitals across the state. Highly utilized providers would be able to generate need determinations, regardless of underutilized providers in the same service area. Underutilized providers would be prevented from applying for any need determinations as they would not be qualified applicants. It should be noted any need determination generated under the proposed change would still be subject to Certificate of Need review, whereby any qualified provider could apply for, and demonstrate the need to acquire, additional cardiac catheterization equipment. Finally, the threshold for a need determination should be lowered so that in order to ensure that need determinations are generated when providers reach capacity (especially given the use of cardiac catheterization equipment for patients on an emergency basis).

The proposed change will further the efforts of those healthcare systems that are working to improve their quality and continuity of care. As noted above, patients and physicians generally do not wish to utilize a site of care under the control of a different provider. Under the proposed change, systems will have a process to acquire needed cardiac catheterization equipment.

Petition: Cardiac Catheterization Need Determination Methodology

Rex Healthcare

Page 6 of 9

Rex also believes this change would be consistent with other recent recommendations from the SHCC. Specifically, the 2014 *SMFP* includes an adjusted need determination for a linear accelerator in Service Area 20 resulting from a petition from Duke Raleigh Hospital (DRH). The SHCC concluded that even with a significant surplus of linear accelerator capacity in the service area, the need shown by the utilization at DRH was not mitigated by the surplus capacity of other providers in the service area or the pending implementation of two additional linear accelerators. One of the central themes of the DRH petition was that the available capacity at other providers was “not available as a practical matter to alleviate demand” on its unit. Rex believes that to the degree this notion motivated the SHCC to allocate another linear accelerator in the service area, the same rationale should lead to the approval of this proposed change in the cardiac catheterization methodology.

Additionally, the 2013 *SMFP* included an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Robeson County resulting from a petition from Southeastern Regional Medical Center (SRMC). The SHCC concluded that SRMC’s utilization of its one existing fixed cardiac catheterization unit demonstrated the need for additional equipment as it exceeded 100 percent of defined capacity, yet did not generate a need determination due to the rounding factor in the methodology. Rex believes that its proposed changes to the rounding rules for cardiac catheterization equipment will alleviate this issue for the future.

The approval of this methodology change will provide a clear and consistent path for highly utilized providers to generate need determinations and thus prevent potentially repetitive special need adjustment requests from the facilities in the service areas that are inequitably treated in the current methodology.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

As noted above, the current fixed cardiac catheterization need determination methodology can perpetuate imbalances between highly utilized and underutilized providers in the same service area. An underutilized provider diminishes the need demonstrated by a highly utilized provider. 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. Physicians and patients are increasingly reluctant to shift to another site of care under the control of a different healthcare system for their care as this can lead to disruptions in the continuity and quality of care. There is no remedy for the patients, physicians, and providers in such a situation for cardiac catheterization services outside of a methodology change, as proposed, or a special need adjustment.

ALTERNATIVES CONSIDERED

File a Petition for a Special Need Adjustment

As noted above, the current cardiac catheterization methodology is unequitable and perpetuates imbalances between providers. A petition in the summer for a special need adjustment would, at best, result in a one-time allocation and would fail to address the problematic aspects of the current methodology. While Rex believes a special need determination can remedy the growing issues for cardiac catheterization capacity in Wake County, it would not address potential issues in other counties or issues that arise in future years. For these reasons, Rex has chosen to file a methodology change petition. However, if the SHCC determines that this methodology change is not desirable and would prefer a special need adjustment request to remedy these issues, Rex respectfully requests that the SHCC express this preference during its deliberations on this proposal.

Exclude Chronically Underutilized Facilities

The operating room methodology excludes chronically underutilized facilities in order to remedy the imbalances between highly utilized and underutilized providers. Rex does not believe this approach is appropriate for the cardiac catheterization methodology for several reasons. First, there is no consensus around an appropriate definition of a chronically underutilized cardiac catheterization provider. Such a definition would need to account for the emergency, life-saving nature of the service and its subsequent vital importance in many communities, regardless of utilization. More importantly, the majority of the state is already treated with a facility-specific methodology, effectively, and an extension of that approach to the remainder of the state would provide the needed remedy. Finally, the number of cardiac catheterization units in each service area is much lower than the number of operating rooms, and most providers have at least modest utilization levels. Thus, the exclusion of chronically underutilized facilities would not be as useful for this methodology. However, Rex does propose that only appropriately utilized facilities be qualified applicants for additional cardiac catheterization equipment.

UNNECESSARY DUPLICATION

Rex does not believe the proposed change will result in unnecessary duplication of health resources. The current acute care bed and PET methodologies use facility-specific methodologies consistent with the change proposed by Rex for cardiac catheterization. Need determinations for acute care beds and PET scanners are generated by facilities regardless of the utilization of other facilities within the same service area. Based on its adoption of these methodologies, it is clear that the SHCC understands that this approach to healthcare planning does not result in the unnecessary duplication of health resources. In fact, as discussed above, this approach provides a more specific and flexible methodology for allocating healthcare resources, as needed, across the state.

BASIC PRINCIPLES

Safety and Quality

The proposed methodology change will provide a process for facilities to generate cardiac catheterization capacity regardless of the utilization of other providers. Without this methodology change, a provider could indefinitely operate its cardiac catheterization equipment at high levels of utilization without any possibility of acquiring additional capacity through the current methodology. In such a situation, a facility may not be able to provide optimal safety and quality of care. Cardiac catheterization services must be available immediately for patients who present to a hospital with certain cardiology issues. These emergency situations inevitably delay scheduled patients or cause rescheduling. If the demand for cardiac catheterization services at a facility exceeds its reasonable capacity, then these delays and reschedules result in patients beginning their procedures late in the day, thus requiring a more expensive and inconvenient overnight stay, or waiting until a later scheduled time. Scheduled procedures, while not emergency cases, are needed to improve the health of these patients and the delays that may result from overcapacity equipment results in delays in their recovery and return to normal life. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment. If patients and physicians are forced to access care at another facility which has available capacity, they may encounter disruptions in the continuity of care. Physicians and providers work every day to improve the systems of care which leverage information technology, multidisciplinary teams, and processes of care to deliver the right care at the right time to the right person. A facility under the control of another healthcare system cannot provide that same system of care to an unfamiliar physician and patient. As a result, safety and quality may be reduced without the proposed change in the methodology.

Access

The proposed change will enable the development of additional access to cardiac catheterization equipment, as needed throughout the state. Seven service areas are inequitably treated under the current methodology. Any potential need within these service areas could be indefinitely suppressed by underutilization, for whatever reason, at another provider in the same service area. In these areas, access to care for patients of all types is impacted.

Value

The proposed change will enable providers throughout the state to provide greater healthcare value. As noted above, facilities that have a process to add capacity as needed will be able to provide safer and higher quality services than if forced to operate overcapacity. Delays in needed treatment or unanticipated overnight stays at the

Petition: Cardiac Catheterization Need Determination Methodology

Rex Healthcare

Page 9 of 9

hospital add to healthcare expenditures. Overutilized equipment requires greater maintenance which creates additional expenses.

CONCLUSION

In conclusion, Rex requests that the SHCC approve the petition to change the cardiac catheterization need determination methodology. The proposed change would extend the facility-specific approach to cardiac catheterization need determinations to the entire state, rather than just to the majority of providers, and ensure the a need determination is generated when additional capacity is needed. As such, the methodology will become more specific and flexible to the changing needs of the citizens of North Carolina.

Thank you for your consideration.

Attachment 1

Cardiac Catheterization Equipment Service Areas	Facility	Total Planning Inventory	2013 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed
Catawba	Catawba Valley Medical Center	1	658	0.55	0	
	Frye Regional Medical Center	4	4,408	3.67	0	
	TOTAL	5		4		0
Forsyth	N.C. Baptist Hospital	5	3,606	3.00	0	
	Novant Health Forsyth Medical Center	8	4,612	3.84	0	
	TOTAL	13		7		0
Guilford	Cardiovascular Diagnostic Center	1	830	0.69	0	
	Cone Health	7	5,245	4.37	0	
	High Point Regional Health System	4	3,973	3.31	0	
	TOTAL	12		8		0
Iredell	Davis Regional Medical Center	1	441	0.37	0	
	Iredell Memorial Hospital	1	1,194	1.00	0	
	Lake Norman Regional Medical Center	1	53	0.04	0	
	TOTAL	3		1		0
Mecklenburg	Carolinas Medical Center (CMC)	7	6,804	5.67	0	
	CMC Mercy-Pineville	4	3,552	2.96	0	
	CMC-University	1	39	0.03	0	
	Novant Health Matthews Medical Center	1	765	0.64	0	
	Novant Health Presbyterian Medical Center	4	3,447	2.87	0	
	TOTAL	17		12		0
Wake	WakeMed	9	8,570	7.14	0	
	WakeMed Cary	1	222	0.19	0	
	Duke Raleigh Hospital	3	447	0.37	0	
	Rex Hospital	4	5,029	4.19	0	
	TOTAL	17		12		0

PETITION

Petition for Special Need Adjustment for Fixed Cardiac Catheterization Equipment in Wake County

PETITIONER

Rex Healthcare
4420 Lake Boone Trail
Raleigh, NC 27607

Erick Hawkins
System Vice President, Heart and Vascular Services
919-784-4586
Erick.Hawkins@rexhealth.com

STATEMENT OF REQUESTED ADJUSTMENT

Rex Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Wake County in the *2015 State Medical Facilities Plan*.

BACKGROUND

Since 1894, Rex Hospital has provided healthcare, including cardiovascular services, to residents of Raleigh, Wake County, and the surrounding area. Rex Hospital, a member of UNC Health Care, provides the highest quality of care to patients and their families regardless of their ability to pay. Rex is a leader in cardiology in Raleigh, Wake County, and through its physician partners, Eastern North Carolina. From expert surgeons and cardiologists to highly-trained nurses, Rex's heart and vascular team provides exceptional care in the most critical situations for patients. Each of its nurses is trained in advanced cardiac life support (ACLS) in order to manage cardiac arrest in its early stages. Rex offers a variety of diagnostic and procedure options including cardiac catheterization, electrophysiology (EP), and open heart surgery. Notably, Rex was the first provider in Wake County to offer trans-catheter aortic valve replacement (TAVR), an advanced heart valve replacement procedure that provides an option for patients who are too sick or weak to undergo open heart surgery.

The *State Medical Facilities Plan* last added a unit of fixed cardiac catheterization equipment to Wake County in 2006; Rex applied for and was approved to

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 2 of 22

develop that unit. Since that time, Wake County's population has grown 23 percent according to the North Carolina Office of State Budget and Management. While statewide cardiac catheterization volume is declining, Rex's cardiac catheterization utilization has increased 23 percent annually since 2011. The following discussion highlights the unique utilization trends faced by Rex and demonstrate the need for the requested special need adjustment.

REASON FOR THE REQUESTED ADJUSTMENT

Rex's cardiac catheterization volume has increased substantially over the past three years necessitating additional capacity, which cannot be achieved without the requested need determination. As shown in Table 9W of the *Proposed 2015 State Medical Facilities Plan (SMFP)*, Rex has a need for 4.19 units and has an inventory of only four units. As shown in the table below, more recent utilization data from Rex indicate that its volume has grown since the Federal Fiscal Year 2013 (FFY 2013) time period that is represented in the *2015 SMFP* and Rex now demonstrates a need for 4.86 units of catheterization equipment.

Rex Cardiac Catheterization Utilization

	FFY 2011	FFY 2012	FFY 2013	FFY 2014*
Diagnostic	1,697	2,067	2,666	3,055
Interventional	820	1,033	1,350	1,587
Total Procedures	2,517	3,100	4,016	4,642
Weighted Procedures Total [^]	3,132	3,875	5,029	5,833
Machines Required[†]	2.61	3.23	4.19	4.86
Annual Growth of Weighted Procedures	4.3%	23.7%	29.8%	16.0%

Source: Rex internal data.

*FFY 2014 volume based on eight months of data (October 1, 2013 to May 26, 2014) annualized.

[^]Weighted Procedures Total = Diagnostic + Interventional x 1.75

[†]Machines Required = Weighted Procedures Total ÷ 1,200 procedures (80 percent of 1,500 procedure capacity) per the *Proposed 2015 SMFP* methodology.

After annual growth in excess of 20 percent in the prior two years, Rex cardiac cath volume has sustained a strong 16 percent growth rate since FFY 2013, the base data year shown in the *Proposed 2015 SMFP*. Rex's growth has been driven by unique circumstances, namely its affiliation in 2011 with Wake Heart & Vascular Associates (WHV), a leading cardiovascular practice in the Triangle. In 2013, WHV joined with Rex Heart & Vascular Specialists to create North Carolina Heart & Vascular, part of the UNC Heart & Vascular Network. The

**Petition: Wake County Cardiac Catheterization Equipment
Rex Healthcare
Page 3 of 22**

combined practice has nearly three dozen physicians working out of 19 offices in ten counties. Since its decision to affiliate with Rex and UNC, WHV has relocated its primary clinic and most of its physician offices to the Rex Hospital campus, and, along with that shift, much of its hospital-related patient care, including cardiac catheterizations. The result is dramatic growth in cardiac catheterization volume at Rex, which stands in stark contrast to the trends in the rest of Wake County and the state. In fact, while it operated at 84 percent of capacity in FFY 2013, Rex’s utilization has increased even further over the past year and now its labs are operating at 97 percent of capacity.

Rex Cardiac Catheterization Utilization

	<i>FFY 2011</i>	<i>FFY 2012</i>	<i>FFY 2013</i>	<i>FFY 2014*</i>
Weighted Procedures Total	3,132	3,875	5,029	5,833
Units of Equipment [^]	3	4	4	4
Capacity [†]	4,500	6,000	6,000	6,000
Percent Utilization	70%	65%	84%	97%

Source: Rex internal data.

*FFY 2014 volume based on eight months of data (October 1, 2013 to May 26, 2014) annualized.

[^]Rex operated three units of equipment in FFY 2011 and added a unit in FFY 2012 based on a prior CON.

[†]Capacity = Units of Equipment x 1,500 procedure capacity per unit according to the *Proposed 2015 SMFP* methodology.

Rex’s weighted cardiac catheterization procedures have grown at a compound annual growth rate of 23 percent since 2011. If Rex’s utilization were to grow 23 percent from 2014 to 2015, it would perform 7,176 weighted procedures or 120 percent of capacity. In fact, Rex will reach 100 percent of its cardiac cath capacity if it only grows 2.9 percent from its FFY 2014 utilization. Given these factors, Rex believes it must act immediately in order to maintain the appropriate capacity needed to care for its patients.

According to the *Proposed 2015 SMFP*, Rex was the third highest utilized cardiac cath provider in North Carolina in 2013 and one of only three operators above 80 percent utilization.

Highest Utilized Cardiac Cath Providers in 2013

	<i>Weighted Procedures</i>	<i>Current Inventory</i>	<i>Capacity</i>	<i>Percent Utilization</i>
Cape Fear Valley Medical Center	3,906	3	4,500	87%
New Hanover Regional Medical Center	6,459	5	7,500	86%
Rex Healthcare	5,029	4	6,000	84%

Source: Proposed 2015 SMFP.

As shown above, Rex is operating at 97 percent of capacity in 2014, which would make it the highest utilized provider in the state. In fact, based on Rex’s 2014 volume (5,833 weighted procedures), even if Rex were to add another unit immediately, bringing its inventory to five units of equipment, **it would still be operating at 78 percent of capacity** (78 percent = 5,833 procedures ÷ 5 units x 1,500 procedures per unit of capacity).

The two other providers in the table above are the only cardiac cath providers in their service areas. As such, their volume and capacity constraints are the sole drivers of additional need for additional units of cardiac cath equipment. In fact, in recent years, need determinations for additional units of equipment have been generated in New Hanover County, but the provider has petitioned to have that need removed. In contrast, Rex is in a service area with three other providers, none of whom has the same level of utilization. If Rex were the only provider in its service area, its 2014 utilization (showing a need for 4.86 units) would generate a need determination for an additional unit of capacity under the SMFP methodology. However, since the SMFP methodology is based on the average utilization of all providers in a service area, Rex is unable to meet the demand of its patients and physicians because other providers are underutilized.

Challenges with High Utilization

The SMFP methodology allocates additional units of catheterization once existing capacity in the service area reaches 80 percent utilization. The criteria and standards for cardiac catheterization used by the Certificate of Need Section require providers to demonstrate that any new equipment will be utilized at 60 percent or above. These standards recognize that providers cannot operate at or near 100 percent of capacity because some time must be allowed for emergencies or unforeseen delays. Due to its high cath lab utilization, Rex has no extra time during the day, and any emergency or delay can multiply, impacting the rest of the days’ patients, as well as staff and physicians. Unlike other diagnostic or even interventional services, the unique qualities of cardiac catheterization make

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 5 of 22

operating at high utilization difficult for the facility, for physicians, and most importantly, for patients. The following discussion explains some of these challenges.

Emergency Cases

Cardiac catheterization, particularly for patients presenting with ST-elevated myocardial infarction, or STEMI, is provided on an emergency basis to save patients' lives. When a hospital's labs are operating at 97 percent of capacity and a patient presents with a need for emergency intervention, the lack of an available lab can lengthen the time until that care is available. In such instances at Rex, the cardiologist and cath team deal with the issue in an effective, evidence-based manner. The clinical team determines if a patient can be safely removed from a room or if a case can be completed expeditiously. If the selected patient is in the middle of the procedure but has yet to have his or her procedure completed, the patient is removed from the room with the sheath left in place until another room becomes available to complete the case. Clearly, this is not optimal patient care for the delayed patient, and it can delay treatment of the emergency patient. At facilities with adequate capacity, such a scenario would be much less likely to occur. As the SHCC is no doubt aware, prolonged door-to-balloon or symptom-to-balloon times have been correlated with increased mortality after primary percutaneous coronary intervention (PCI). As a result, the American College of Cardiology has established as part of its "Door-to-Balloon" campaign (known as the "D2B Alliance") that patients should receive interventional treatment within fewer than 90 minutes from the time the patient arrives at the hospital. The Joint Commission has also adopted this parameter as a core quality measure. As part of this 90-minute guideline, the D2B Alliance advocates that the cath lab team be available to perform the procedure within 20 to 30 minutes of the patient's arrival at the hospital. When a provider is operating at nearly 100 percent of capacity, it is significantly more challenging to meet this lifesaving guideline.

Extended Hours

Although cardiac cath is an invasive procedure, the majority of patients are outpatients, and most return home the same day. In a typical day for Rex's cath labs, cases begin at 7:00 am. Most of those patients who are treated earlier in the day go home the same day, particularly those who have only diagnostic procedures. However, due to Rex's full schedule, many patients begin their cases in the late afternoon and then must be monitored for an average of four hours post procedure. These patients, many of whom are older and often have elderly caregivers, are understandably reluctant or unable to leave the hospital and be

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 6 of 22

driven home late at night. As a result, many of these patients must stay overnight rather than being discharged the same day. These overnight stays are an unnecessary healthcare cost and are a substantial inconvenience to patients and their families. While these patients may not be emergency cases, they are scheduled procedures which are needed to diagnose and improve the health of these patients, and the delays that may result from equipment operating near or above capacity result in extended recovery and a postponed return to normal life.

Unpredictable Case Times

Rex strives to schedule its cath labs as effectively as possible, but the nature of the procedure makes it difficult to be precise and inevitably unpredicted delays occur. Because the standard of care is to schedule patients for a diagnostic procedure and then extend the case for an intervention if a stenosis or blockage is found, it is very difficult to consistently predict the length of a case. Cath labs could operate more efficiently if a diagnostic cath was performed and the patient was then brought back at another time for the intervention. However, this would delay care, increase radiation and contrast dose to the patient, and most significantly require a second catheterization procedure increasing the cost of care. This inability to consistently predict the length of each case, particularly in the context of Rex's high utilization, leads to delays for patients, staff, and physicians. For patients, the delay may result in an unnecessary overnight stay or an extended period of fasting. Catheterization patients are typically under physicians' orders to not eat or drink (NPO) for a period of time prior to their procedures; for patients scheduled for a morning procedure, this period often begins at midnight. Patients whose procedures are unexpectedly delayed until later in the day must therefore endure an unusually long time before they are able to eat or drink, which clearly impacts patient comfort and satisfaction.

Staffing Issues

The uncertainty, delays, and emergencies that Rex experiences are also burdensome for physicians and staff. Delays for physicians result in delays for all of their patients, both in and out of the hospital. Since physicians normally have clinic hours after their cases are finished, if a physician is delayed at the hospital then they cannot see patients in their office on time. Moreover, Rex cannot efficiently staff its cath labs in this high utilization environment as staff routinely work overtime which decrease their job satisfaction and adds unnecessary costs.

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 7 of 22

Increased Maintenance Costs

Finally, Rex’s high utilization necessitates that any routine maintenance occur overnight or on the weekends, which is more costly than if completed during work hours. Rex’s schedule simply has no room for unscheduled (not routine) downtime of a machine. The consistent overuse of the equipment may also increase the amount of maintenance required, which will add cost and lead to increased downtime, scheduled and unscheduled.

Rex’s Need Is Unique to the Service Area

For a minimal capital investment, Rex could modify existing vascular equipment with additional software to create an additional cardiac catheterization unit. However, Rex requires a need determination as well as a subsequent certificate of need to do so. While Rex clearly demonstrates a large and growing need for additional capacity, the cardiac catheterization methodology in the *SMFP* determines need on a service area basis. Thus, Rex’s deficit of cardiac catheterization capacity is erased by the surplus of capacity at other facilities in Wake County. As shown in the excerpt below from Table 9W of the *Proposed 2015 SMFP*, all other Wake County cath providers are underutilized and, as a result, there is a surplus of 5.11 units.

Table 9W of Proposed 2015 SMFP: Wake County

	<i>Total Planning Inventory</i>	<i>Machines Required Based on 80% Utilization</i>	<i>Deficit/(Surplus)</i>
Rex Hospital	4	4.19	0.19
WakeMed	9	7.14	(1.86)
WakeMed Cary	1	0.19	(0.81)
Duke Raleigh	3	0.37	(2.63)
Total	17	12	(5.11)

Source: *Proposed 2015 SMFP*.

As the *SMFP* allocates additional cardiac catheterization equipment based on the need for Wake County in total, the excess capacity at WakeMed, WakeMed Cary, and Duke Raleigh restricts the ability of Rex to add capacity now and in the future. Of note, Duke Raleigh has the third largest surplus of cardiac catheterization units among all providers in the North Carolina.

If utilization at each of the other facilities in Wake County remained at 2013 levels, Rex would have to operate at 245 percent of its capacity (which obviously would be impossible) in order for a need for an additional cardiac catheterization

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 8 of 22

unit to be generated in Wake County using the standard methodology. While other providers in North Carolina have exceeded 100 percent of the capacity standard by performing procedures at night or on weekends, none has achieved over 150 percent of capacity. Moreover, utilization in excess of 100 percent has myriad negative implications as detailed above.

Conversely, the other facilities in Wake County would need to add 6,361 weighted procedures (2,230 additional procedures at WakeMed, 978 at WakeMed Cary, and 3,153 at Duke Raleigh) in order to effectively utilize their existing capacity so that Rex's utilization could generate additional need. For perspective on the 6,361 additional weighted procedures needed at other facilities, Rex's 2014 cardiac catheterization utilization is 5,833 weighted procedures. Thus, the other facilities in Wake County would need to add volume equivalent to Rex in total and then over 500 more in order to reach effective utilization of existing capacity. **From Rex's perspective, absent the special need adjustment requested in this petition, it will never be able to acquire additional cardiac catheterization capacity, no matter how needed because other providers in its community are so underutilized.**

Clearly, there is cardiac catheterization capacity available at other Wake County facilities. The idea of ensuring that additional capacity is not prematurely allocated is central to the goal of suppressing unnecessary duplication, a central tenet of the CON statute. This approach may be reasonable for certain services, particularly those for which the service or procedure is merely one adjunct to the overall diagnostic process and treatment plan. For example, a patient needing an MRI scan to support a diagnosis may choose an MRI provider separate from his physician or hospital, without it negatively impacting his diagnosis or treatment, particularly on an outpatient basis, as the vast majority of MRI scans are provided. Other services, however, are much more central to the overall process of diagnosis and treatment, require a physician present to perform the procedure, and may be performed more often on an inpatient basis than other procedures. Such is the case for cardiac catheterization services. The cardiology practice, which is comprised a team of providers, including medical, invasive, interventional and surgical cardiologists, has been chosen by the patient to provide his or her care. This team is central to the diagnosis and treatment, and the interventional cardiologist is directly involved with performing the procedure on the patient. Since those physicians have been chosen by the patient to provide his or her care, the notion of the physician referring the patient to a physician at another facility, just because there may be more capacity available there, is extraordinarily unlikely, as well as being disruptive to the continuity of care. Although cardiologists may be privileged at multiple hospitals, they typically choose a single facility at which to perform most of their procedural

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 9 of 22

work. Physicians and patients are increasingly reluctant to shift to another site of care under the control of a different healthcare system for care as it can lead to disruptions in the continuity and quality of care. The utilization of a particular facility is thus driven primarily by physician and patient preference, not the available capacity at a facility.

Moreover, the central theme of healthcare reform both past and present is the need for greater efficiency and integration in the delivery of healthcare. Hospitals and physicians are working together with the benefit of information technology to deliver coordinated services to patients. At Rex, patients see their cardiologist in the adjacent medical office building and receive their ancillary tests such 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 (and even to the patients themselves through an online portal). This integrated database has numerous benefits for patient care. For example, if a physician notices something of interest in a patient's EKG, he/she can review that patient's entire history of EKG results from all of UNC/Rex Healthcare to see if that issue has been consistent in that patient's medical history, rather than ordering an unnecessary additional test. The medical record also enables the cardiologist to understand the most appropriate way to treat the patient, based on any possible future scheduled procedures. For example, if a patient is scheduled for another surgical case at a future date, such as a hip replacement, the cardiologist can access that information in the patient's medical record prior to the catheterization. In such a case, if the hip replacement is scheduled after the cardiac cath, the cardiologist may choose to use a bare-metal stent instead of a drug-eluting one to reduce the risk of hemorrhage during the future surgical case. 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) within UNC/Rex Healthcare.

For these reasons, Rex does not believe that its need for additional cardiac catheterization capacity can be served by underutilized capacity at other facilities. There is no remedy for Rex's patients and physicians for cardiac catheterization services outside of a special need adjustment.

The *SMFP* implicitly recognizes this dynamic in its acute care bed methodology which allocates bed need based on facility-specific need regardless of the presence of underutilized facilities in the service area. For example, the *Proposed 2015 SMFP* has a need determination for 26 beds in Mecklenburg County based

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 10 of 22

on the bed deficit of one system even though the other system shows a surplus of 24 beds. This instance is representative of understanding shown by the *SMFP* and the SHCC that underutilized assets at one provider do not meet the needs of other providers.

More pointedly, the SHCC approved a petition by Duke Raleigh for an adjusted need determination for one additional linear accelerator in Service Area 20 (Wake and Franklin counties) in the 2014 *SMFP*. The SHCC acted specifically to alleviate Duke Raleigh's lack of linear accelerator capacity despite the absence of an overall need in the service area and in spite of the underutilization of multiple providers. Rex believes that its issue is very similar. As shown in the excerpt below in the October 2, 2013 Technology Committee report to the SHCC on this petition, additional capacity was found to be needed based on the overutilization of Duke Raleigh:

Petitioner: Duke University Health Systems dba Duke Raleigh Hospital

- **Request:** Duke Raleigh Hospital requested an adjusted need determination for one additional linear accelerator to meet a perceived unmet need in Service area 20 (Wake and Franklin Counties).
- **Committee Recommendation:** The Committee discussed the petition and agency report, which recommended denial of the petition request. The discussion included an update on one CON approved linear accelerator that was approved on February 2011 but has not been developed. This project is still on target to become operational in early 2014. The linear accelerator standard methodology demonstrates that the current inventory, including the CON approved linear accelerator to be developed, is providing sufficient access to linear accelerator services in Service Area 20. However, the consensus of the Committee recognized that Duke Raleigh is unable to increase its inventory to meet demonstrated excess patient demand. Therefore, the Committee recommends to the SHCC that the petition request be approved for one additional linear accelerator in Service Area 20.

As stated in the committee recommendation above, just as Duke Raleigh was not able to increase its linear accelerator capacity to meet the demands of its patients, Rex cannot increase its cardiac catheterization capacity to care for its patients. Duke Raleigh was overutilized while other facilities had excess capacity and there was a linear accelerator for the service area that had yet to be developed. Rex similarly is overutilized and its volumes continue to grow while other facilities in Wake County are substantially underutilized.

The SHCC's discussion at its October 2, 2013 meeting further underscores the similarities between the Duke Raleigh linear accelerator petition and Rex's current petition. In response to a request for greater detail about the Technology Committee's reasons for recommending approval of Duke Raleigh's petition, Dr. Dennis Clements, III stated, "*the linear accelerator presently operating in Duke Raleigh Hospital is basically over capacity. That unlike other things, like an MRI, where*

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 11 of 22

you may go get one and then if you need a different MRI you can go somewhere else. Most of these are cancer patients and once 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. And so I think that was part of the issue” (transcribed from the audio recording of the October 2, 2013 SHCC meeting). As noted above, Rex believes the cardiac catheterization services and their physicians are similarly associated with one hospital and that capacity is not interchangeable as the SHCC determined in the case of Duke Raleigh.

On the same topic, Dr. Pulliam stated, “[t]he other thing we can’t lose sight of, and again I don’t live around Raleigh, but if one facility is attracting a tremendous number of patients, they’re attracting them for some reason. They probably offer something the others don’t. There is a level of expertise possibly. It’s hard to say. And I don’t think we should constrain those who are doing the job right and well to the fact, to the point that they need more capacity just because we have these rules that might somehow try to redistribute the care” (transcribed from the audio recording of the October 2, 2013 SHCC meeting). Rex and its physician partners have been tremendously successful in attracting a growing number of cardiology patients since 2011 due to its quality, innovation, and overall patient care. Rex should not be penalized by its success. The SHCC recognized and alleviated Duke Raleigh’s capacity issues in 2013 and Rex believes that it faces the same issue with the cardiac catheterization and requests that the SHCC act accordingly.

The SHCC’s position in this area is supported by historical data in competitive cardiac catheterization markets. Rex performed a detailed review of the last ten years of utilization for each of the counties in North Carolina with multiple cardiac cath providers (Catawba, Forsyth, Guilford, Iredell, Mecklenburg and Wake counties, excluding Durham, where both cath providers are part of the Duke University Health System). Based on Rex’s review of the data there is no evidence to suggest that underutilized cardiac catheterization capacity alleviates the needs of overutilized cardiac catheterization facilities or that the addition of cardiac catheterization capacity to a provider harms the cardiac catheterization services at other facilities in the market. Each market is analyzed below in detail.

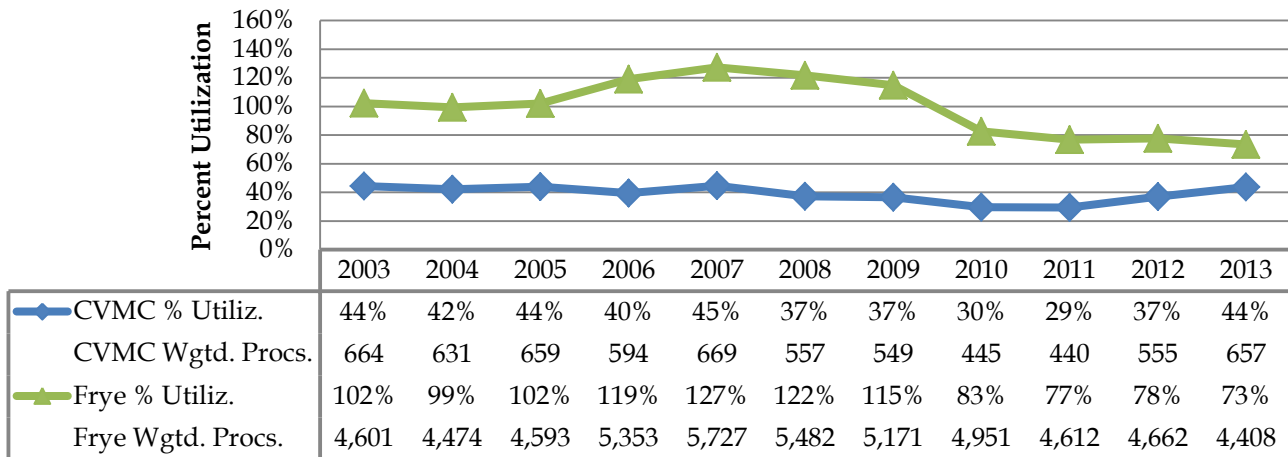
CATAWBA COUNTY

Frye Regional Medical Center (Frye) in Catawba County operated at or above 100 percent of the SMFP-defined capacity of its cardiac catheterization equipment from 2003 until 2009. Frye operated at these high utilization levels despite the underutilization of the cath equipment at Catawba Valley Medical Center (CVMC), which never exceeded 45 percent of capacity over the past ten

**Petition: Wake County Cardiac Catheterization Equipment
Rex Healthcare
Page 12 of 22**

years. Frye’s utilization was such that a need was generated in the 2008 SMFP for an additional unit of equipment despite CVMC’s underutilization. Please note that this need generation was only possible because there was only one other provider in the county whose surplus was small (less than one unit of excess capacity). Frye applied to develop that equipment, was approved, and began operation of its fourth unit in 2010. In the years following the addition of capacity at Frye, CVMC’s cath utilization has increased and its 2013 utilization is just 12 procedures below its highest utilization in the last ten years.

Catawba County Cardiac Catheterization Utilization



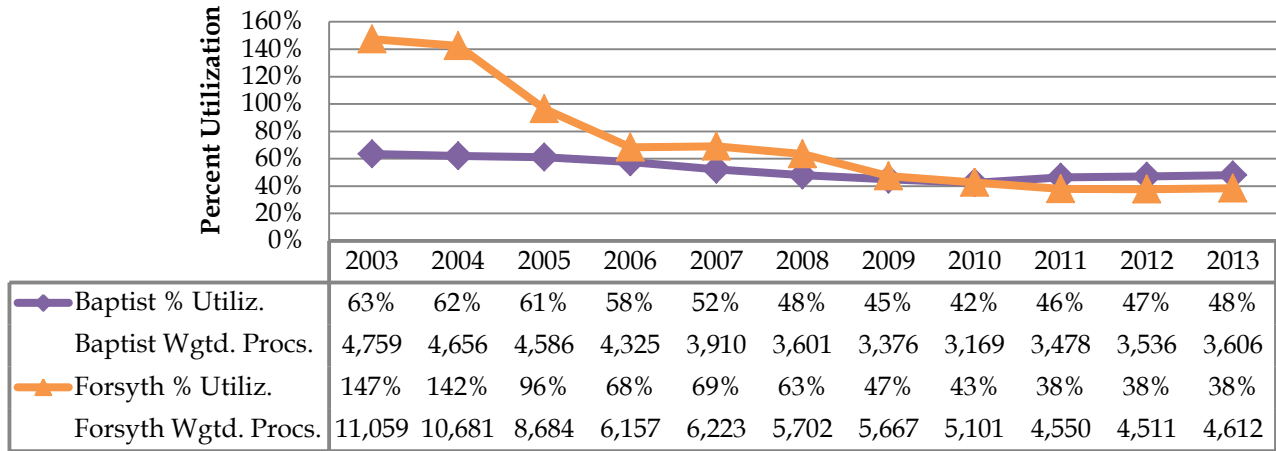
Note: CVMC operated one unit of cardiac catheterization equipment throughout the time period; Frye operated three units from 2003 to 2009, and four units from 2010 to 2013.

Source: 2005 to Proposed 2015 SMFPs and 2004 to 2014 License Renewal Applications.

FORSYTH COUNTY

Novant Health Forsyth Medical Center (Forsyth) operated above or near 100 percent of the SMFP-defined capacity of its cardiac catheterization equipment from 2003 to 2005. Forsyth operated at these high utilization levels despite the underutilization of the cath equipment at North Carolina Baptist Hospital (Baptist), which never exceeded 63 percent utilization over that same time period. Baptist’s cardiac cath volume declined in every year from 2003 to 2010, and this consistent trend appears unrelated to Forsyth’s increase in capacity in 2005 and 2009. Nonetheless, Baptist’s utilization began increasing in 2011 and now is at its 2008 levels. Overall, volume in the county has increased since 2011 indicating that some regions are experiencing growth in cardiac catheterization utilization despite statewide trends of decreasing utilization.

Forsyth County Cardiac Catheterization Utilization

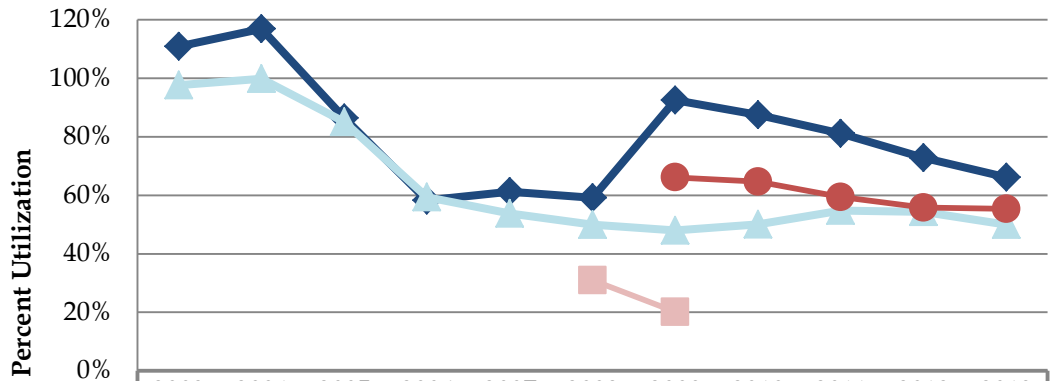


Note: Baptist operated five units of cardiac catheterization equipment throughout the time period; Forsyth operated five units from 2003 to 2005, six units from 2005 to 2008, and eight units from 2009 to 2013.
Source: 2005 to Proposed 2015 SMFPs and 2004 to 2014 License Renewal Applications.

GUILFORD COUNTY

From 2003 until 2008, utilization at High Point Regional Health System (High Point) and Cone Health (Cone) were very similar, with high utilization in 2003 and 2004 followed by decline and then stabilization. While Cone Health’s volume also declined in 2006, that loss was consistent with its trend since 2004 and does not appear to be a result of High Point’s addition of one unit in 2006. Greensboro Heart Center (GHC) opened in 2008, and while utilization at both High Point and Cone declined in that year, it subsequently rebounded. In particular, High Point’s utilization spiked in 2009, the same year that Cardiovascular Diagnostic Center (CDC), owned by Cone Health, opened. High Point’s utilization remained above its 2008 levels through 2013. Thus, the additional capacity at CDC appears to not have negatively impacted High Point. Moreover, the development of CDC has increased volume for the Cone Health system overall (Cone Health and CDC combined) as its utilization also remained above 2008 levels through 2013.

Guilford County Cardiac Catheterization Utilization



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
High Point % Utiliz.	111%	117%	86%	58%	61%	59%	93%	88%	81%	73%	66%
High Point Wgtd. Procs.	4,990	5,264	3,887	3,495	3,676	3,550	5,552	5,252	4,870	4,371	3,973
Cone % Utiliz.	98%	100%	85%	59%	54%	50%	48%	50%	55%	54%	50%
Cone Wgtd. Procs.	10,257	10,484	8,933	6,238	5,651	5,244	5,044	5,261	5,749	5,701	5,245
CDC % Utiliz.							66%	65%	59%	56%	55%
CDC Wgtd. Procs.							992	970	891	837	830
GHC % Utiliz.						31%	20%				
GHC Wgtd. Procs.						464	302				

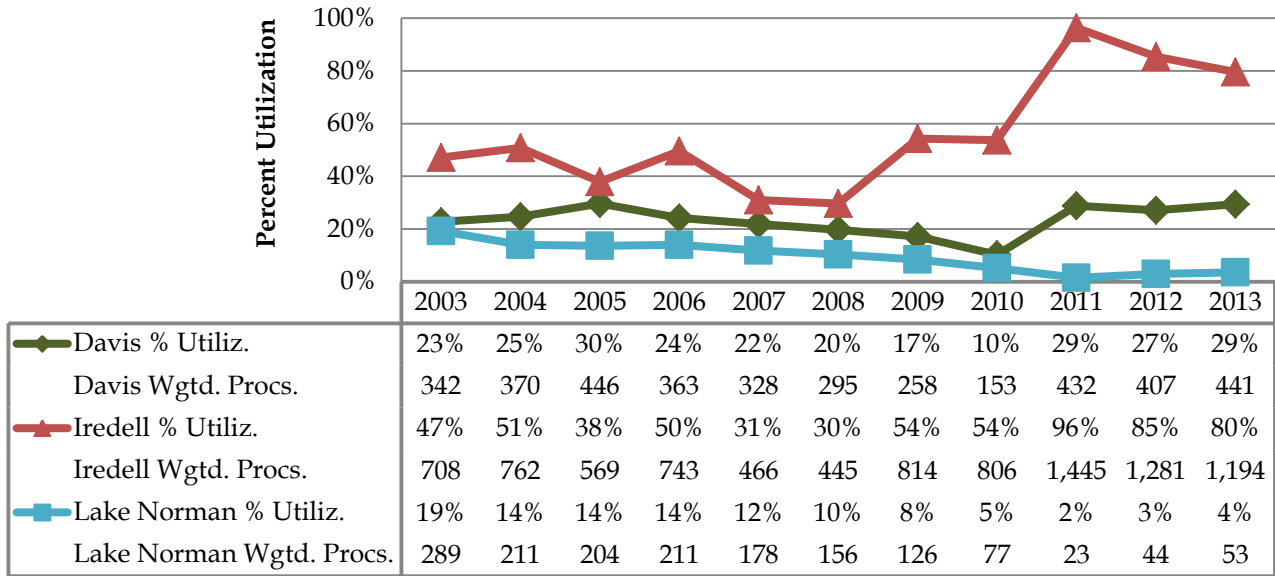
Note: High Point operated three units of cardiac catheterization equipment from 2003 to 2005, and four units from 2006 to 2013. Cone operated seven units throughout the time period. GHC and CDC each operated one unit. High Point’s 2008 weighted procedures are based on its 2009 Hospital License Renewal Application and not on the incorrect data shown in *SMFP* tables.

Source: 2005 to Proposed 2015 *SMFPs* and 2004 to 2014 License Renewal Applications.

IREDELL COUNTY

From 2003 to 2010, no cardiac catheterization provider in Iredell County operated above 80 percent of the *SMFP*-defined capacity of its cardiac catheterization equipment. However, Iredell Regional Medical (Iredell) began operating above 90 percent from 2011 to 2013 and this utilization does not appear to have been alleviated by available capacity at other providers. Utilization at Davis Regional Medical Center (Davis) increased alongside Iredell’s volume in 2011, but has declined since that time. Utilization at Lake Norman Regional Medical Center (Lake Norman) declined only slightly as Iredell reached its high levels of utilization.

Iredell County Cardiac Catheterization Utilization



Note: Davis, Iredell, and Lake Norman each operated one unit of cardiac catheterization equipment throughout the time period.

Source: 2005 to Proposed 2015 SMFPs and 2004 to 2014 License Renewal Applications.

MECKLENBURG COUNTY

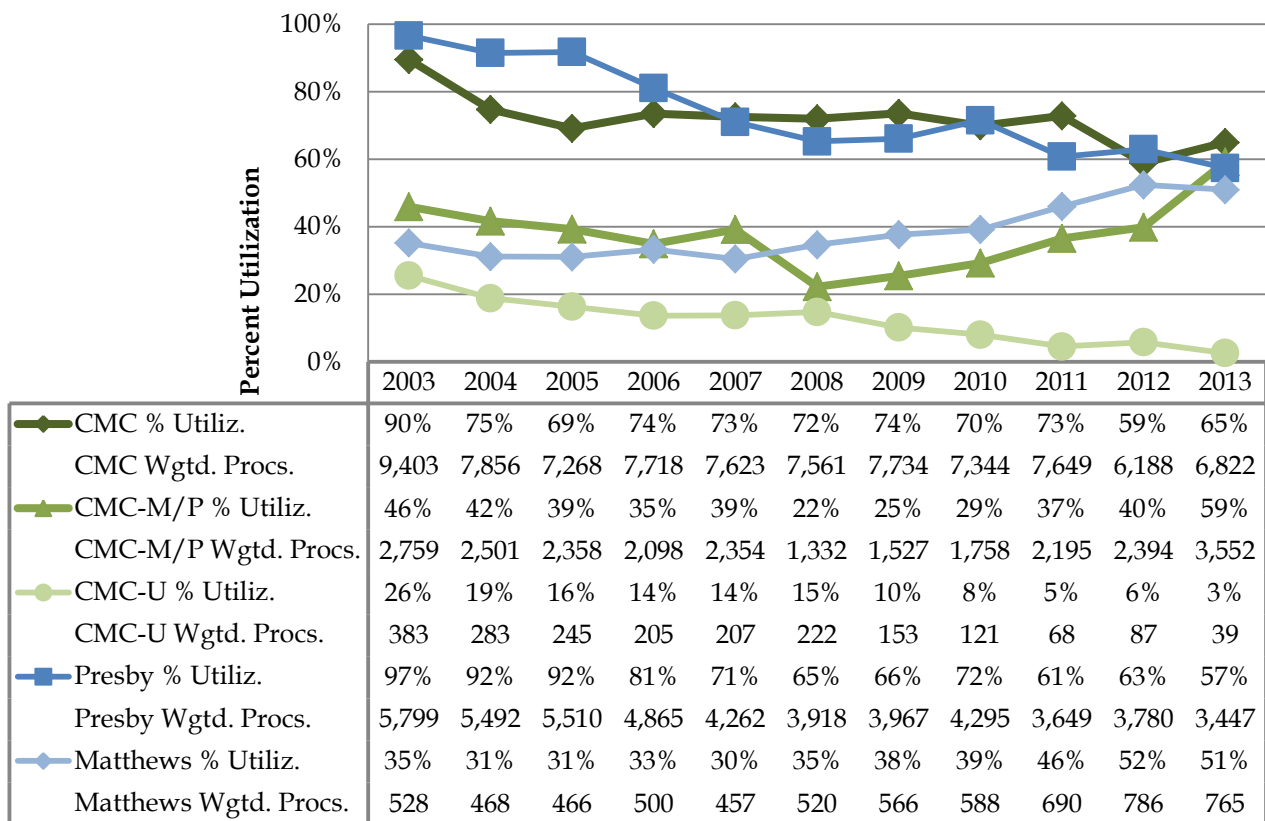
Mecklenburg County is unique statewide as two hospital systems, Carolinas HealthCare System and Novant Health, each operate two or more hospitals with cardiac catheterization equipment: Carolinas Medical Center (CMC), CMC-Mercy/Pineville (CMC-M/P), and CMC-University (CMC-U) within Carolinas HealthCare System and Novant Health Presbyterian Medical Center (Presby) and Novant Health Matthews Medical Center (Matthews) within Novant Health. Capacity at other providers, even within their own parent healthcare system, does not appear to have alleviated high utilization at CMC or Presby in the 2003 to 2010 time period. For example, while CMC operated at between 69 and 90 percent from 2003 to 2010, its sister hospitals, CMC-U and CMC-M/P operated at a maximum of 46 percent of capacity. Similarly, Presby operated at between 65 and 97 percent from 2003 to 2010 and Matthews operated below 39 percent. Since 2010, it appears that Carolinas HealthCare System and Novant Health are more effectively rationalizing services among their hospitals as utilization has declined at CMC and Presby and increased at CMC-M/P and Matthews. CHS made specific efforts to shift tertiary business to CMC-Pineville in an effort to decompress CMC through the transfer of assets under multiple CON projects, and that appears to have increased utilization at CMC-Pineville with only modest decreases at CMC. Also, of note, Mecklenburg County cardiac

**Petition: Wake County Cardiac Catheterization Equipment
Rex Healthcare
Page 16 of 22**

catheterization equipment (in total and at each of the facilities) has remained unchanged since 2003.

Rex contends that the experience in Mecklenburg County indicates that underutilized cardiac catheterization capacity does not alleviate the needs of cardiac catheterization overutilization at other facilities unless a hospital system, in coordination with its physicians, specifically plans for and directs that business to shift. Such a shift does not occur naturally.

Mecklenburg County Cardiac Catheterization Utilization



Note: The capacity of CMC (seven units), CMC-M/P (four units), CMC-U (one unit), Presby (four units), and Matthews (one unit) was unchanged throughout the time period.

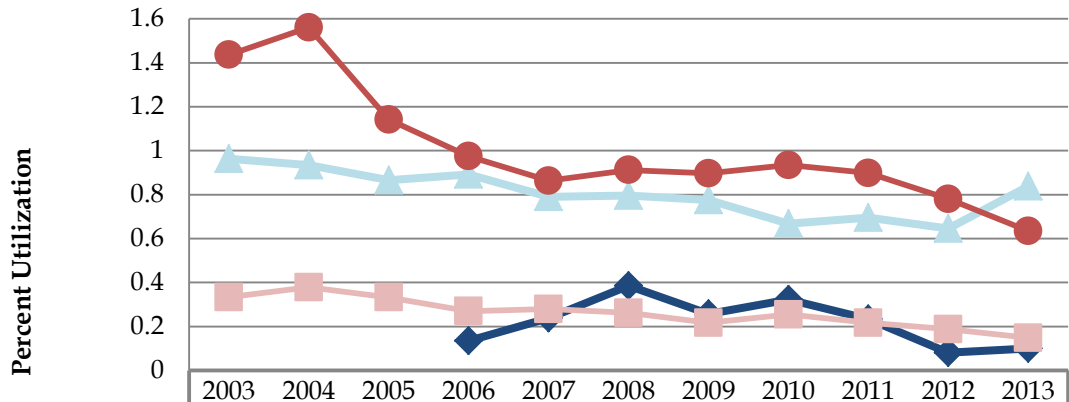
Source: 2005 to Proposed 2015 SMFPs and 2004 to 2014 License Renewal Applications.

WAKE COUNTY

Both WakeMed and Rex operated above or near 100 percent of the SMFP-defined capacity of their cardiac catheterization equipment from 2003 to 2006 despite the underutilization of the cath equipment at WakeMed Cary (a sister hospital of WakeMed), which never exceeded 38 percent utilization over that same time period. Between 2005 and 2007, all providers except WakeMed Cary added

capacity and volume at each facility has largely remained flat with the exception of the recent increase at Rex due to the affiliation with WHV and a corresponding decrease at WakeMed.

Wake County Cardiac Catheterization Utilization



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
◆ Duke Raleigh % Utiliz.				13%	24%	38%	26%	32%	23%	8%	10%
◆ Duke Raleigh Wgtd. Procs.				202	357	1,154	770	967	701	366	447
▲ Rex % Utiliz.	96%	93%	87%	89%	79%	80%	78%	67%	70%	65%	84%
▲ Rex Wgtd. Procs.	4,333	4,206	3,897	4,015	3,557	3,581	3,489	3,002	3,132	3,875	5,029
● WakeMed % Utiliz.	144%	156%	114%	97%	86%	91%	90%	93%	90%	78%	63%
● WakeMed Wgtd. Procs.	10,772	11,709	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570
■ WakeMed Cary % Utiliz.	33%	38%	33%	27%	28%	26%	22%	25%	22%	19%	15%
■ WakeMed Cary Wgtd. Procs.	499	567	498	405	418	393	325	382	325	282	222

Note: Duke Raleigh began operation of one unit of fixed equipment in 2006 and added 2nd unit in 2006 and a 3rd unit in 2012. Rex operated two units from 2003 to 2005, three units from 2006 to 2011, and four units in 2012 and 2013. WakeMed operated five units in 2003 and 2004, seven units in 2005, eight units in 2006, and nine units from 2007 to 2013. WakeMed Cary operated one unit through the 2003 to 2013 time period.

Source: 2005 to Proposed 2015 SMFPs.

COUNTY DATA SUMMARY

To reiterate, Rex believes that historical data from the last ten years in every county with competing cardiac catheterization providers show that underutilized cardiac catheterization capacity does not alleviate the needs of overutilized cardiac catheterization overutilization facilities and that the addition of cardiac catheterization capacity to a provider does not harm the cardiac catheterization services at other facilities in the market. It should also be noted that in some of these service areas, including Wake County, the available capacity at some facilities cannot be used to alleviate the overutilization at others. Specifically, some providers within a service area use cardiac catheterization for diagnostic procedures only, while some perform both diagnostic and elective

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 18 of 22

(scheduled) interventional procedures. Facilities with open heart surgical capabilities and emergency PCI capabilities, such as Rex, cannot rely on capacity at facilities without these capabilities. Wake County EMS protocols require the transport of STEMI patients to the closest hospital with these capabilities; within Wake County, Rex is one of only two facilities. Thus, the capacity of WakeMed Cary and Duke Raleigh should arguably not be considered as mitigating the capacity constraints at Rex. Further, as noted above, physicians and patients are choosing care at Rex over other facilities, which will continue to drive need for capacity at Rex, notwithstanding available capacity at other facilities.

These findings support the need for Rex's requested special need adjustment. The existing underutilized capacity in Wake County will not alleviate Rex's capacity needs as the historic above indicate. Moreover, this historic data analysis also demonstrates that the addition of cardiac catheterization capacity at Rex will not harm other providers in the market.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

The most obvious adverse effect of the failure to approve the petition is the negative impacts that Rex's continuing capacity constraints have on patient safety, quality, and convenience as detailed above. As volume continues to increase, the *SMFP* methodology will not provide additional capacity. The ability to provide timely emergency procedures, high quality and convenient outpatient diagnostic procedures, and seamless care within the Rex system will increasingly be more challenging.

ALTERNATIVES CONSIDERED

As described above, the status quo is already creating a situation in which maintaining a high quality of care is challenging, particularly considering the need for emergent catheterization procedures. Moreover, without a special need determination, the current methodology in the *SMFP* would require Rex to operate at an impossible 245 percent of capacity in order to overcome the underutilized cardiac cath capacity at other facilities in Wake County. Rex would need to achieve that utilization and then wait for two or more years: a year at that volume to be reported on its licensure application, a year for that volume data to be incorporated into the planning process for the next *SMFP*, and at least six months, if not another year, to file the CON, have it reviewed, and, if granted, develop the additional lab. The status quo will not provide additional access, and therefore, it is not a valid consideration.

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 19 of 22

Rex has also considered expanding its capacity through the use of a mobile catheterization service. While this service may be helpful to rural providers, as the SHCC is aware, it is not an optimal long-term solution for a provider with sufficient volume to sustain an additional fixed catheterization lab and a robust cardiac program. Within the past couple years, the SHCC approved the development of shared fixed catheterization labs in Scotland and Lee counties to replace mobile service, in part due to the issues surrounding the use of mobile catheterization at higher volume sites. Moreover, the number of available mobile catheterization labs in the state is limited, largely under the control of a main competitor of Rex (Duke), and subject to contracts with providers; thus, the availability of a mobile catheterization lab for long-term use at Rex is inadequate.

Finally, Rex filed a petition in the spring of 2014 for a methodology change that requested that the cardiac catheterization methodology determine the need for additional capacity based on the utilization of individual facilities rather than the aggregate utilization of all of the facilities in the service area. This change would have allowed providers in need of additional capacity to generate a need determination regardless of the underutilization of other providers in the service area. However, the SHCC denied that petition and the Agency Report indicated an opposition to a methodology that would consider the need for individual facilities.

Given that none of the other potential alternatives are suitable, Rex seeks the adjusted need determination proposed in this petition.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

Rex does not believe the proposed change will result in unnecessary duplication of health resources. As set forth above, other providers in Wake County appear to have capacity on their existing equipment, but the utilization data from the last ten years in competitive cardiac catheterization markets demonstrates that this excess capacity does not relieve high utilization at other providers nor does the addition of capacity in a service area harm existing providers. Therefore, while the proposed change would increase the number of linear accelerators in the Wake County, the expansion is necessary to provide adequate access.

Moreover, Rex believes that the SHCC's approach to capacity planning in other services indicates that the allocation of capacity based on the utilization of specific facilities does not result in unnecessary duplication. Specifically, the current acute care bed and PET methodologies use facility-specific methodologies and, as a result, need determinations for acute care beds and PET

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 20 of 22

scanners are generated by facilities regardless of the utilization of other facilities within the same service area. Moreover, the SHCC's recent approval of Duke Raleigh's petition for additional linear accelerator capacity in Wake County specifically included a discussion of the merits of allowing a provider to increase capacity based on its utilization, regardless of capacity at other providers.

As noted above, Rex understands that the approval of this petition does not guarantee that it can obtain a certificate of need for an additional unit of fixed cardiac catheterization equipment. However, the SHCC should be reasonably confident that Rex would be approved given the underutilization of other providers in the service area, Rex's demonstrated need for additional capacity, and the requirement that cardiac catheterization equipment shall only be approved for development on hospital sites.

EVIDENCE OF CONSISTENCY WITH THE THREE BASIC PRINCIPLES

Rex believes the petition is consistent with the three basic principles: safety and quality, access, and value.

SAFETY AND QUALITY

Quality and safety are clearly enhanced through the development of additional cardiac catheterization capacity. Without sufficient capacity, particularly for a service often provided on an emergent basis, like interventional cardiac catheterization, quality can suffer and patient care may not be optimal. Without this adjusted need determination, Rex could operate its cardiac catheterization equipment at high utilization levels indefinitely without any possibility of acquiring additional capacity. Cardiac catheterization services must be available immediately for emergency patients who present to a hospital. These emergency situations often require a patient to be taken out of a room before the case is finished. Emergency patients inevitably delay scheduled patients or cause rescheduling. The American College of Cardiology has established that patients should receive interventional treatment within fewer than 90 minutes from the time the patient arrives at the hospital. When a provider is operating at nearly 100 percent of capacity, it is more challenging to meet this lifesaving guideline.

If the demand for cardiac catheterization services at a facility exceeds its reasonable capacity, then any delays result in patients beginning their procedures late in the day, thus requiring a more expensive and inconvenient overnight stay, or waiting until a later scheduled time. Scheduled procedures, while not emergency cases, are needed to improve the health of these patients and the delays that may result from overcapacity equipment results in delays in

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 21 of 22

their recovery and return to normal life. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment.

If patients and physicians are forced to access care at another facility which has available capacity, they may encounter disruptions in the continuity of care. Physicians and providers work every day to improve the systems of care which leverage information technology, multidisciplinary teams, and processes of care to deliver the right care at the right time to the right person. Rex's electronic medical record allows providers to access all of the patient's records including relevant diagnostic tests that can provide vital information to guide the care of the patient. A facility under the control of another healthcare system cannot provide that same system of care to an unfamiliar physician and patient. As a result, safety and quality will be enhanced with the proposed adjusted need determination.

ACCESS

Additional cardiac catheterization capacity is needed to provide sufficient access for Rex patients. In particular, Rex is a leading provider of care to the elderly population in Wake County. According to 2014 Hospital License Renewal Application data, Rex provides a greater percentage of its inpatient and emergency services care to the Medicare population than any other facility in the county. Elderly patients, in particular, need sufficient access to cardiac catheterization services. Moreover, 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 provided on a diagnostic basis. For example, patients in Franklin, Harnett, and Sampson counties who see North Carolina Heart and Vascular physicians in local offices will have greater access to cardiac catheterization services, which are not available in their home county.

VALUE

The petition also promotes value. As discussed above, overutilization of cardiac catheterization capacity sometimes results in expensive and inconvenient overnight stays for patients that could have been discharged on the same day.

Petition: Wake County Cardiac Catheterization Equipment

Rex Healthcare

Page 22 of 22

Additional catheterization lab capacity will ensure that patients—both inpatients and outpatients—receive care in a timely manner, enabling patients to be discharged within an appropriate timeframe, which will prevent unnecessary expenditures by the patients and payors. Delays in needed treatment or unanticipated overnight stays at the hospital add to healthcare expenditures. Rex's high utilization necessitates that any routine maintenance occur overnight or on the weekends, which is more costly than if completed during work hours. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues, which increases cost. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment. Finally, Rex cannot efficiently staff its cath labs in this high utilization environment as staff routinely work overtime which decrease their job satisfaction and adds unnecessary costs.

CONCLUSION

In conclusion, Rex requests that the SHCC approve the petition for an adjusted need determination of one cardiac catheterization unit in Wake County. Rex believes the unique circumstances in the county warrant additional capacity. Specifically:

- Since 2011, Rex's partnerships with its cardiologists have resulted in 23 percent annual growth in cardiac catheterization volumes.
- Rex's cardiac catheterization labs are currently operating at 97 percent of capacity, which would make it the highest utilized provider in the state.
- Rex's utilization levels make it more difficult to deliver optimal care, particularly given the emergent nature of conditions requiring cardiac intervention, consistent with the Basic Principles of the *SMFP*.
- Absent the special need adjustment requested in this petition, Rex will never be able to acquire additional cardiac catheterization capacity no matter how needed as other providers in its community are sufficiently underutilized.

Thank you for your consideration.