

PETITION

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

PETITIONER

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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

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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

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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

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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

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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.

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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

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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

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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

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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*

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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.

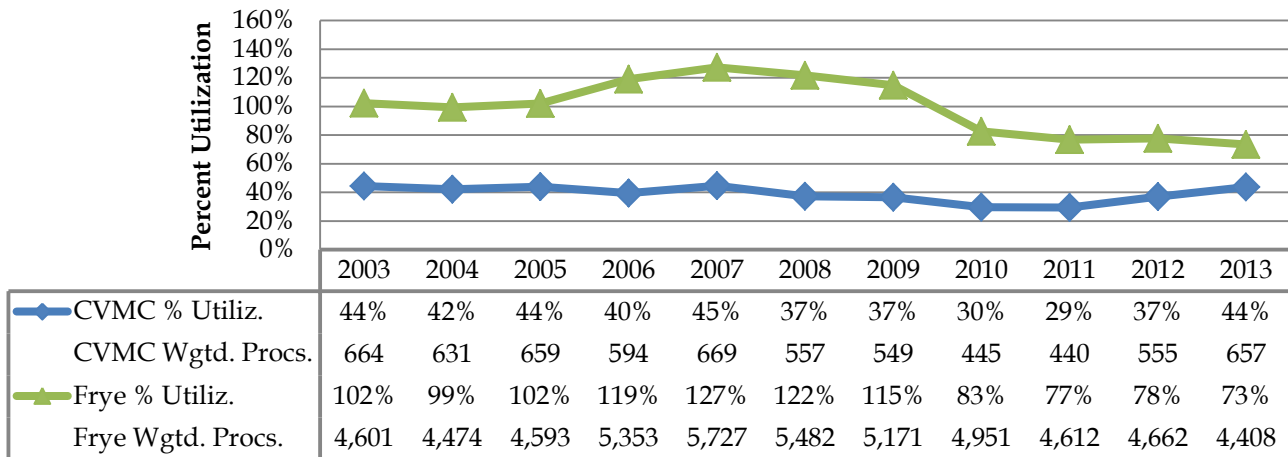
CATAWBA COUNTY

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

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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



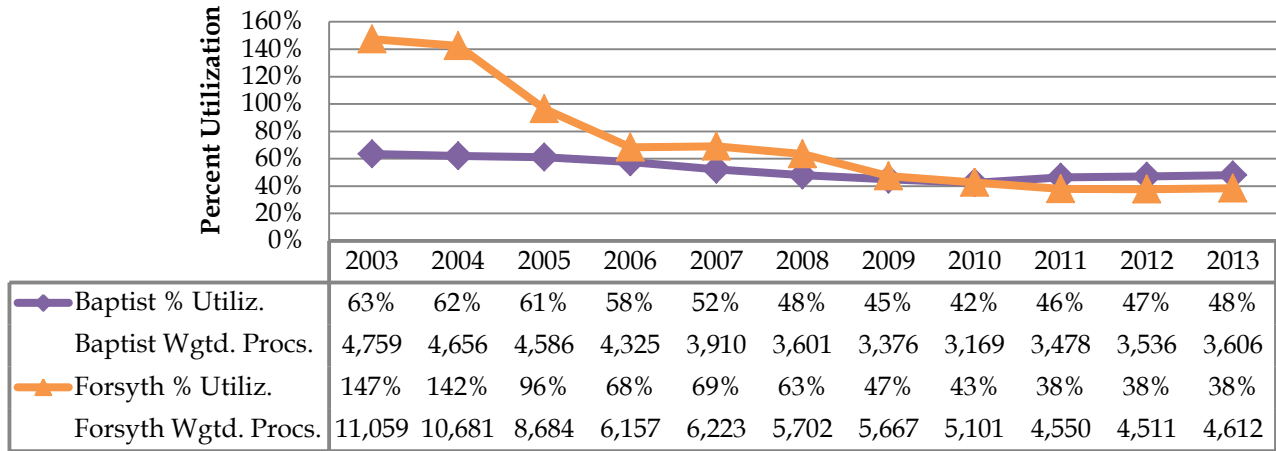
Note: CVMC operated one unit of cardiac catheterization equipment throughout the time period; Frye operated three units from 2003 to 2009, and four units from 2010 to 2013.

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

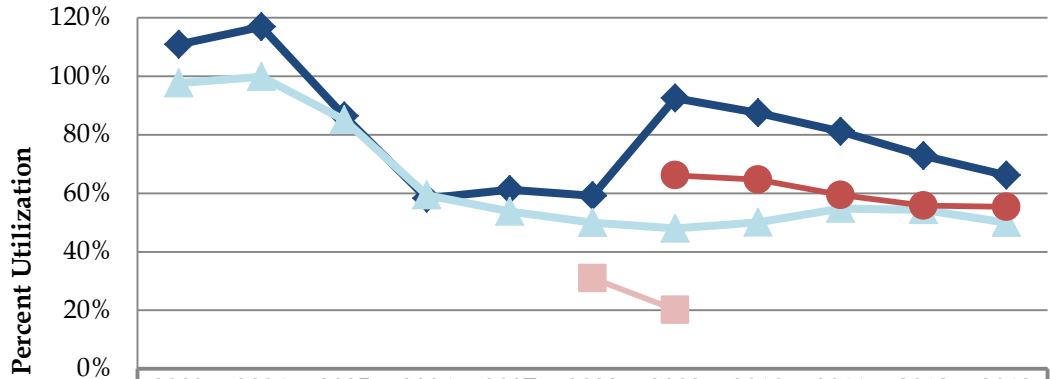


Note: Baptist operated five units of cardiac catheterization equipment throughout the time period; Forsyth operated five units from 2003 to 2005, six units from 2005 to 2008, and eight units from 2009 to 2013.
Source: 2005 to Proposed 2015 SMFPs and 2004 to 2014 License Renewal Applications.

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				

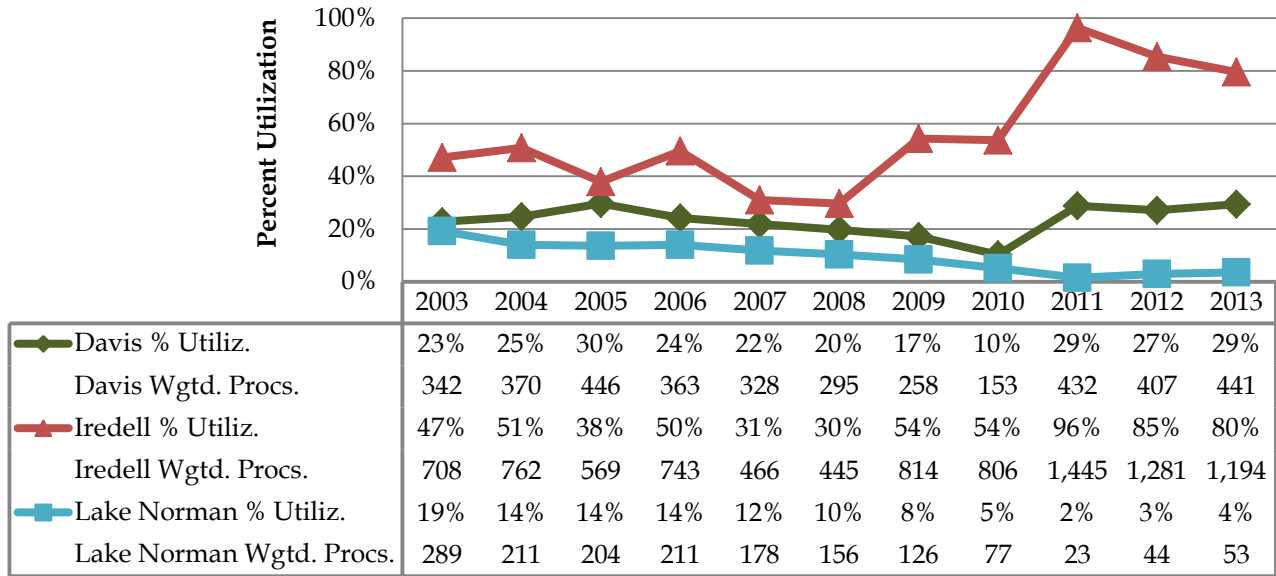
Note: High Point operated three units of cardiac catheterization equipment from 2003 to 2005, and four units from 2006 to 2013. Cone operated seven units throughout the time period. GHC and CDC each operated one unit. High Point’s 2008 weighted procedures are based on its 2009 Hospital License Renewal 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

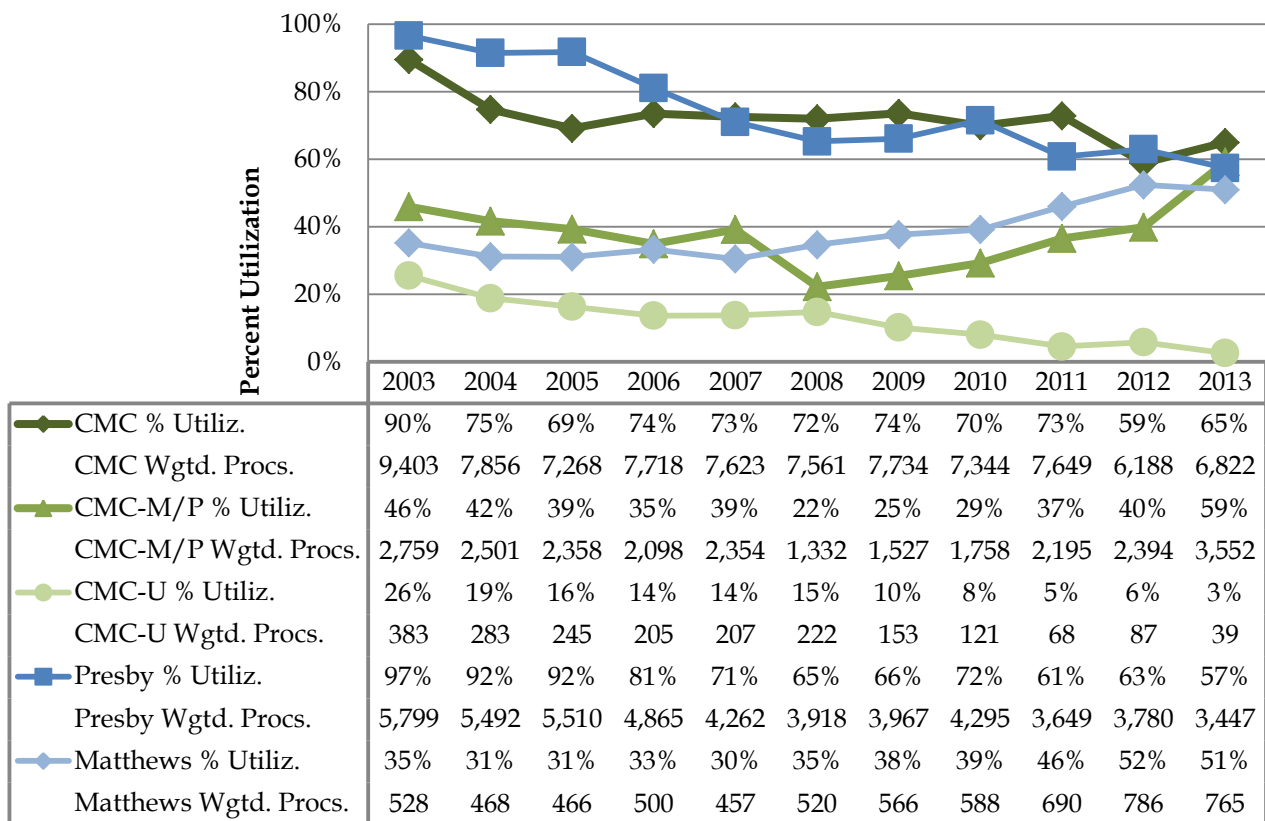
Mecklenburg County is unique statewide as two hospital systems, Carolinas HealthCare System and Novant Health, each operate two or more hospitals with cardiac catheterization equipment: Carolinas Medical Center (CMC), CMC-Mercy/Pineville (CMC-M/P), and CMC-University (CMC-U) within Carolinas HealthCare 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

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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.

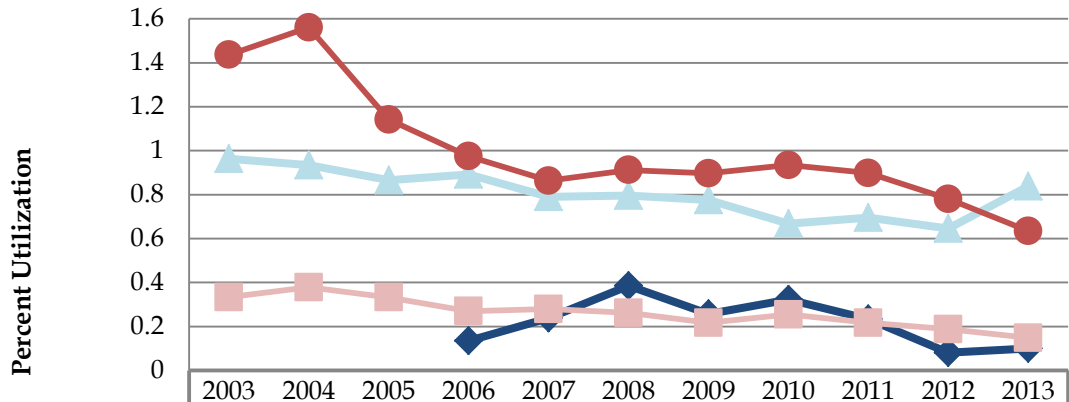
Source: 2005 to Proposed 2015 SMFPs and 2004 to 2014 License Renewal Applications.

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



◆ 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

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(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.

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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

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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

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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.

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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.