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PETITION

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

PETITIONER

UNC REX Healthcare
4420 Lake Boone Trail
Raleigh, NC 27607

Steve Burriss
President, UNC REX Healthcare
919-784-2244
Stephen.Burriss@unchealth.unc.edu

STATEMENT OF REQUESTED ADJUSTMENT

UNC REX Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination for two additional units of fixed cardiac catheterization equipment in Wake County in the *2017 State Medical Facilities Plan (2017 SMFP).*

SUMMARY

This request is the most recent in a series of five petitions over the last three years from Rex including both methodology change and adjusted need determination petitions. Rex's goal throughout this process has been to accommodate a substantial increase in cardiac catheterization procedures, while continuing to provide exceptional patient care. Today, and for the last three years, Rex's cardiac catheterization capacity is insufficient to care for the needs of its patients. Specifically, using the capacity definitions in the *SMFP*, Rex currently has a deficit of 1.78 cardiac catheterization labs, which indicates a need for two additional cath labs.

Last year, the Healthcare Planning and Certificate of Need Section recommended approval of Rex's petition for an adjusted need determination for one additional unit of fixed cardiac catheterization equipment, stating:

> The Agency supports the standard methodology for fixed cardiac catheterization equipment. As discussed above, the deficits at Rex in the last two years have been offset by the surpluses at other facilities in Wake County. While cardiac catheterization procedures are declining statewide,

> Wake County showed an increase in the current data year. Wake County and Rex Healthcare are experiencing recent increases in the utilization of cardiac catheterization laboratories. Given available information and comments submitted by the August 14, 2015 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends approval of the petition. (emphasis added)
>
> See Exhibit 1.

As shown in the *Proposed 2017 SMFP* and in the analysis below, the language of the statement above can be even stronger this year, as the deficits at Rex have continued and grown over the last three years and continue to be offset by surpluses at other facilities in Wake County. Unlike previous years, cardiac catheterization procedures increased last year statewide. Similarly, cardiac catheterization procedures increased in Wake County, marking two consecutive years of increases. Finally, Rex's utilization of cardiac catheterization increased 15.4 percent over its prior year and now demonstrates a deficit of two units. In summary, each of the factors given as evidence by the Healthcare Planning and Certificate of Need Section in recommending approval of Rex's petition last year is still present and shows an increased need for additional capacity at Rex.

Of utmost importance, Rex's capacity issues have a negative impact on patients including long wait times, cancelled procedures, unnecessary overnight stays, and more. These procedures are needed to improve the health of patients and the delays that result from equipment operating above its optimal capacity also delay their recovery and return to normal life. Unfortunately, the opponents of Rex's petitions have attempted to shift the focus away from these patients, instead choosing to politicize the process, providing some SHCC members with incorrect information that has surfaced in the SHCC meetings. This misinformation and consideration of secondary issues removes the focus from where it should be: patients. If approved, patients would benefit from more timely, more efficient, lower cost, and higher value care. Rex has responded to numerous criticisms of its petitions over the last three years, but none of the criticisms address the greatest need for this petition--that Rex's patients will benefit from additional cath lab capacity.

Once again, Rex urges the SHCC to consider that the approval of this petition would result in better patient care, while the arguments against Rex's petition and continued delay in meeting the need for additional capacity would do nothing to improve patient care.

REASON FOR THE REQUESTED ADJUSTMENT

Rex's cardiac catheterization volume has increased substantially over the past five years necessitating additional capacity, which cannot be achieved without the requested need determination. As shown in Table 9W of the *Proposed 2017 SMFP*, Rex's cardiac cath procedures grew 15.4 percent in the most recent year and Rex now demonstrates a need for 5.78 units and has an inventory of only four units. Thus, Rex has a deficit of two units.

Rex Cardiac Catheterization Utilization

	FY2011	*FY2012*	*FY2013*	*FY2014*	*FY2015*
Diagnostic	1,697	2,067	2,666	3,050	3,332
Interventional	820	1,033	1,350	1,689	2,058
Total Procedures	2,517	3,100	4,016	4,739	5,390
Weighted Procedures Total^	3,132	3,875	5,029	6,006	6,934
Annual Growth of Weighted Procedures	**4.3%**	**23.7%**	**29.8%**	**19.4%**	**15.4%**
Machines Required†	**2.61**	**3.23**	**4.19**	**5.00**	**5.78**

Source: *SMFPs*.
^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 2017 SMFP* methodology.

Despite Rex's situation, the *Proposed 2017 SMFP* does not show a need for additional capacity in Wake County due to the underutilization of other providers. Please note that while some have attempted to limit this discussion to WakeMed only, all three of the other cardiac cath providers in Wake County (WakeMed, WakeMed Cary, and Duke Raleigh) operate with surplus capacity.

Wake County Cardiac Catheterization Utilization

	Total Planning Inventory	*Percent Utilization*	*Machines Required Based on 80% Utilization*	*Deficit/(Surplus)*
Rex Hospital	4	116%	5.78	1.78
WakeMed	9	56%	6.31	(2.69)
WakeMed Cary	1	14%	0.17	(0.83)
Duke Raleigh	3	10%	0.39	(2.61)
Total	**17**		**13**	**(4.36)**

Source: *Proposed 2017 SMFP*.

Nonetheless, Wake County demonstrated an increase in the annual number procedures in each of the last two years. Statewide, the trend in cardiac cath procedures increased in the most recent year.

Cardiac Catheterization Utilization

	2011	*2012*	*2013*	*2014*	*2015*
Wake Total Procedures (Weighted)	16,287	15,057	14,268	14,794	15,169
Annual Change		**-7.55%**	**-5.24%**	**3.69%**	**2.53%**
NC Total Procedures (Weighted)	114,567	112,060	109,885	106,185	107,853
Annual Change		**-2.19%**	**-1.94%**	**-3.37%**	**1.57%**

Source: *SMFPs.*

While the overall growth trends in Wake County can be accommodated by each of the other providers in the county with excess capacity, i**t is Rex's remarkable and unique growth, which has not been experienced by other cardiac catheterization providers in the state, that drives the need for an adjusted need determination for two additional units of cardiac catheterization equipment in Wake County.**

Rex's growth has been driven by unique circumstances, namely its affiliation with Wake Heart & Vascular Associates (WHV), a leading cardiovascular practice in the Triangle. As discussed in detail below, according to information presented at the July 28, 2016 SHCC public hearing in Raleigh, WHV first sought to affiliate with WakeMed due to economic pressures facing its practice, but WakeMed's administration created a toxic environment that resulted in WHV's affiliation with Rex. Then, even after WHV physicians attempted to continue practicing at WakeMed, WakeMed withdrew support for services that it had been providing to WHV. As a result, despite the best efforts and intentions of the physicians, WHV had no choice but to leave WakeMed and give up their privileges in order to ensure that their patients received the best quality care. Most recently, Rex has attempted to work in good faith to collaborate with WakeMed, but in what must now be assumed to be an attempt to delay a resolution to this situation, WakeMed has failed to respond for four months, leading Rex to doubt the sincerity of WakeMed's desire to collaborate on this issue.

While it is true that the Rex-WHV affiliation and the creation of North Carolina Heart & Vascular began the initial growth in cardiac catheterization volume at Rex, that growth has continued even after the completion of the affiliation. Moreover, cardiac catheterization volume has continued to increase in Wake County, overall, in stark contrast to the trends in the rest of the state. Since 2011, Rex's weighted cardiac catheterization volume has grown 22 percent annually. In fact, while it operated at 100.1 percent of capacity in FY2014, Rex's utilization continued to increase over the following

year (15.4 percent year over year growth) and its labs are operated at 116 percent of their capacity in FY2015.

Rex Cardiac Catheterization Utilization

	FY2011	*FY2012*	*FY2013*	*FY2014*	*FY2015*
Weighted Procedures Total	3,132	3,875	5,029	6,006	6,934
Units of Fixed Equipment^	3	4	4	4	4
Capacity†	4,500	6,000	6,000	6,000	6,000
Percent Utilization	**69.6%**	**64.6%**	**83.8%**	**100.1%**	**115.6%**

Source: *SMFPs*.
^Rex operated three units of fixed equipment in FY2011 and added a unit in FY2012 pursuant to a prior Certificate of Need. See discussion below of recent addition of mobile equipment.
†Capacity = Units of Fixed Equipment x 1,500 procedure capacity per unit according to the *Proposed 2017 SMFP* methodology.

If Rex's utilization were to grow another 15.4 percent from 2015 to 2016, it would perform 8,004 weighted procedures or 133 percent of capacity. Given these factors, Rex believes it must act immediately in order to maintain the appropriate capacity needed to care for its patients.

Expanded Capacity at Rex

In order to accommodate this utilization, Rex operates extended hours and contracts with a mobile cardiac catheterization provider. Rex staffs two of its catheterization labs 14.5 hours per weekday (7:00 am to 9:30 pm) and the other two labs for 12.5 hours per weekday (7:00 am to 7:30 pm). This is an expansion of scheduled hours over last year when Rex staffed two of its catheterization labs 12 hours per weekday (7:00 am to 7:00 pm) and the other two labs for 10 hours per weekday (7:00 am to 5:00 pm). The *SMFP* does not provide a planning assumption for the number of hours per day that a cardiac catheterization is staffed. However, the *SMFP* assumes that operating rooms are staffed nine hours per weekday; thus, Rex's cardiac cath labs are currently staffed 3.5 to 5.5 hours per day more than the *SMFP's* assumption for that service.

Despite these expanded hours, scheduled cases often finish after 9:30pm. These last patients must fast for an extended period prior to their procedure and then stay in the hospital overnight for observation. Rex also now staffs one cath lab for non-emergent inpatients on the weekend to relieve the congestion that occurs during week. The remaining labs are not staffed on weekends as they are used for emergencies only; however, the labs are in use for four hours each weekend day, on average, for these emergency cases.

Due to the severe capacity constraints and lack of other alternatives, Rex has contracted with FirstHealth to use its mobile catheterization lab since May 2015 in order to further

expand capacity. This mobile unit has been at Rex for five days a week since that time. While this alternative has provided some relief to Rex's capacity issues, it is far from ideal. In order to reach the mobile unit, patients must exit the hospital, travel along a covered walkway, and enter a mobile trailer. The mobile unit's equipment is older and less technologically advanced than Rex's fixed equipment. As such, both patients and physicians would prefer to utilize the fixed labs, but unfortunately the mobile must be used due to the sheer volume of patients that Rex treats.

The most frustrating aspect of Rex's current capacity issues is that equipment in existing peripheral vascular labs could be modified with a software upgrade with minimal expense so that two of these labs could be used as a cardiac catheterization laboratory. However, because of the regulatory limits on cardiac catheterization equipment (and the exclusion of grandfathered mobile units from those limits), Rex's best option to serve its patients, without the adjusted need determination requested in this petition, is to utilize mobile equipment parked in a trailer next to the hospital.

Need to Respond to Changing Federal Payment Models

Over the past few years, the Centers for Medicare & Medicaid Services (CMS), have instituted numerous programs that are designed to move healthcare reimbursement from the fee-for-service model to a more holistic, population health model that focuses on improving health, advancing care coordination, enhancing quality and lowering costs. These programs include a variety of models, such as Accountable Care Organizations, shared savings programs and bundled payment models. The bundled, or episodic payment model, replaces the separate payments for the various types of care provided for a certain condition with a single payment for all healthcare services related to that condition within a specified timeframe around an inpatient admission. Last year, CMS initiated the Comprehensive Care for Joint Replacement (CJR) model, a bundled payment model for lower extremity joint replacement in several metropolitan statistical areas (MSAs) around the country, including some in North Carolina. This is not a voluntary program; all providers that are Medicare-certified and paid under the inpatient prospective payment system must participate. In addition, while only certain MSAs are included, the inclusion relates to the certified hospitals within those counties, not the county of origin for the patients receiving care. In other words, patients receiving care at hospitals in the included MSAs are included in the bundled payment model. In a bundled payment program, the hospital admitting the patient is paid by Medicare and incentivized to improve the coordination of care and to positively impact the quality and cost of care.

On July 25, 2016, CMS announced its next bundled payment program, which will include episodic payments for patients with acute myocardial infarctions (AMI) and coronary artery bypass graft (CABG) procedures. The program would commence July 1, 2017. Under this program, like the CJR model, the acute care hospital in which the

patient has an initial hospitalization for one of the clinical conditions included in the model would be held accountable for the spending during the episode of care, which includes all related care within 90 days of discharge. According to CMS' proposed rule, the services reimbursed through the bundled payment program would include not only the inpatient hospital services, but also physicians' services, hospital outpatient services and post-acute services. The bundled payment would also reimburse for cardiac catheterizations (PCI) for patients under the included diagnoses. It is clear from the inclusion of PCI as part of the episodic payment model that CMS does not view cardiac catheterizations as stand-alone, individual procedures that can be provided at any hospital with the equipment; rather, it recognizes that they are an integral part of providing comprehensive care for patients with various cardiac conditions within a clinically integrated system of care.

While the final selection of which MSAs will be included in the model has not yet been made, the Raleigh MSA (which includes Rex Hospital), is one of the regions eligible for inclusion. If Raleigh is included in the model, at least a portion of its cardiac catheterizations will be included in the bundled payment, and Rex will need to ensure that it has access to sufficient capacity for all its patients needing cardiac catheterizations—at Rex Hospital—where it can directly impact the cost and quality of the care being received. Regardless of whether Rex is ultimately included in the model, the ongoing evolution of payment away from fee-for-service to episodic care—by both CMS and private payors—will certainly continue. In order to most effectively achieve the goals of payment transformation, Rex needs to be able to provide all of the components of care to all of its patients, which it is currently struggling to do with limited cardiac catheterization capacity. Rex recognizes that the SHCC is not responsible for federal payment policy; however, Rex believes that the SHCC should respond to the evolution in healthcare to the extent of its authority to do so, including the approval of this petition to provide sufficient capacity for Rex's cardiac catheterization patients.

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. Other providers in Wake County appear to have capacity on their existing equipment but Rex's volume continues to grow despite its high utilization levels. As set forth in its 2014 petition, the utilization data from the last ten years in competitive cardiac catheterization markets demonstrates that 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 cardiac catheterization units in Wake County, the expansion is necessary to provide adequate access.

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 scanners are generated by facilities regardless of the utilization of other facilities within the same service area. Moreover, the SHCC has approved numerous past petitions allowing a provider to increase capacity based on its utilization, regardless of capacity at other providers. Please see the discussion below for these examples.

As noted above, Rex understands that the approval of this petition does not guarantee that it can obtain a CON for an additional unit of fixed cardiac catheterization equipment. However, the SHCC should be reasonably confident that the additional capacity will go where it is most needed given that the cardiac catheterization performance standards in the CON rules require that applicants proposing to acquire such equipment must demonstrate historical utilization of at least 80 percent and other hospitals in the county do not meet this standard.

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 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. 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, cares for patients in 15 offices in nine counties. Increasing these physicians' access to cardiac catheterization capacity will in turn expand 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 are treated by North Carolina Heart and Vascular physicians in local offices will have greater access to cardiac catheterization services, which are not currently 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. 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.

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

The proposed change would provide additional capacity to Rex, which has significantly lower costs per procedure for Blue Cross Blue Shield patients than Duke Raleigh or WakeMed and its providers as well as lower Medicare reimbursement. As noted above, Rex's plan to add cardiac catheterization capacity is to upgrade the software of a peripheral vascular lab for approximately $30,000. Due to its capacity constraints, Rex has contracted with a mobile cardiac catheterization lab since May 2015 at a cost of $16,000 per month. Clearly, a lower cost, value-driven solution would be a one-time upgrade for $30,000 rather than a monthly expense of $16,000, or 192,000 per year.

RESPONSES TO PRIOR CRITICISMS OF REX'S PETITIONS

Despite the clear statistical data demonstrating that Rex's cardiac catheterization capacity is insufficient, its opponents, the Healthcare Planning and Certificate of Need Section, and the SHCC has criticized Rex's petitions over the last three years. These criticisms are often misinformation, misperceptions, or attempts to politicize this issue. They serve to distract the SHCC from whether patients would benefit from additional cath capacity at Rex. As the latest example of this misinformation, at the Raleigh SHCC public hearing on July 28, 2016, following the presentation by Dr. Lance Landvater, a cardiac surgeon at Rex, a member of the SHCC, Dr. Patel, asked a question about the charges for cardiac catheterization at Rex versus WakeMed, citing specific information that he had apparently brought with him to the SHCC meeting. Although Rex had not spoken at a single SHCC public hearing prior to that day, and though the petition had not yet been filed, and though no public announcement had been made prior to that meeting regarding Rex's intention to file a petition, a member of the SHCC presented information to ask about the petition. Although Dr. Patel said that "it's not my affiliation with WakeMed as part of WKCC[1]" that was driving the question, such an

[1] Rex believes WKCC to be a reference to WakeMed Key Community Care, is an ACO that is composed of networks of individual practices of ACO professionals, and a hospital (WakeMed) employing ACO professionals. Cary Internal Medicine & The Diabetes Center, Dr. Patel's practice, participates in the ACO and a joint venture, according to the WKCC website, http://www.wakemedkeycc.org/wkcc-accountable-care-organization. Dr. Patel is also a member of the WKCC Quality Committee/Networking & Credentialing Committee.

affiliation, with the organization most competitive with Rex concerning these issues, raises serious questions about the independence and lack of bias from Dr. Patel.

Nonetheless, the data point provided by Dr. Patel is only one of many for multiple payors. As explained by Mr. Steve Burriss, Rex President, following Dr. Patel's question, the single procedure referenced in the question was historically one for which Rex's charges to Blue Cross were higher than those for WakeMed. Rex has since adjusted its charges to reflect the reality of its other charges for Blue Cross patients compared to WakeMed, which are lower than WakeMed's charges, as discussed in further detail below and in previous petitions. Moreover, the majority of heart and vascular patients served at Rex are Medicare recipients, as an explained below, WakeMed's DRG base rate from Medicare is higher than Rex's. As shown in the table below, Rex's Medicare payment for outpatient cardiac catheterization (diagnostic and interventional) is significantly lower than WakeMed's, providing the vast majority of cardiac catheterization patients and Medicare a significant cost savings:

APC Code	*WakeMed*	*Rex*	*National Average*
0080-Diagnostic Cardiac Catheterization	$13,035	$7,628	$13,067
0656-Transcatheterization Placement of Intracoronary Drug Eleuting stents	$23,028	$18,096	$18,643

As shown, actual, current data demonstrate the positive impact and cost savings from allowing Rex's patients to continue accessing care at Rex.

In addition to this most recent criticism based on misinformation, Rex has provided a summary table below of criticisms of its petitions over the past three years and its responses. Each is discussed in detail below following the table.

Criticism	*Response*
Criticisms of Spring 2016 Petition	
Increases at Rex Result from Decreases at Other Providers	It is precisely because of the underutilization of other providers in Wake County that Rex's situation is unique and needs to be addressed by the SHCC. In essence, WakeMed is arguing that the very factors that require Rex to seek an adjusted need determination disqualify Rex from approval.
Rex's Problem is of its Own Creation	In fact, WakeMed has been the greatest force in the shift of physicians and patients away from its facility.
Rex and WakeMed Should Work To Resolve Issue	Rex doubts the sincerity of WakeMed's desire to collaborate as it has been non-responsive for

Criticism	*Response*
	four months.
Physician Reimbursement Not a Proxy for Cost	The data provided by Rex and WakeMed show that Rex is not in fact "reimbursed at a much higher rate" as alleged.
Supply of Cardiologists and Practice Patterns	In order to begin using WakeMed's cath labs, Rex's physicians would need to duplicate its extensive support team staff, duplicate its PACS system or manually create and exchange CDs, and duplicate its physician call (thereby reducing its coverage in other counties across the region). WakeMed did not respond to these issues.
No Positive Effects on Safety and Quality, Access, or Value	WakeMed is not concerned with the surplus of cardiac cath lab capacity. It could immediately close its unneeded cath labs but instead recently replaced cath equipment for $2.7 million.
Criticisms of 2015 Petition	
Approval Would be Precedent Setting	The special need adjustment petition process is expressly designed to allow changes outside of standard methodologies and changes to methodology. There is nothing precedent-setting about Rex's petitions. The SHCC has approved numerous petitions in the past with similar circumstances to Rex.
Negative Impact on Cost of Care	Contrary to the statements made by some SHCC members, Rex is not an academic medical center and does not receive additional reimbursement for medical training. Rex and its affiliated physicians have the lowest average reimbursements for cardiac catheterization in the region.
Rex Physicians Can Use Other Labs	Rex and its physician partners do not believe that this would be an effective solution to its capacity constraints as it would require a significant duplication of existing resources and a reduction in access for patients in nearby counties.
Criticisms of 2014 Petitions	
Statewide and Wake County Declines in Cardiac Catheterization Volume	Wake County cath volume has increased over the past two years. It is precisely because of overall state trends that Rex's strong increase is a unique circumstance that needs to be addressed by the SHCC.
Lack of Multi-Year Trend	Rex's cath lab utilization has increased every year since 2011. Rex has operated above target utilization (80 percent) for the last three years and above 100 percent of capacity for the last

Criticism	*Response*
	two years.
Potential for Duplication of Health Services	It is precisely because there are several significantly underutilization cath providers in Wake County that Rex's situation is a unique situation that needs to be addressed by the SHCC.
Historic Ability to Operate at High Utilization	High utilization levels are possible, but they are detrimental to patient care. Rex is operating above 100 percent of the standard established by the SHCC. If the SHCC believed that higher utilization was reasonable, the capacity standard would be higher.
Changing Capabilities at Nearby Facilities	Rex's utilization has continued to increase since the initiation of new interventional programs at Johnston Health and Central Carolina Hospital.

Increases at Rex Result from Decreases at Other Providers

In its March 2016 comments, WakeMed stated that Rex's petition should be denied because the increases at Rex were the result of decreases at other providers noting that "[e]ven with Rex's increase in volume, Wake County still has an overall surplus of 4 units of fixed cardiac catheterization equipment. Approving additional cardiac catheterization capacity, which is the ultimate goal of this petition, will do nothing to address this surplus."

First, as with many of the criticisms of Rex's petition, this argument ignores the patients at Rex that would benefit from additional catheterization capacity. Unlike WakeMed's recent replacement cardiac cath equipment, for just $60,000, Rex could convert two existing vascular labs into rooms capable of providing catheterizations and help patients immediately where they are currently seeking care. WakeMed would prefer to avoid this fact and turn attention to its underutilized capacity and that of other hospitals in Wake County. However, since the equipment used in vascular labs is essentially the same as that used in cardiac cath labs, with the exception of the software used for the studies, the cost of converting the vascular labs into cardiac labs is minimal, a fact with which most clinicians are aware.

Second, as Rex has pointed out, this argument is illogical as it is precisely because of the significant underutilization of other cath providers in Wake County that Rex's situation is unique and needs to be addressed by the SHCC. If volumes were growing at other facilities commensurate with their capacity, then the standard *SMFP* methodology would generate a need and Rex would compete to develop that additional capacity. In essence, WakeMed is arguing that the very factors that require Rex to seek an adjusted

need determination (i.e. underutilization at other providers) disqualify Rex from approval. The SHCC should recognize that these issues are not confined to WakeMed and Rex but exist county-wide. Both WakeMed Cary and Duke Raleigh are significantly underutilized, as shown below. In fact, Duke Raleigh's surplus of machines is nearly identical to that of WakeMed.

Wake County Cardiac Catheterization Utilization

	Total Planning Inventory	*Percent Utilization*	*Machines Required Based on 80% Utilization*	*Deficit/(Surplus)*
Rex Hospital	4	116%	5.78	1.78
WakeMed	9	56%	6.31	(2.69)
WakeMed Cary	1	14%	0.17	(0.83)
Duke Raleigh	3	10%	0.39	(2.61)
Total	**17**		**13**	**(4.36)**

Source: Proposed 2017 SMFP.

While it may be reasonable for WakeMed Cary to operate a sole unit of equipment for access in case of emergency, it is unclear why Duke Raleigh requires three units of cardiac catheterization equipment. In fact, Duke Raleigh added its third unit in 2013 through the use of grandfathered equipment outside of the CON process even though it was already significantly underutilized. The SHCC should consider whether it is reasonable to punish a provider (in this case, Rex) because another provider (Duke Raleigh) is severely underutilized and able to increase its capacity as it has recently done. If Rex and Duke Raleigh were the only two providers in the county, there would be a surplus of capacity. Without an adjusted need determination, there would be no remedy for such a situation.

Third, as Rex discusses in detail below, its affiliation with Wake Heart & Vascular was the result of WakeMed's unwillingness or inability to partner with that practice and Rex's willingness to save it and its physicians from economic demise. Rex should not be penalized for its efforts and success in saving a vital physician resource in Wake County.

Finally, Rex believes it has created the leading cardiovascular program in the Triangle through a system of care that includes a seamless coordination among physicians, staff, and hospital. Patients are choosing North Carolina Heart & Vascular and Rex due to the level of service provided, the lower cost of care and the excellence with which they are cared for. Rex does not believe that it is effective for the SHCC to tell patients, essentially, that their decisions are wrong or that because of their choice of provider they will have to wait longer for treatment.

Again, Rex asks the SHCC to consider that allowing one facility to be continually overutilized, while others are consistently underutilized is not better for patient care. Patients do not benefit from maintaining the status quo where care is delayed, rescheduled, or results in unnecessary overnight stays.

Rex's Problem is of its Own Creation

In its March 2016 comments, WakeMed stated that "[t]o the extent that Rex Healthcare has a problem with cardiac catheterization capacity is entirely self-inflicted. No one other than Rex and NCHV determined that physicians in the group would no longer work at WakeMed facilities as they had previously done."

In its previous petitions, Rex has attempted to address the need for additional capacity without publically discussing the issues that led to the current situation. However, this comment, like so many others from WakeMed, is simply untrue. As discussed in public hearing statements from Dr. Lance Landvater in Raleigh on July 28, 2016, it is apparent that WakeMed itself has been the greatest force in the shift of physicians and patients away from its facility. In the face of declining reimbursement and changes in the delivery of healthcare, like many other physician practices, including cardiology groups, WHV sought first and foremost to affiliate with WakeMed, not Rex. For 18 months WHV negotiated with WakeMed and attempted to find a reasonable solution that would preserve patient care while enabling the WHV physicians to remain in the area, continuing to serve their patients. Despite all of their efforts, the physicians eventually realized they could not work out a solution with WakeMed as the then-current administration had created a toxic environment. So WHV reached out to Duke and to Rex, the other two providers in Wake County. Within 30 days, WHV and Rex reached an agreement. WHV did not select a partner based on who offered them more money. Rather, with Rex, WHV found an administration with whom they could partner, and one that would ensure that WHV could continue to provide their patients with the highest quality care. WakeMed failed to help these physicians while Rex came to their rescue. If not for Rex, WHV could have broken apart and left Wake County, creating a significant loss for the community.

Subsequently, WakeMed and its administrator at the time, Bill Atkinson, announced a hostile takeover bid to purchase Rex, further exacerbating the toxic situation. That bid ultimately failed and Bill Atkinson separated from WakeMed. In fact, as Dr. Landvater suggested, WakeMed continued to exhibit anger over the affiliation between WHV and Rex, which manifested itself in WakeMed withdrawing support from Wake Heart & Vascular physicians. Historically, WakeMed provided midlevel coverage on nights and weekends to assist Wake Heart and Vascular physicians in managing their inpatient census. While WHV physicians continued to practice at WakeMed following the affiliation with Rex, WakeMed stopped supporting the midlevel service in July 2013. Wake Heart and Vascular attempted to work with the medical staff and the cardiology

physicians at WakeMed to address this issue to no avail. After much consideration, Wake Heart and Vascular resigned physician privileges at WakeMed because it did not believe it could maintain the high quality standard of care at WakeMed given the withdrawal of that support. Given these facts, it is clear that WakeMed—and no one else—is culpable in the loss of physicians from their hospital.

Finally, consider what WakeMed is arguing here: that Rex's patients should be punished for Rex's success in attracting too many patients and that Rex physicians should be punished for leaving the toxic and untenable situation at WakeMed. The SHCC should consider whether it is in the best interest of patient care to require patients and physicians to use a hospital because of the historic distribution cath capacity, regardless of any other factor.

Rex and WakeMed Should Work To Resolve Issue

In denying Rex's 2015 petition for an adjusted need determination, some SHCC members encouraged Rex and WakeMed to work together to more effectively utilize the county's cardiac catheterization equipment. At the September 16, 2015 SHCC Meeting, SHCC Member Trey Adams commented that "one of the goals is to force providers to place nice and utilize everything in a health system" (see Exhibit 2; page 32, lines 8-9). At the October 7, 2015 SHCC Meeting, Trey Adams further explained his position, stating "I encourage Duke and WakeMed and Rex to talk together and figure out a way to play nice in the sandbox, to utilize the resources that we have in hand. You know, per my personal opinion is that this can't be solved, doesn't be solved, can't be solved, you know, it needs to come up again and -- and if patient's care is being inhibited, I'll probably switch my vote, but, you know, currently, we need to, I think there are quality resources and the basic principle of this plan is to allow the community to use those resources collaboratively, and I'm not sure we've, at this point, exhausted all collaborative opportunities" (see Exhibit 2; page 70, lines 24 and 25; page 71, lines 1-10).

As suggested, Rex did reach out to WakeMed to try to find an agreeable arrangement that would, most importantly, ensure consistent, high quality care to patients. Following an initial exchange of letters between Rex and WakeMed, WakeMed's comments on Rex's 2016 methodology petition stated "WakeMed is committed to working with Rex to develop a mutually beneficial solution that utilizes current capacity . . . [a]pproval of Rex's petition now would only undermine these ongoing negotiations." At a meeting of the hospitals' administrative and cardiology leadership, several approaches to resolving the issues were discussed, including Rex physicians using WakeMed cath labs and Rex leasing or purchasing a WakeMed cath lab. Immediately following the meeting, Rex sent a letter to WakeMed confirming the discussions and asking several questions that would move the process forward, such as how WakeMed would work with the Rex physicians in their hospital and what would

be the price and terms of a purchase or lease agreement for the cath lab. This letter is included in Exhibit 3. Rex sent this letter on March 28, 2016, four months ago as of the date of this petition, and has not received a response. At this point, given the length of time and the lack of any answers to a single question, Rex doubts the sincerity of WakeMed's desire to collaborate on this issue. The SHCC encouraged collaboration and Rex has pursued that path in good faith without reciprocation from WakeMed.

Given WakeMed's failure to respond in a timely fashion, it is fair to consider whether WakeMed is "committed to working with Rex" as it previously stated. WakeMed previously commented that action by the SHCC on this issue "would only undermine these ongoing negotiations." Of course, Rex believes otherwise. Rex is committed to pursuing all avenues to better serve its patients and so it has not prematurely assumed that the discussions with WakeMed will result in meeting the need that clearly exists: additional cardiac catheterization capacity at Rex. As such, Rex has continued to submit petitions and encourages the SHCC to consider their merits and to not assume that the discussions with WakeMed will correct the imbalance in the allocation of cardiac catheterization equipment in Wake County. Given its actions, it is fair to consider whether WakeMed is dragging out negotiations while at the same time arguing that SHCC action would undermine them, so that it can obstruct Rex's efforts indefinitely.

Again, Rex asks the SHCC to consider, are the outcomes of a potential Rex-WakeMed agreement better for patient care? As Rex has made clear in previous petitions and discusses below, there are significant inconveniences, costs, and inefficiencies for patients, physicians, and the healthcare system as a whole that would be incurred in order for Rex cardiologists to use the underutilized cath labs at WakeMed. While WakeMed has, to this point, been unwilling to provide cost and terms for the potential purchase or lease of its cath capacity, it is likely to exceed $60,000 cost for the software that would allow Rex to convert its two existing vascular labs. Neither of these alternatives is better for patient care.

Finally, since the last petition was discussed in the spring, the volume at Rex now shows the need for two additional cardiac cath labs. Given WakeMed's lack of response to-date when a need for only one cath lab was shown, it is even more unlikely that a response regarding two labs will be forthcoming.

Physician Reimbursement Not a Proxy for Cost

In its March 2016 comments, WakeMed stated that "Rex's position, that were it granted additional cardiac catheterization equipment that the cost of care for these procedures would be lower, is not supported by the payer data." In support of that statement, WakeMed argued that the data Rex had provided was not a proxy for cost. Yet, at the same time, WakeMed provided more of the same data that it had just argued was

unreliable. WakeMed states that "[t]he purpose of this comparison is not to highlight the lowest-cost or highest-cost facilities, but rather to illustrate that differences in cost exist for medical procedures across payers, and even among a payer's products."

WakeMed ignores the reason that Rex provided this cost comparison – namely, to respond directly to criticism that approval of Rex's petitions would result in an increase in the cost of care. At the September 16, 2015 Technology and Equipment Meeting, Dr. Prashant Patel, physician representative member of the SHCC, stated that approval of Rex's petition "would reduce competition because it is very clear that academic institutions, in general, which Rex is a part of, clearly get reimbursed at a much higher rate because they're teaching institutions" (see Exhibit 2 page 38, lines 8-12). It is fair to conclude that the data provided by Rex and WakeMed show that Rex is not in fact "reimbursed at a much higher rate" as alleged.

Moreover, although academic institutions do receive some benefit in reimbursement, **Rex is not an academic medical center or a teaching hospital and does not receive any increased reimbursement as such**. While Rex has attempted to focus on patient care issues, given these misstatements, it believes it must respond to this incorrect information. In contrast to what was raised during the SHCC meeting noted above, the very opposite is true: WakeMed's Medicare base rate DRG payment is higher than Rex's, and part of that payment is because WakeMed is a teaching hospital, and receives payments related to the training of residents. Thus, under this rationale, maintaining the status quo, the oversupply of cath labs at WakeMed, a teaching hospital, "would reduce competition because it is very clear that academic institutions, in general, which [WakeMed] is a part of, clearly get reimbursed at a much higher rate because they're teaching institutions."

Supply of Cardiologists and Practice Patterns

In its March 2016 comments, WakeMed responded to Rex's discussion of physician privileges. Some SHCC members have asked if the physicians using Rex's cardiac catheterization labs could begin using other labs in the county where capacity exists. Rex and its physician partners do not believe that this would be an effective solution to its capacity constraints as it would require a significant duplication of existing resources and a reduction in access for patients in nearby counties, as discussed below.

In addressing this issue, WakeMed, notably, did not respond to the substance of Rex's argument. Rex noted that in order to begin using WakeMed's cath labs, its physicians would need to duplicate its extensive support team staff, duplicate its PACS system or manually create and exchange CDs, and duplicate its physician call (thereby reducing its coverage in other counties across the region). WakeMed did not respond to these issues.

Further, Rex asked WakeMed specifically for assistance on these issues in the letter following the meeting of the hospitals' administrative and cardiology leadership, stating:

> WakeMed desires to move cases from UNC REX to WakeMed as a solution for UNC REX's high volume of cases. There would be significant challenges to this idea including having UNC REX physicians apply for WakeMed privileges, which would require their taking call at more than one hospital. Did you have thoughts on another type of privilege that would not require them to take call? Scheduling cases also could prove problematic. Would you be able to guarantee desirable block scheduling for cases? Continuity of care is important to the ongoing treatment of heart and vascular patients. How would studies/cases performed at WakeMed be integrated into the UNC REX Epic system? Finally, UNC REX has spent considerable effort on developing quality systems for patient safety, and to avoid readmissions and achieve other CMS quality goals. Would your organization be able to follow our protocols?
>
> See Exhibit 3.

As noted above, WakeMed has not responded to this letter after four months. Given WakeMed's apparent lack of desire to work with Rex to develop a timely solution to this issue, it is unclear how this collaborative solution can be developed.

Finally, as noted above, WakeMed previously withdrew support for Rex-affiliated physicians, effectively forcing them to leave WakeMed and give up their privileges in order to ensure that their patients received the best quality care.

No Positive Effects on Safety and Quality, Access, or Value

In its March 2016 comments, WakeMed stated that Rex's petition would not have a positive impact on safety and quality, access, or value. Rex believes just the opposite.

WakeMed argues that "Rex seeks to add to [the Wake County cardiac cath] surplus." Rex seeks to care for its patients which are being harmed by insufficient cardiac cath capacity. WakeMed and Duke Raleigh operate with more than two units of surplus cardiac cath capacity. At any point, WakeMed or Duke Raleigh could cease to operate its excess capacity in order to address the surplus in the Wake County. Instead, both continue to oppose Rex. In June 2015, WakeMed submitted an exemption request and received approval to replace one of its cardiac catheterization labs for a cost of $2.7 million. If WakeMed was truly concerned with addressing the surplus capacity of cardiac catheterization labs in Wake County, it could have closed that lab rather than making a significant capital investment to replace it.

It has been suggested that Rex's physicians should begin using other cardiac catheterization labs in the county to address this surplus. While this action may reduce the capacity surplus, it would not be an effective solution to as it would require a significant duplication of existing resources and a reduction in access for patients in nearby counties, as discussed below. As Rex has argued throughout this process, it simply does not make sense to redirect patients, duplicate call, and duplicate a system of care, when Rex could purchase software for $60,000 and convert two vascular labs from single purpose to multi-purpose.

WakeMed argues that "[d]elays that result from emergencies happen occasionally in all busy cardiac catheterization programs." WakeMed fails to address the fact that Rex is operating at 116 percent of capacity where the target standard is 80 percent. If Rex had more cardiac cath capacity, it could better treat patients as scheduled, better accommodate emergency patients, and reduce unnecessary overnight stays.

WakeMed argues that patients and physicians would not be disrupted if forced to access care at another facility because "physicians in many practices split their practices between more than one hospital." The key difference in the current situation for Rex is that all of Rex's patients and physicians are currently served at Rex and additional capacity could be added cheaply, efficiently, and without disruption. In order to split the cardiology practice, Rex would have to redirect patients, duplicate call, and duplicate a system of care. In the interests of its patients, Rex has chosen to pursue the first option rather than the latter. WakeMed fails to demonstrate that it would benefit patients to split the practice because there is no benefit, only cost.

WakeMed asserts that access to cardiac cath capacity would not be enhanced if Rex's petition is approved. As Rex has noted, 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 2015 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 15 offices in nine 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.

WakeMed asserts that Rex's petition will not promote value because of the excess capacity in the service area. At any point, WakeMed could cease to operate its excess

capacity in order to address the surplus in the Wake County. Instead, WakeMed recently replace one of its cardiac catheterization labs for a cost of $2.7 million. If WakeMed was truly concerned with addressing the surplus capacity of cardiac catheterization labs in Wake County, it could have closed that lab rather than making a significant capital investment to replace it.

<u>Approval Would Be Precedent Setting</u>

In opposing Rex's petitions, several SHCC members have stated that an approval would be precedent-setting (see Exhibit 2; page 31, lines 15-16; page 32, line 18; page 39, lines 8-9; page 70, line 3; page 73, line 1; page 75, line 25, page 76, line 25; page 77, line 5) Based on its interpretation of those comments, Rex believes that some SHCC members were concerned about approving additional capacity outside of the standard methodologies in the *SMFP* (see Exhibit 2; page 63, lines 4-24). The *SMFP* specifically outlines an annual petition process for changing basic policies and methodologies and for adjusted need determinations. In other words, the petition process is <u>expressly designed to allow for changes outside of the standard methodologies or changes to the methodology</u>. In fact, Rex would argue that the petition process actually strengthens the *SMFP* planning process, by allowing the SMFP to evolve to meet the ever-changing needs of the healthcare community. Therefore, Rex's petitions are consistent with the process outlined in the *SMFP*, as well as many other petitions approved in the past.

In an attempt to resolve its ongoing capacity issues, Rex has submitted petitions for methodology changes and for adjusted need determinations without success. During the development of *2016 SMFP*, the SHCC received six petitions for basic policies and methodologies and 11 petitions for adjusted need determinations. The SHCC approved nine of those 17 total petitions, either directly or indirectly. Rex believes its petitions should not be treated any differently from the dozens of petitions that are filed every year. In the past, Rex has requested modest changes to the cardiac catheterization methodology, just as dozens of other petitioners have requested changes to other *SMFP* methodologies. Similarly, Rex has requested adjusted need determinations, just as dozens of other petitioners do every year. In each instance, either the methodology is found to no longer be as responsive as it once was, and it needs to be changed, or the methodology does not consider a particular need that exists in a specific area. There is nothing precedent-setting about Rex's petitions.

More specifically, some SHCC members appear to be concerned a precedent would be set if they approved additional capacity when surplus capacity exists in the service area, particularly when those needs are related to physician affiliation activity. Other SHCC members have expressed concern about setting a precedent by becoming involved in the "business decisions" within a particular county. Rex does not believe that the approval of its petitions would set a precedent based on this issue, either, given the recent history of approved petitions. The SHCC has historically approved numerous

petitions where surplus capacity exists and, frequently, those needs are related to physician affiliation activity, even if that activity is unknown. The SHCC has also historically approved petitions have involved competitive situations between providers within counties. Further, as shown below, the SHCC has revised methodologies so that need can be created as a result of physician affiliation in service areas where surplus capacity exists. In other words, the SHCC has approved many petitions in the past with similar circumstances to Rex. In the context of the examples below, Rex believes that the approval of its petitions would be similar to many of these SHCC actions; thus, the approval of Rex would not in any way be precedent-setting.

Please note this list is not comprehensive but is used to demonstrate the similarity of Rex's petitions to other SHCC actions.

- The SHCC approved a 2015 petition by Raleigh Radiology for an adjusted need determination for one additional fixed MRI unit in Wake County, despite the standard methodology showing a small surplus of capacity. The SHCC created the opportunity for Raleigh Radiology to develop fixed MRI capacity <u>so that it could end a business relationship with Alliance for the lease of its existing unit</u>. Raleigh Radiology argued that the growth in its practice was due to its selection as preferred provider to the Key IPA and WakeMed accountable care organization, a physician-hospital affiliation.

- The SHCC approved a 2015 petition by J. Arthur Dosher Memorial Hospital (Dosher) for an adjusted need determination for one additional MRI unit in Brunswick County in the *2016 SMFP*, despite the standard methodology showing a surplus of capacity. The SHCC created the opportunity for Dosher to develop fixed MRI capacity because its existing business relationship with Alliance for the lease of an MRI was not optimal for providing excellent patient care at a low cost.

- The SHCC approved a 2013 petition by Duke Raleigh Hospital 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 and approved but not yet developed capacity. Duke Raleigh's growth was due to significant investment in the recruitment of cancer physicians to Wake County.

- The SHCC approved a 2010 petition by Brookdale Senior Living for an adjusted need determination for 240 nursing care beds in Wake County.

The SHCC created additional capacity despite the existence of underutilized capacity in the service area which prevented need from being generated under the standard methodology.

- The SHCC approved a 2010 petition by Graystone Eye Surgery Center for an adjusted need determination for one additional operating room in Catawba County. The SHCC created additional capacity despite the existence of underutilized capacity in the service area which prevented a need from being generated under the standard methodology.

- In 2010, the SHCC approved a revised acute care bed methodology which changed the growth rate factors to use a county-specific growth rate instead of a statewide average growth rate. This change, combined with the existing calculation of need by facility rather than for a service area in total, allows the creation of need determinations as a result of the need expressed by a single facility or group of hospitals under common ownership without regard for other potentially underutilized capacity in the service area.

- The SHCC approved a 2008 petition by Hospice of Wake County for an adjusted need determination for ten inpatient hospice beds in Wake County in the *2009 SMFP*. The SHCC acted to create additional capacity despite the existence of underutilized capacity in the county which prevented need from being generated under the standard methodology. The demand for hospice services was related, in part, due to an affiliation between Hospice of Wake County and Rex Hospital.

- In 2007, the SHCC approved a revised operating room methodology that excluded chronically underutilized licensed facilities, defined as facilities operating at less than 40 percent utilization for the past two fiscal years, from the planning inventory so that they would not suppress the need for additional capacity. As such, the SHCC revised a methodology to allow for the creation of additional need determinations, through whatever cause including physician affiliation, without regard for other underutilized capacity in the service area.

Given the examples above, it is clear that the approval of Rex's petitions would not be precedent setting. Moreover, Rex believes that the SHCC should give greater consideration to the need for additional cardiac catheterization capacity due to emergency, life-saving nature of the service than the needs for diagnostic or non-emergent services such as MRIs or linear accelerators.

Negative Impact on Cost of Care

In opposing Rex's petitions, several SHCC members have argued that an approval would result in an increase in the cost of care and that no analysis of the value of Rex's proposal has been presented (see Exhibit 2; page 30, lines 7-25; page 31, lines 1-16; page 38, lines 8-25; page 39, lines 1-4). Rex believes just the opposite for several reasons.

As noted above, Rex is not an academic medical center and as such, does not receive additional reimbursement for medical training. Rex is a member of UNC Health Care, and as part of that system, provides lower cost services to patients through economies of scale. Hospital affiliation across the state and more regionally is occurring as formerly independent hospitals recognize the need to lower their expenses in a national and local environment which has reduced reimbursement to providers. Further, UNC Health Care's physician affiliations, particularly with cardiologists, most relevant in this instance, reduce the cost of care and expand access across the region. In fact, due to its relationship with cardiologists, Rex is able to bill globally for cardiac catheterization procedures, resulting in lower costs and simplified billing (something that would not be possible if these cardiologists performed the procedures elsewhere). Rex has been successful in building physician relationships, in part due to its ability to realize these affiliation benefits, and should not be penalized for it.

Rex's sister hospital, UNC Hospitals in Chapel Hill, is an academic medical center and receives additional reimbursement based on that status. Rex does use its cath labs for teaching with the recent launch of a fellow program for UNC-Chapel Hill School of Medicine, with fellows in each of Rex's four labs five days each week. However, Rex does not receive any additional reimbursement related to these teaching programs or any other academic teaching status.

Further, Rex and its affiliated physician have the lowest average reimbursements for cardiac catheterization in the region. The table below presents data Blue Cross Blue Shield of North Carolina's "Estimate Your Health Care Costs" tool[2] comparing the average costs for catheterization procedures for providers in Raleigh.

Blue Cross Blue Shield of North Carolina – Estimate Your Health Care Costs

	Left Heart Cath	***Coronary Bypass with Cardiac Cath***
Rex Hospital	$5,747	$66,975
WakeMed	$8,560	$84,706
Duke Raleigh	$10,883	
Lowest Cost Physicians for Each Hospital		
James Zidar, Rex Hospital	$5,139	

2 Accessed at http://www.bcbsnc.com/content/providersearch/treatments/index.htm#/ on February 23, 2016.

Joseph Guzzo, Rex Hospital	$5,292	
Joseph Falsone, Rex Hospital	$5,301	
Robert Bruner, Rex Hospital	$5,478	
George Adams, Rex Hospital	$5,454	
J. Richard Daw, WakeMed	$7,698	
Maitreya Thakkar, WakeMed	$8,022	
Jimmy Locklear, WakeMed	$8,237	
Siddhartha Rao, WakeMed	$8,274	
Pratik Desai, WakeMed	$8,294	
Mark Leithe, Duke Raleigh	$10,468	
James Mills, Duke Raleigh	$12,114	

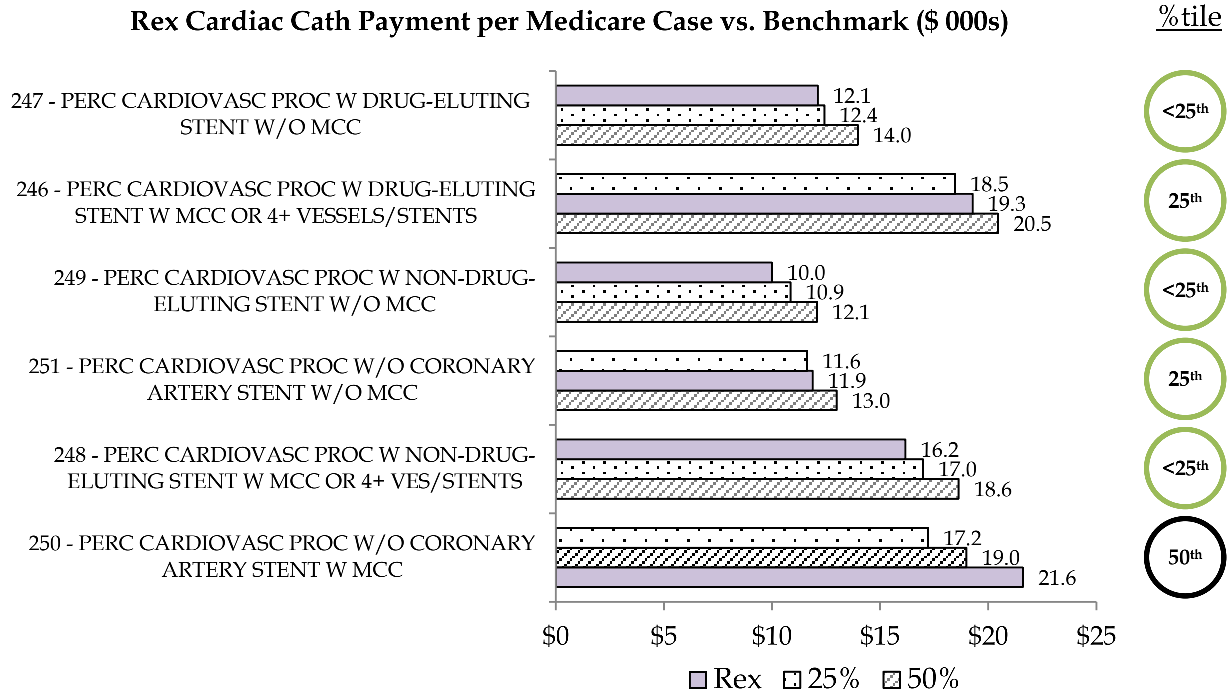
Note: The costs for Blue Options, Blue Advantage are shown for comparison purposes. Please see Attachment 1 of Rex's 2016 methodology change petition included Exhibit 4 for the complete data available from Blue Cross Blue Shield of North Carolina tool.

At the March 2, 2016 SHCC public hearing, Dr. James Zidar, speaking on behalf of Rex's petition noted that Rex's Medicare reimbursement was lower than other providers in the region for the reasons cited above. However, he misspoke when discussing Blue Cross Blue Shield reimbursement. As the data clearly show, Rex and its affiliated physicians are reimbursed at a lower rate than other area providers.

As shown, Rex and its affiliated physicians have significantly lower costs per procedure for Blue Cross Blue Shield patients than Duke Raleigh or WakeMed and its providers. In fact, the highest cost at Rex is lower than the lowest cost at WakeMed or Duke Raleigh. Of note, WakeMed receives additional reimbursement due to its status as a teaching hospital and for disproportionate share payments. For Medicare reimbursement, this amounts to 25.7 percent higher reimbursement than Rex. Rex is not arguing the merits of Duke Raleigh or WakeMed's reimbursement; nonetheless, the evidence simply does not support that argument that the approval of Rex would increase the cost of care, but that it would, in fact, lower it.

As further evidence of Rex's lower cost of care compared to other providers in Wake County, it should be noted that North Carolina Heart & Vascular clinics remain provider-based, unlike other practices operated by Duke and WakeMed. In particular, Raleigh Cardiology, now affiliated with WakeMed, has shifted to hospital-based reimbursement, operating the physician practice as an outpatient clinic of the hospital. As a result, payors pay a facility fee that provider-based practices cannot charge, and patients end up paying substantially more out of pocket. Rex believes this practice is at least partially responsible for the higher fees between Rex's cardiologists and WakeMed's shown above.

As shown by the following data, Rex's inpatient Medicare payments are at or below the 25th percentile for most cardiac catheterization procedures, with one at the 50th percentile.



Source: Rex Internal. Advisory Board Hospital Benchmark Generator. MedPAR 2014 Revenue per Case by MS-DRG

While the available data are for inpatient procedures only, as a proxy for the service, they clearly demonstrate that Rex is a high value provider of cardiac catheterization services in Wake County.

Finally, Rex's plan to add cardiac catheterization capacity is to upgrade the software of two vascular labs for approximately $60,000 in total. Due to its capacity constraints, Rex has contracted with a mobile cardiac catheterization lab since May 2015 at a cost of $16,000 per month. Clearly, a lower cost solution would be a one-time upgrade for $60,000 rather than a monthly expense of $16,000, or $192,000 per year.

The information provided above and in past petitions demonstrates that Rex's proposed petitions would lower the cost of care and provide value to Wake County area residents. Rex believes that it is has provided the SHCC with significant information and data to support its petitions in contrast with many past petitions approved by the SHCC that do not provide estimates of capital cost, monthly expenses, or reimbursement impact.

Rex Physicians Can Use Other Labs

In the SHCC's prior discussions of Rex's petitions, some SHCC members have questioned if the physicians using Rex's cardiac catheterization labs could begin using other labs in the county where capacity exists (see Exhibit 2; page 32, lines 8-9; page 70, lines 24 and 25; page 71, lines 1-10; page 72, lines 12-25).

Rex and its physician partners do not believe that this would be an effective solution to its capacity constraints as it would require a significant duplication of existing resources, a reduction in access for patients in nearby counties, as discussed below.

Following the affiliation, the cardiologists in question, now part of North Carolina Heart & Vascular, relocated their clinic and patients to the Rex Hospital campus, and along with that shift, much of its hospital-related patient care, including cardiac catheterizations. Today, North Carolina Heart & Vascular's sole Raleigh office is in the Medical Office Building adjacent to Rex Hospital's Emergency Department. North Carolina Heart & Vascular patients can visit one site of care for all of their physician visits, diagnostic testing, pre-procedure testing, cardiac catheterizations, cardiac surgery, etc. The benefits of this centralized site of care are substantial. North Carolina Heart & Vascular's team (physicians, nurses, catheterization lab technicians, and other ancillary staff) is able to standardize care for its patients to ensure that the care is high quality, consistent, and cost effective for each patients. Patient care processes are streamlined and supplies and technology are standardized, improving safety and throughput, improving patient care. Patients can be seen in the office, any emerging issues can be diagnosed through testing such as echo or ultrasound, and if needed, the patient can be scheduled for a cardiac catheterization that same day, depending on acuity and lab availability. Images from all of the patient's tests are stored on the UNC Health Care's PACS system so that interventionalists and surgeons can review them prior to a case. North Carolina Heart & Vascular employs a team of advanced practice providers (nurse practitioners and physician assistants) that admit to the hospital, round, consult, follow-up on testing, and discharge patients which greatly increases the efficiency and effectiveness of the physicians. North Carolina Heart & Vascular physicians working at Rex have one Raleigh hospital for emergency call; and their Raleigh patients do not have to guess where their physicians are available for emergency or routine care. Finally, as partners, Rex and North Carolina Heart & Vascular are actively engaged together in decision making (for purchasing, policies, and protocols), in research and innovation (for care redesign and technology), and in achieving excellent patient experiences and outcomes and low costs.

In order to begin using WakeMed's cath labs, North Carolina Heart & Vascular physicians would need to obtain privileges at WakeMed and meet the medical staff bylaw's requirements for emergency department and inpatient coverage. Further, extra time and effort would be required to transition from one culture of care to another,

which slows down work flow and processes impeding patient throughput and outcomes. North Carolina Heart & Vascular physicians could not meet WakeMed's coverage requirements without redeploying physicians currently providing care across the practice's service area, thereby reducing access to patients in other counties across the region. Specifically, these cardiologists currently provide services in Johnston, Franklin, Harnett, Nash, Sampson, Wayne, and Wilson counties.

WakeMed has a robust medical staff with more than sufficient cardiologist coverage currently: according to its website, WakeMed Heart & Vascular Physicians employs more than 30 physicians. Thus, if North Carolina Heart & Vascular physicians obtain privileges at WakeMed, WakeMed would have a surplus of cardiologists, and North Carolina Heart & Vascular would be covering two hospitals in Wake County, instead of one, at the expense of patients in nearby counties. This action would thus create another surplus—a surplus of cardiologists at WakeMed—while creating a deficit of cardiologists at Rex and other hospitals throughout the region. While this surplus at WakeMed may not be obvious to the SHCC as the surplus of cardiac catheterization equipment at WakeMed and Duke Raleigh, it would still exist and create access issues as great as those that exist due to the need for additional cardiac catheterization capacity at Rex.

In addition to duplicating its physician call, North Carolina Heart & Vascular would need to unnecessarily duplicate its support staff team. Two sites of interventional and inpatient care would require two different teams doing the same things, but unable to create efficiencies and economies of a scale by caring for a critical mass of patients. For example, North Carolina Heart & Vascular would need to double its number of advanced practice providers in order to maintain the required 24 hours a day, seven days a week coverage for its inpatients. North Carolina Heart & Vascular would not be able to control all the required ancillary hospital staff at another facility in order to meet desired quality and cost standards. Another hospital would be reluctant to share decision-making with an outside physician group, particularly given the number of cardiologists from other groups that already practice at WakeMed. As a result, the practice overall would be less efficient and less cost-effective.

In order to support patients at WakeMed, North Carolina Heart & Vascular would need to duplicate its PACS system or manually create and exchange CDs containing the images taken during procedures that are saved on the UNC Health Care PACS system. While UNC Health Care (including Rex) and WakeMed are both on the EPIC electronic health system, that record that does not include the actual images from procedures. EPIC only includes the written reports. Using non-technical terms, a physician with access to the PACS system can see the X-ray and can therefore make an interpretation relevant to the patient's care at that moment. If the physician only has access to EPIC, only the written report from the initial evaluation of the procedure is available. Access to these images is most vital in emergency situations, when a patient presents with

chest pain and the physician can immediately review images from previous procedures to assess and provide treatment.

Rex and its physician partners do not believe that the most effective solution to its capacity constraints is to duplicate its call, its staff, and its system at a tremendous addition to its operating costs when instead, with the permission of the SHCC and the CON Section, it could quickly and cost-effectively add capacity by purchasing a $30,000 software upgrade to an existing vascular lab, or $60,000 for two.

Notably, even if North Carolina Heart & Vascular physicians were to practice at other hospitals, their patients could be prevented from receiving care at those other sites or made to pay higher out of pocket costs depending on their health care insurance. Many insurers are utilizing "narrow networks" which direct patients to a network of low cost, high quality providers and hospitals in order to better control costs. Thus, some of North Carolina Heart & Vascular's patients may not be able to receive their care at other facilities or may have to pay high out-of-pocket costs.

Finally, while Rex appreciates that the SHCC is looking for alternative solutions to these problems, it does not believe that the SHCC's purview includes directing where physicians should practice or, more importantly, where patients should receive care. Rex believes it has created the leading cardiovascular program in the Triangle through a system of care that includes a seamless coordination among physicians, staff, and hospital. Patients are choosing North Carolina Heart & Vascular and Rex due to this level of care. Rex does not believe the SHCC should tell patients, effectively, that their decisions are wrong or that because of their choice of provider they will have to wait longer for treatment.

<u>Statewide and Wake County Declines</u>

The Agency Report on Rex's 2014 adjusted need determination petition begins by showing that cardiac catheterization volumes "in the last 10 years [in] Wake County and NC have experienced declines greater than 10 percent and 18 percent, respectively" and noting that Wake County, "in recent years, has experienced a sharper decline in utilization than the state as a whole" (see Exhibit 1 for Agency Report). The most recent cardiac catheterization utilization data as shown in the *Proposed 2017 SMFP* shows that statewide utilization increased over the last year. In addition, Wake County's cardiac catheterization data shows two consecutive years of increases in procedures.

Rex does not dispute that statewide and county-wide trends indicate declining utilization overall for cardiac catheterization over the past decade. **In fact, it is precisely because of these overall trends that Rex's sharp increase in utilization represents a unique circumstance that needs to be addressed through the adjusted need determination process**. The Agency Report on Rex's 2014 adjusted need determination

petition agrees that Rex's circumstances are unique, stating that "the data presented in Rex's petition suggests that they have had **unique utilization trends in recent years**" (page 3, **emphasis added**).

Lack of Multi-Year Trend

While acknowledging Rex's unique circumstances, the Agency Report stated that "Rex has only one year in the last five recent years of utilization greater than 80 percent. Application of the methodology does generate a deficit for this facility for this one year, but it is difficult to forecast the changes and trends in healthcare utilization based on one year's worth of data" (page 4). The *Proposed 2017 SMFP* now provides the Medical Facilities Planning Section with three years of data showing Rex's utilization above 80 percent (84 percent utilization in FY13, 100 percent utilization in FY14, and 115 percent in FY15).

The 2014 Agency Report concludes that "[c]*consistent data trends over more than one year would be essential to ensure that cardiac catheterization services are not being duplicated in Wake County*" (page 5). Rex believes that its three-year trend is more than adequate to demonstrate the need for additional capacity. Notably, the cardiac catheterization methodology in the *SMFP* only considers one year in determining need; it does not attempt to forecast changes or trends. In other words, if Rex were the only provider in its service area, a single year of utilization above the utilization threshold would result in a need determination for additional capacity. It is only because Rex is in a service area with other cardiac catheterization providers that a one year trend is insufficient.

More importantly, a longer timeline would force a provider to operate above capacity for more than five years due to the *SMFP* and Certificate of Need (CON) process. For example, if the SHCC were to approve Rex's current petition, the *2017 SMFP* would include a need determination for an additional cardiac catheterization unit in Wake County and Rex could submit a CON sometime in 2017 to develop that unit. Even if the CON application is approved under an expedited review, it would require four and one-half months after submission to begin development at a minimum. So if the SHCC were to find that Rex currently demonstrates a need for additional capacity, it would be at least a year until Rex could develop that capacity and possibly even longer. At that point, Rex would have been operating above capacity for five years. No reasonable approach to healthcare planning would require an even longer time horizon to demonstrate the need for a service like cardiac catheterization which is essential to emergency life-saving treatment.

Potential for Duplication of Health Services

In recommending denial of Rex's 2014 adjusted need determination petition, the Agency Report noted that "[t]*he standard methodology considers procedure volume and number of machines of the entire service area. Thus, Rex's deficit is offset by a surplus of machines in Wake County as a whole . . . Therefore, approval of this petition may introduce duplication of health services into Wake County*" (page 4). Again, Rex does not dispute that other providers have underutilized equipment in Wake County; however, **it is precisely because there are several significantly underutilized cardiac catheterization providers in Wake County that Rex's situation represents a unique circumstance that needs to be addressed through the adjusted need determination process**.

Of note, while Table 9W of the *Proposed 2017 SMFP* indicates that WakeMed has more than two cath labs of excess capacity, WakeMed's recent actions suggest that it needs all of its cath lab capacity. In June 2015, WakeMed submitted an exemption request and received approval to replace one of its nine cardiac catheterization labs (see Attachment 3 of Rex's 2015 petition for an adjusted need determination included in Exhibit 4). If WakeMed truly had unnecessary capacity, then it would not be making a significant capital investment in order to replace an existing lab.

From Rex's perspective, absent the adjusted need determination requested in this petition, it will never be able to acquire additional fixed cardiac catheterization capacity, no matter how needed because other providers in its community are so underutilized. Rex discussed this same dynamic in its 2014 and 2015 petitions, but the Agency Report did not respond to this issue. Rex urges the Medical Facilities Planning Section to consider that Rex's unique circumstances indicate that a duplication of cardiac catheterization equipment in Wake County is necessary.

As Rex noted above, the SHCC has approved additional healthcare capacity in multiple other instances where there is not an overall need in the service area due to the underutilization of other providers. Most notably, 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.

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 approved 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 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). Rex's cardiac catheterization services and its 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 or its willingness to work with physicians who had tried to work with another hospital to no avail. 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.

As with linear accelerator capacity in the Duke Raleigh case, there is cardiac catheterization capacity available at other Wake County facilities, yet Rex's volume continues to grow. Both the *2016 SMFP* and *Proposed 2017 SMFP* show that Rex's utilization continues to grow despite operating well above capacity and at much higher utilization than any other provider. Yet, the underutilized capacity at other Wake County facilities is not alleviating the overutilization at Rex. This is because of the nature of cardiac catheterization services as compared to other services. 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. Preventing duplication 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. The physicians that perform cardiac catheterizations at Rex do not have privileges at any other facility and so cannot treat their patients at another hospital which may have excess capacity. 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 cardiac catheterization capacity available there, is extraordinarily unlikely, as well as being disruptive to the continuity of care. 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. For these reasons, Rex does not believe that its need for additional cardiac catheterization capacity can be served by

underutilized capacity at other facilities. Under these circumstances, responsible healthcare planning requires **necessary duplication**.

Historical data from North Carolina's competitive cardiac catheterization markets provides strong evidence that capacity at underutilized facilities does not alleviate the needs of overutilized cardiac catheterization facilities. Rex performed a detailed review of the last ten years of utilization for each of the counties in North Carolina with multiple cardiac catheterization providers (Catawba, Forsyth, Guilford, Iredell, Mecklenburg and Wake counties, excluding Durham, where both providers are part of the Duke University Health System). Further, based on Rex's review of data there is no evidence to suggest that the addition of cardiac catheterization capacity to a provider harms the cardiac catheterization services at other facilities in the market. Each market was analyzed in detail in Rex's 2014 petition (please see Attachment 1 of Rex's 2015 adjusted need petition which is included in Exhibit 4 which includes a copy of that petition).

Historic Ability to Operate at High Utilization

The Agency Report on Rex's 2014 adjusted need determination petition states that "both Rex Hospital and WakeMed operated at over 80 percent of capacity for five and eight years, respectively, of the 10 year time frame. In some of those years, utilization was well over 100 percent for both facilities. The petitioner argues that utilization greater than 80 percent poses difficulties for both providers and patients. While higher facility utilization does come with challenges, previous historical trends have demonstrated several years' volumes over 80 percent have occurred in Wake County" (page 4). Rex is operating well above 80 percent of capacity today and has for almost three years consistently, with no end in sight. High utilization levels are possible, but are detrimental to patient care. The Agency Report acknowledges that there are challenges of operating at these levels. Rex would encourage the SHCC to consider that these challenges are not just logistical or operational but they impact people's lives. As noted below, high utilization levels mean that patients wait longer (hours and days) to get the care they need, or that a patient must be removed from a room in the middle of a scheduled procedure in order to accommodate an emergency, or that patients and their families spend a night in the hospital, instead of at home. 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. Rex and WakeMed operated at high utilization levels ten years ago, surely, but they also understood that the *SMFP* would (and did) provide additional capacity through need determinations. Both WakeMed and Rex added capacity to alleviate the high utilization levels. The current situation in Wake County is very different. Absent the adjusted need determination requested in this petition, Rex will never be able to acquire additional cardiac catheterization capacity, no matter how needed because other providers in its community are so underutilized.

The SHCC should also understand that high utilization levels are more difficult for Rex to achieve today than in the past due to several factors:

- There is more variability in the types and length of cardiac catheterization procedures provided by Rex than in past. Historically, cardiac catheterization procedures could be reasonably expected to require 60 to 90 minutes to complete and were either standard diagnostic or interventional cases. Today, Rex's cases are extremely variable in terms of length (anywhere from 60 minutes to four hours) and type (Transcatheter Aortic Valve Replacements (TAVRs), mitral clips, chronic total occlusions, etc. in addition to standard diagnostic and interventional cases).
- New technology and tools are used for Rex's cases which add to the logistical complexity of operating the labs efficiently.
- Rex now uses its labs for teaching with the recent launch of a fellow program for UNC-Chapel Hill Medical School with fellows in each of Rex's cath labs, five days a week.
- Rex now conducts research in its labs including hundreds of patients annually under the care of North Carolina Heart and Vascular as well as other Rex physicians.

All of these factors make the high utilization of Rex's cath labs more challenging than in year's past. While Rex is intimately aware of these factors in its own cardiac catheterization labs, it is not specifically aware of the circumstances at WakeMed. However, it is likely that WakeMed has also experienced the change in the variability of catheterization cases and introduction of new technology and tools that reduce a facility's ability to operate at consistently at high utilization levels. This may explain why WakeMed is replacing one of its existing cardiac catheterization labs despite operating at 56 percent of capacity.

Of note, the Agency Report on Rex's 2014 adjusted need determination petition overstates Rex and WakeMed's historic utilization percentages. Specifically, the Agency Report notes that "[t]*he number of machines assigned to each facility is not based on the number that were actually operated by the facility, but the number of machine listed in the inventory for each facility in each year's state medical facility plan"* (page 4). In other words, the analysis did not match utilization with the actual number of machines providing the utilization. Rex reviewed the facilities' hospital licensure renewal application from the pertinent years in order to determine the number of machines that were actually operated by the facility (revisions are highlighted in yellow and bolded). As the revised table below shows, Rex never operated over 100 percent of capacity until 2014 and WakeMed only operated above 100 percent of capacity in one year.

Revised Tables 4 & 5
from 2014 Agency Report on Rex Adjusted Need Determination Petition
Wake County Cardiac Catheterization Procedures by Facility from 2004 to 2015

		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Duke Raleigh	Total weighted procedures	0	1,288	202	357	262	770	967	701	366	447	393	463
	No of machines	0	1	2	2	2	2	2	2	2	3	3	3
	Procedures for 100% Utilization	0	1,500	3,000	3,000	3,000	3,000	3,000	3,000	3,000	4,500	4,500	4500
	Utilization	0%	86%	7%	12%	9%	26%	32%	23%	12%	10%	9%	10%
Rex Hospital	Total weighted procedures	4,206	3,897	4,015	3,557*	3,616	3,489	3,002	3,132	3,875	5,029	6,006	6,934
	No of machines	3	3	3	3	3	3	3	3	4	4	4	4
	Procedures for 100% Utilization	4,500	4,500	4,500	4,500	4,500	4,500	4,500	4,500	6,000	6,000	6,000	6,000
	Utilization	93%	87%	89%	79%	80%	78%	67%	70%	65%	84%	100%	116%
WakeMed	Total weighted procedures	11,709	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570	8,172	7,567
	No of machines	8	8	8	8	8	9	9	9	9	9	9	9
	Procedures for 100% Utilization	12,000	12,000	12,000	12,000	12,000	13,500	13,500	13,500	13,500	13,500	13,500	13,500
	Utilization	98%	99.9%	97%	97%	103%	90%	93%	90%	78%	63%	61%	56%
WakeMed Cary	Total weighted procedures	567	498	405	418	393	325	382	325	282	222	223	205
	No of machines	1	1	1	1	1	1	1	1	1	1	1	1
	Procedures for 100% Utilization	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500
	Utilization	38%	33%	27%	28%	26%	22%	25%	22%	19%	15%	15%	14%
Wake County (Total)	Total weighted procedures	16,482	17,667	16,319	15,988	16,583	16,692	16,969	16,287	15,057	14,268	14,794	15,168
	No of machines	12	13	14	14	14	15	15	15	16	17	17	17
	Procedures for 100% Utilization	18,000	19,500	21,000	21,000	21,000	22,500	22,500	22,500	24,000	25,500	25,500	25,500
	Utilization	92%	91%	78%	76%	79%	74%	75%	72%	63%	56%	58%	59%

Source: *2006-2016 SMFP; Proposed 2017 SMFP.* 2005-2016 Hospital License Renewal Applications.
*Rex Hospital 2007 weighted procedures revised to match *2009 SMFP* which excludes cases performed on a temporary mobile unit in that year.

Changing Capabilities at Nearby Facilities

The Agency Report on Rex's 2014 adjusted need determination petition also considered the changing capabilities at other nearby facilities noting that "*a facility located in a contiguous county was approved to perform interventional procedures, even though it does not have an open heart surgery on site. A similar request in a different county located near Wake County is being evaluated by the Agency. This may have some impact on procedure volumes in Wake County and could potentially accelerate the decline of cardiac catheterization procedures*

performed in Wake County". It is Rex's understanding that the Agency Report is referring to the initiation of an interventional catheterization services at Johnston Health (in Johnston County, which is adjacent to Wake County) and Central Carolina Hospital (in Lee County, which is near Wake County. Rex believes that these new interventional programs have not decreased its need. In fact, the available data suggests that Rex's need has grown in spite of the initiation of these programs. As noted above, catheterization volume served by Wake County providers has increased in both of the last two years indicating a reversal in the historical decline of volume in the county. Rex is Johnston Health's partner in developing its interventional service and based on the evidence to-date, Rex believes that Johnston Health's program has not had led to any decline in Rex's volumes. Rex does not have any information on the state of Central Carolina's program; however, it is clear that Rex's interventional volumes are growing regardless of that program's status.

CONCLUSION

In conclusion, Rex requests that the SHCC approve the petition for an adjusted need determination for two cardiac catheterization units 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 22 percent annual growth in cardiac catheterization volumes.
- Rex's fixed cardiac catheterization labs are currently operating at 116 percent of capacity and demonstrate a deficit of two labs, which is the largest 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 adjusted need determination 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.

This is the fifth time that Rex has petitioned for a solution to its cardiac cath capacity problems. Throughout this process, Rex has been responsive to the comments and concerns of the SHCC. Rex believes that misinformation has contributed to the denial of its previous petitions and it has attempted to correct the record. While Rex has tried to maintain the integrity of the health planning process pursued by the SHCC, its opponents have politicized this issue and reframed it as a conflict between hospitals.

Rex believes that SHCC must now act to resolve its cardiac catheterization capacity deficit. The *Proposed 2017 SMFP* shows that Rex now has a deficit of two cath units, up from a deficit of one in prior years. Continued delays will result in negative impacts on the patients in need in Wake and surrounding counties.

Thank you for your consideration.