Exhibit 1

Technology and Equipment Committee
Agency Report
Petition for Special Need Adjustment for Fixed Cardiac Catheterization Equipment in Wake County in the Proposed 2016 State Medical Facilities Plan

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Petitioner:
Rex Healthcare
4420 Lake Boone Trail
Raleigh, NC 27607

Contact:
Erick Hawkins
System Vice President, Heart and Vascular Services
(919) 784-4586
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Request:
Rex Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Wake County in the *North Carolina 2016 State Medical Facilities Plan* (SMFP).

Background Information:
The *Proposed 2016 SMFP* provides two standard need determination methodologies for cardiac catheterization equipment. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment and Methodology Two is the need determination methodology for shared fixed cardiac catheterization equipment. Application of these methodologies to utilization data in the *Proposed 2016 SMFP* does not generate a need determination for fixed or shared fixed cardiac catheterization equipment in Wake County.

Chapter Two of the *Proposed 2016 SMFP* allows persons to petition for an adjusted need determination in consideration of "unique or special attributes of a particular geographic area or institution…," if they believe their needs are not addressed by the standard methodology. Rex has submitted a petition to add a need determination for one unit of fixed cardiac catheterization equipment in Wake County. Rex is requesting the adjusted need determination based on "the unique utilization trends faced by Rex".

There are several providers in Wake County that offer cardiac catheterization services. Wake County has a total of 17 cardiac catheterization machines in the *Proposed 2016 SMFP*. Of those, Rex has a total current inventory four machines. Using the standard methodology of 80% utilization, the number of machines for Wake County and Rex is 12.33 and 5.00, respectively.

Thus, in the *Proposed 2016 SMFP* Rex has a one machine deficit and Wake County has a 4.67 machine surplus as seen in Table 1 below.

Table 1: Wake County Fixed Cardiac Catheterization Equipment and Weighted Procedures, 2005-2014

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Duke Raleigh Hospital	Total Number of Procedures	1288*	202	357	262	770	967	701	366	447	393
	No of Machines in Inventory	0	1	1	2	2	2	2	3	3	3
	Machines required based on 80% Utilization	1.07	0.17	0.30	0.22	0.64	0.81	0.58	0.30	0.37	0.33
Rex Hospital	Total Number of Procedures	3,897	4,015	3,646	3,616	3,489	3,002	3,132	3,875	5,029	6,006
	No of Machines in Inventory	2	3	3	3	4	4	4	4	4	4
	Machines required based on 80% Utilization	3.25	3.35	3.04	3.01	2.91	2.50	2.61	3.23	4.19	5.00
WakeMed	Total Number of Procedures	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570	8,172
	No of Machines in Inventory	7	8	9	9	9	9	9	9	9	9
	Machines required based on 80% Utilization	9.99	9.75	9.71	10.26	10.09	10.52	10.11	8.78	7.14	6.81
WakeMed-Cary	Total Number of Procedures	498	405	418	393	325	382	325	282	222	223
	No of Machines in Inventory	1	1	1	1	1	1	1	1	1	1
	Machines required based on 80% Utilization	0.42	0.34	0.35	0.33	0.27	0.32	0.27	0.23	0.19	0.19
County Totals	Total Number of Procedures	17,667	16,319	16,077	16,582	16,692	16,969	16,287	15,057	14,268	14,794
	No of Machines in Inventory	10	13	14	15	16	16	16	17	17	17
	Machines required based on 80% Utilization	14.72	13.60	13.40	13.82	13.91	14.14	13.57	12.55	11.89	12.33

Note: The number of machines assigned to each facility is not based on the number that were actually operated by the facility, but the number of machines listed in the inventory for each facility in each year's state medical facility plan.

*Duke Raleigh reported 1288 procedures on the 2006 HLRA, but no fixed cardiac catheterization machine was reported in the plan as in use and procedures were not reported as mobile.

Sources: 2006-2015 SMFP's; Proposed 2016 SMFP

Analysis/Implications:

In the face of steady increases and aging of the population, in North Carolina cardiac catheterization has remained fairly stable over the last decade. Table 2 illustrates the compound annual growth rate (CAGR) and the overall change in the weighted procedures for both Wake County and North Carolina from 2005 to 2014. In Wake County, the last 10 years of data shows an average annual CAGR of -1.76%, a decline, while the NC CAGR over the same time period had an average annual decline of –1.94%. This indicates a slow and steady reduction in the number of procedures in both regions, with Wake County experiencing a slower decline than the state overall.

However, the data presented in Table 2 provides an opportunity to review these utilization trends on an annual basis. In 2014, the most recent data year, Wake County demonstrates an increase in the annual number of procedures by 3.69% while the state experienced a steeper decline of -3.37%. Thus, Wake County is experiencing recent unique growth as compared to statewide trends.

Table 2: Wake and NC Cardiac Catheterization Growth from 2005-2014

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	CAGR 2005-2014
Wake	**Total Procedures (weighted)**	17,667	16,319	16,077	16,582	16,692	16,969	16,287	15,057	14,268	14,794	-1.76%
	Annual Change		-7.63%	-1.48%	3.14%	0.66%	1.66%	-4.02%	-7.55%	-5.24%	3.69%	
		2005	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2013**	**CAGR 2005-2014**
NC	**Total Procedures (weighted)**	129,104	118,892	113,643	119,910	115,865	115,017	114,567	112,060	109,885	106,185	-1.94%
	Annual Change		-7.91%	-4.41%	5.51%	-3.37%	-0.73%	-0.39%	-2.19%	-1.94%	-3.37%	

Sources: 2006-2015 SMFP's; Proposed 2016 SMFP

Rex's petition suggests they have had unique utilization trends in recent years. The petition cites an increase in procedure volume as a result of the professional affiliation with Wake Heart & Vascular Associates (WHV). A review of the data in Table 3 provides further support of support of this assertion.

As seen in Table 3 below, Rex Hospital is the only provider in Wake County that has shown a consistent increase in the number of procedures over the last five years of data. More notably, Rex, in the most recent two years, has demonstrated utilization greater than 80%- the utilization threshold for determining a need in the health service area. Application of the methodology does generate deficits for this facility for both years. However, the 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. Finally, Rex's utilization has increased from 84% last year to 100% in the most current year of data, which calculates to the equivalent of one machine.

Table 3: Wake County Cardiac Catheterization Procedures by Facility, 2005 to 2014

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Duke Raleigh Hospital	Total weighted procedures	1,288*	202	357	262	770	967	701	366	447	393
	No of Machines	0	1	1	2	2	2	2	3	3	3
	Procedures for 100% Utilization	0	1,500	1,500	3,000	3,000	3,000	3,000	4,500	4,500	4,500
	Utilization	0%	13%	24%	9%	26%	32%	23%	8%	10%	9%
Rex Hospital	Total weighted procedures	3,897	4,015	3,646	3,616	3,489	3,002	3,132	3,875	5,029	6,006
	No of Machines	2	3	3	3	4	4	4	4	4	4
	Procedures for 100% Utilization	3000	4,500	4,500	4,500	6,000	6,000	6,000	6,000	6,000	6,000
	Utilization	130%	89%	81%	80%	58%	50%	52%	65%	84%	100%
WakeMed	Total weighted procedures	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570	8,172
	No of Machines	7	8	9	9	9	9	9	9	9	9
	Procedures for 100% Utilization	10500	12,000	13,500	13,500	13,500	13,500	13,500	13,500	13,500	13,500
	Utilization	114%	97%	86%	91%	90%	93%	90%	78%	63%	61%
WakeMed Cary	Total weighted procedures	498	405	418	393	325	382	325	282	222	222
	No of Machines	1	1	1	1	1	1	1	1	1	1
	Procedures for 100% Utilization	1500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500
	Utilization	33%	27%	28%	26%	22%	25%	22%	19%	15%	15%

Note: The number of machines assigned to each facility is not based on the number that were actually operated by the facility, but the number of machines listed in the inventory for each facility in each year's state medical facility plan.

*Duke Raleigh reported 1288 procedures on the 2006 HLRA, but no fixed CC machine was reported in the plan as in use and procedures were not reported as mobile.

Sources: 2006-2015 SMFP's; Proposed 2016 SMFP

Agency Recommendation:

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.

Technology and Equipment Committee
Agency Report
Petition for Special Need Adjustment for Fixed Cardiac Catheterization Equipment in Wake County in the Proposed 2015 State Medical Facilities Plan

Petitioner:
Rex Healthcare
4420 Lake Boone Trail
Raleigh, NC 27607

Contact:
Erick Hawkins
System Vice President, Heart and Vascular Services
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Request:
Rex Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Wake County in the 2015 *State Medical Facilities Plan.*

Background Information:
The Proposed 2015 State Medical Facilities Plan (SMFP) provides two standard need determination methodologies for cardiac catheterization equipment. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment and Methodology Two is the need determination methodology for shared fixed cardiac catheterization equipment. Application of these methodologies to utilization data in the Proposed 2015 SMFP does not generate a need determination for fixed or shared fixed cardiac catheterization equipment in Wake County.

Chapter Two of the North Carolina Proposed 2015 SMFP allows persons to petition for an adjusted need determination in consideration of "unique or special attributes of a particular geographic area or institution…," if they believe their needs are not addressed by the standard methodology. Rex has submitted a petition to add a need determination for one unit of fixed cardiac catheterization equipment in Wake County. Rex is requesting the adjusted need determination based on "the unique utilization trends faced by Rex".

There are several providers in Wake County that offer cardiac catheterization services. Wake County has a total of 17 cardiac catheterization machines in the Proposed 2015 SMFP. Of those, Rex has a current total inventory four machines. Using the standard methodology of 80% utilization, the number of calculated machines for Wake County and Rex is 11.89 and 4.19

respectively. Thus, in the Proposed 2015 SMFP Rex has a 0.19 machine deficit and Wake County has a 5.11 machine surplus as seen in Table 1 below.

Table 1: Wake County Fixed Cardiac Catheterization Equipment from 2004 to 2013

		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Duke Raleigh Hospital	Total Number of Procedures	0	1288*	202	357	262	770	967	701	366	447
	No of Machines in Inventory	0	0	1	1	2	2	2	2	3	3
	Machines required based on 80% Utilization	0.00	1.07	0.17	0.30	0.22	0.64	0.81	0.58	0.30	0.37
Rex Hospital	Total Number of Procedures	4,206	3,897	4,015	3,646	3,616	3,489	3,002	3,132	3,875	5,029
	No of Machines in Inventory	2	2	3	3	3	4	4	4	4	4
	Machines required based on 80% Utilization	3.50	3.25	3.35	3.04	3.01	2.91	2.50	2.61	3.23	4.19
WakeMed	Total Number of Procedures	11,709	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570
	No of Machines in Inventory	5	7	8	9	9	9	9	9	9	9
	Machines required based on 80% Utilization	9.76	9.99	9.75	9.71	10.26	10.09	10.52	10.11	8.78	7.14
WakeMed-Cary	Total Number of Procedures	567	498	405	418	393	325	382	325	282	222
	No of Machines in Inventory	1	1	1	1	1	1	1	1	1	1
	Machines required based on 80% Utilization	0.47	0.42	0.34	0.35	0.33	0.27	0.32	0.27	0.23	0.19
County Totals	Total Number of Procedures	16,482	17,667	16,319	16,077	16,582	16,692	16,969	16,287	15,057	14,268
	No of Machines in Inventory	8	10	13	14	15	16	16	16	17	17
	Machines required based on 80% Utilization	13.74	14.72	13.60	13.40	13.82	13.91	14.14	13.57	12.55	11.89

Note: The number of machines assigned to each facility is not based on the number that were actually operated by the facility, but the number of machines listed in the inventory for each facility in each year's state medical facility plan.

*Duke Raleigh reported 1288 procedures on the 2006 HLRA, but no fixed cardiac catheterization machine was reported in the plan as in use and procedures were not reported as mobile.

2006-2014 SMFP's; Proposed 2015 SMFP

Analysis/Implications:

In the face of steady increases and aging of the population, in NC cardiac catheterization has remained fairly stable over the last decade. Table 2 illustrates the compound annual growth rate (CAGR) and the overall change in the weighted procedures for both Wake County and NC from 2004 to 2013. In Wake County, the last 10 years of data shows an average annual CAGR of -1.09%, a decline, while the NC CAGR over the same time period had an average annual decline of - 2.02%. This indicates a slow and steady reduction in the number of procedures in both regions, with Wake County experiencing a slower decline than the state overall. These figures add up significantly when looking at the cumulative change percentage. In the last 10 years Wake County and NC have experienced declines greater than 10% and 18%, respectively.

Table 2: Wake and NC Cardiac Catheterization Growth from 2004-2013													
		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	CAGR 2004-2013	CHANGE
Wake	Total Procedures (weighted)	15,919	17,667	16,319	16,077	16,582	16,692	16,969	16,287	15,057	14,268	-1.09%	-10.37%
	Annual Change		10.99%	-7.63%	-1.48%	3.14%	0.66%	1.66%	-4.02%	-7.55%	-5.24%		
		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	CAGR 2004-2013	CHANGE
NC	Total Procedures (weighted)	134,801	129,104	118,892	113,643	119,910	115,865	115,017	114,567	112,060	109,885	-2.02%	-18.48%
	Annual Change		-4.23%	-7.91%	-4.41%	5.51%	-3.37%	-0.73%	-0.39%	-2.19%	-1.94%		

2014 SMFP

Table 3 below serves to further evaluate the actual changes in procedure volumes as compared to Table 2. When analyzing the Wake County and statewide data over the same time frames as those used in the petition, excluding FFY 2014, the picture looks a little different. While the CAGR from 2004-2013 indicates a slow, steady decline, the more recent numbers as shown in Table 3 indicate a steeper drop in Wake County with a CAGR of -4.32% as compared to the statewide CAGR of -1.38%. Thus, demonstrating that Wake, in recent years, has experienced a sharper decline in utilization than the state as a whole.

Table 3: Wake and NC Cardiac Catheterization Growth from 2011-2013						
		2011	2012	2013	CAGR 2011-2013	CHANGE
Wake	Total Procedures (weighted)	16,287	15,057	14,268	-4.32%	-12.40%
	Annual Change		-7.55%	-5.24%		
		2011	2012	2013	CAGR 2011-2013	CHANGE
NC	Total Procedures (weighted)	114,567	112,060	109,885	-1.38%	-4.09%
	Annual Change		-2.19%	-1.94%		

2014 SMFP

The petition provides procedure data at Rex Healthcare from 2011 through 2014 to demonstrate increased and unique utilization rates. An important point to note is that although the petitioner reports procedure volumes from FY2014, this information is not used in this analysis per the practice of the agency. Analysis is conducted on only data used prior to and in the current Proposed 2015 State Medical Facilities Plan. The plan's data year is FY2013.

Despite the decline in total procedures in Wake County, the data presented in Rex's petition suggests they have had unique utilization trends in recent years. The petition cites an increase in procedure volume as a result of the professional affiliation with Wake Heart & Vascular Associates (WHV). However, the utilization data demonstrates a few points pertinent to the discussion.

First, as seen in Table 4, Rex has only one year in the last five recent years of utilization greater than 80%. 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.

Additionally, this one year of utilization creates the deficit of 0.19 machines for Rex. The 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. Table 5 demonstrates there is a 56% utilization rate in this service area. According to Table 5 there has been a drop in the last three years of utilization from 68% to 56%. Therefore, approval of this petition may introduce duplication of health services into Wake County, further eroding the already declining utilization rates.

Finally, both Rex Hospital and WakeMed operated at over 80% capacity for five and eight years, respectively, of the 10 year time frame (Table 4). In some of those years, utilization was well over 100% for both facilities. The petitioner argues that utilization greater than 80% 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% have occurred in Wake County.

Table 4: Wake County Cardiac Catheterization Procedures by Facility from 2004 to 2013

		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Duke Raleigh Hospital	Total weighted procedures	0	1,288*	202	357	262	770	967	701	366	447
	No of Machines	0	0	1	1	2	2	2	2	3	3
	Procedures for 100% Utilization	0	0	1,500	1,500	3,000	3,000	3,000	3,000	4,500	4,500
	Utilization	0%	0%	13%	24%	9%	26%	32%	23%	8%	10%
Rex Hospital	Total weighted procedures	4,206	3,897	4,015	3,646	3,616	3,489	3,002	3,132	3,875	5,029
	No of Machines	2	2	3	3	3	4	4	4	4	4
	Procedures for 100% Utilization	3000	3000	4,500	4,500	4,500	6,000	6,000	6,000	6,000	6,000
	Utilization	140%	130%	89%	81%	80%	58%	50%	52%	65%	84%
WakeMed	Total weighted procedures	11,709	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570
	No of Machines	5	7	8	9	9	9	9	9	9	9
	Procedures for 100% Utilization	7500	10500	12,000	13,500	13,500	13,500	13,500	13,500	13,500	13,500
	Utilization	156%	114%	97%	86%	91%	90%	93%	90%	78%	63%
WakeMed Cary	Total weighted procedures	567	498	405	418	393	325	382	325	282	222
	No of Machines	1	1	1	1	1	1	1	1	1	1
	Procedures for 100% Utilization	1500	1500	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%

Note: The number of machines assigned to each facility is not based on the number that were actually operated by the facility, but the number of machines listed in the inventory for each facility in each year's state medical facility plan.

*Duke Raleigh reported 1288 procedures on the 2006 HLRA, but no fixed CC machine was reported in the plan as in use and procedures were not reported as mobile.

2006-2014 SMFP's; Proposed 2015 SMFP

Table 5: Wake County Cardiac Catheterization Procedures from 2004 to 2013

		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Wake County	Total weighted procedures	16,482	17,667	16,319	16,077	16,582	16,692	16,969	16,287	15,057	14,268
	No of Machines	8	10	13	14	15	16	16	16	17	17
	Procedures for 100% Utilization	12,000	15,000	19,500	21,000	22,500	24,000	24,000	24,000	25,500	25,500
	Utilization	137%	118%	84%	77%	74%	70%	71%	68%	59%	56%

2006-2014 SMFP's; Proposed 2015 SMFP

Other factors to consider regarding this petition include the changing capability of facilities. Recently, based on changes in recommended guidelines for interventional procedures, a facility located in a contiguous county was approved to perform interventional procedures, even though it does not have an open heart surgery program 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. Therefore, changes in medical practice makes predicting utilization for facilities difficult.

Consistent data trends over more than one year would be essential to ensure cardiac catheterization services are not being duplicated in Wake County. Additionally, if cardiac catheterization procedure volumes continue to decline as anticipated, Rex's volume may decrease as well. In essence, this could lower the facility's overall utilization below 80% and below the methodology's deficit threshold.

Agency Recommendation:

Given available information and comments submitted by the August 15, 2014 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends denial of the petition. The current declining trend in cardiac catheterization volumes, the surplus of machines in Wake County, the changes in regulations and medical practice, indicate approving the proposed change would result in unnecessary duplication of services. The Agency supports the standard methodology for fixed cardiac catheterization equipment.

Exhibit 2

TRANSCRIPTION

MEETINGS OF THE

HEALTH COORDINATION COUNCIL OF NORTH CAROLINA

JULY 15, 2016

Garrett
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PROCEEDINGS

(NOTE: "SPEAKER" was listed when the person speaking changed. If possible, the speakers were numbered, but on occasion it was impossible to differentiate between the various voices because there were so many different speakers, in which case just "SPEAKER" was noted.)

9/9/2014 - Technology

37:01 to 43:30

SPEAKER 1: So we'll move on to the cardiac catheterization equipment section of Chapter 9. Paige, if you'll review the Petition and the Agency recommendation.

SPEAKER 2: Okay. The Agency received two petition submissions for cardiac catheterization. Both were for the Wake County service area. The first, from WakeMed Hospitals, did not request any change to the State Medical Facilities Plan, but asked that the committee not make changes to the cardiac catheterization for Wake County.

The Agency determined that this request did not meet the standards outlined in the State Medical Facilities Plan to be considered a petition. Therefore, the Agency is requesting the committee consider the WakeMed request a comment. We did provide a written

response stating as to why we felt the request was a comment and this response can also be found online.

The second submission is from Rex Healthcare. We received two comments about this petition. Both were in opposition. Additionally, there were 42 letters of opposition that were submitted to us. And now I'm going to give a brief summary of what the petition -- the Agency report on the petition.

So Rex Healthcare is petitioning the State Health Coordinating Council to create an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Wake County in the 2015 State Medical Facilities Plan.

For background, in the proposed 2015 SMFP, Wake County has a total of 17 cardiac catheterization machines and Rex Healthcare has four machines of those 17.

Using the standard methodology of 80% utilization, the number of calculated machines for Wake County should be 11.89 and Rex's facility-based calculation is 4.19. Therefore, Rex has a .19 machine deficit and Wake County has a 5.11 machine surplus. In the methodology, the Wake County surplus offset the facility deficit.

So cardiac catheterization in North Carolina

has remained fairly stable over the last decade, but actually is very -- slightly declining. In Wake County, the last ten years of data show an average compound annual growth rate of negative .0 -- 1.09%, while the North Carolina compound annual growth rate over the same time period was negative 2.0%.

So this decline is even sharper when you look at recent years of data from 2011 to 2013. Wake County has a compound annual growth rate of negative 4.32 and the statewide has a compound annual growth rate of negative 1.38, so that's demonstrating that Wake County, in recent years, has experienced a sharper decline than the state as a whole in utilization.

Despite the decline in the procedures in Wake County, the data presented in Rex's petition suggests that Rex has unique utilization trends as a result of their professional affiliation with Wake Heart and Vascular Associates. The data that Rex has submitted shows only one year in the last five years of utilization greater than 80% and there is a 50% utilization rate in the service area.

There has been a drop in the last three years of utilization in the service area from 68 to 56%. Therefore, approval of this petition may introduce duplication of health services into Wake County, further

eroding the already declining utilization rates.

Other factors to consider regarding this petition include the changing capabilities of facilities recently based on changes in recommended guidelines for interventional procedures. A facility located in a contiguous county has been approved to perform interventional procedures, even though it does not have an open-heart surgery program.

A similar request in a different county located near Wake County is being currently evaluated by the Agency and so this potentially may have impact on the volumes in Wake County and could potentially accelerate the decline in cardiac catheterizations.

So the Agency feels like it was difficult forecast changes and trends in healthcare utilization based on one year's worth of data, and given the available comments and information submitted by the August 15th deadline in consideration of other factors such as decline in trending cardiac catheterization volumes, the surplus of machines in Wake County and the changes in regulation, the Agency finds that it would be -- that it might potentially create duplication of services and recommends not approving the petition.

SPEAKER 1: Thank you. I will treat the Agency recommendation as a motion for the purposes of our

discussion, so the Agency recommendation is to deny the petition for additional cardiac catheterization CON availability for the 2015 plan. Comments, discussion, concerns?

(No response.)

SPEAKER 1: A vote to -- seeing no further discussion, a vote "yes" is to accept the Agency recommendation for denial. A vote "no" would be to reopen the question.

Because this is a relatively controversial petition, I'm going to ask members to vote by signature of their hand rather than by voice vote.

All of those in favor of adopting the Agency recommendation, please signify by raising your hands. I see no opposition. The Agency's position is adopted. I believe that's -- that's it for this -- this section. We need to now -- do we need to go through the tables at all for this one?

SPEAKER 2: No.

SPEAKER 1: Okay.

SPEAKER 2: No tables.

SPEAKER 1: So we need a motion, then, to accept the revised or the current cardiac catheterization equipment section before we move on.

SPEAKER 3: So moved.

SPEAKER 1: Moved.

SPEAKER 4: Second.

SPEAKER 1: Any further discussion?

(No response.)

SPEAKER 1: All those in favor of acceptance say "aye."

SPEAKER: Aye.

SPEAKER: Aye.

SPEAKER: Aye.

SPEAKER 1: It is accepted

10/1/2014 - Digital SHCC Minute

48:15 to 53:21

SPEAKER 1: With regard to cardiac catheterization equipment section, since the proposed 2015 SMFP, there have been no changes in need projections for cardiac catheterization equipment. The proposed 2015 SMFP showed no need determinations for fixed, shared or fixed cardiac catheterization or mobile cardiac catheterization equipment anywhere in the state.

During the summer, one petition for an adjusted need determination in cardiac catheterization section of the 2015 SMFP was received. The petition was from Rex Healthcare and concerned Wake County. Rex Healthcare requested an adjusted need determination for

one additional unit of fixed cardiac catheterization equipment in Wake County in the 2015 SMFP.

The committee discussed the petition and the Agency report, which recommended denial of the petition request. The concurrence was that Wake County, one, has a trend of declining volume of cardiac catheterization, two, has a surplus of machines in the service area and, three, will potentially see further volume declines because of changes in statewide regulation, payment and medical practice.

The committee recommends to the CHIC that the petition request be denied for an adjusted need determination for one unit of fixed cardiac catheterization equipment in Wake County.

In the magnetic resonance imaging section, the SMFP proposal showed two need determinations for additional fixed MRI scanners in Lincoln and in New Hanover Counties.

Over the summer, the medical facilities planning (indiscernible) received an updated data resulting in corrections to the MRI scanner inventory table. The changes did not add any MRI scanners to the inventory, nor did they add any additional need determinations.

The committee received one petition over the

summer for an adjusted need determination in the MRI scanner section of the 2015 SMFP. The petition request and the committee recommendation are summarized as follows.

The Carolinas Healthcare System petition concerning the Lincoln County MRI fixed need. Carolinas Healthcare System requested an adjusted need determination to remove the need for one fixed MRI scanner in Lincoln County. The committee discussed the petition and the Agency report, which recommended approval of the petition request. This results in deleting the need.

The concurrence was that Lincoln County does not -- does have unique circumstances, including a slow projected growth rate in the county that would probably preclude existing or new providers from meeting the CON standards for a qualified applicant and potential changes to future MRI volumes. The committee recommends to the CHIC that the petition request be approved for an adjusted need determination.

In the linear accelerator section, there have been no changes in need projections for linear accelerators. The proposed 2015 SMFP included one need determination for linear accelerator in Harnett County. Harnett County becomes a new service area due to Harnett

County's population increasing above 120,000 people with no linear accelerator in the county. There was no need indicated anywhere else in the state for an additional linear accelerator.

The lithotripsy and Gamma Knife section also has shown no changes in need projection for either piece of equipment. There is no identified need for lithotripters or Gamma Knives anywhere in the state. The committee received no petitions or comments over the summer regarding lithotripsy or Gamma Knife sections of the plan.

The committee recommends to the State Healthcare Coordinating Council approval of Chapter 9, Technology and Equipment, with the understanding that the staff is authorized to continue making necessary updates to both narratives, tables and need determinations as indicated.

That concludes the report of the Technology and Equipment Committee. Is there a motion to adopt the committee report?

SPEAKER 2: So moved.

SPEAKER 1: Moved and seconded by Dr. Parik (phonetic). The report is now open for discussion.

(No response.)

SPEAKER 1: I see no indication of a need

for discussion. A vote "yes" or "aye" will be to adopt the report as submitted. If you oppose the report, you should vote "no."

All of those in favor of adoption of Chapter 9, please indicate by saying "aye."

SPEAKERS: Aye.

SPEAKER 1: It is adopted. We will now move on to the report of the long-term and behavioral health committee.

4/22/2015 - Technology

57:18 to 1:06:45

SPEAKER 1: All right. We are moving on to cardiac catheterization. Paige will initially review the policies and need methodologies.

SPEAKER 2: First, I'll start with the methodology, which can be found on page 172 of the 2015 State Medical Facilities Plan. The cardiac catheterization equipment planning areas are the same as the acute care beds service areas as defined in Chapter 5, acute care beds as shown in Figure 5.1.

The cardiac catheterization equipment area is a single county unless there is no licensed acute care hospital located within the county and those counties are grouped with the single county where the largest

proportion of patients receive inpatient services.

There are two standard need determination methodologies for cardiac catheterization equipment. Methodology one is the standard methodology for determining need for additional fixed cardiac catheterization equipment and methodology two is for shared, fixed cardiac -- cardiac catheterization equipment.

The steps in methodology part one. For fixed cardiac catheterization equipment, procedures are weighted based on complexity, as described on page 199. The CHIC defines "capacity" as 1500 diagnostic equivalent procedures per year.

We determine the number of fixed cardiac catheterization equipment required by dividing the number of weighted or diagnostic equivalent procedures performed at each facility by 1200 procedures, which is 80% of the 1500 capacity. We then compare the calculated number of acquired units of equipment with the current inventory to determine if there is a need.

The steps for methodology part two. If no unit of fixed cardiac catheterization equipment is located in a service area, a need exists for one shared, fixed cardiac catheterization equipment when the number of mobile procedures done in the service area exceeds 240

or 80% of 300 capacity per year for each eight hours per week in operation at that site. And with that, that concludes the methodology review.

SPEAKER 1: Thank you, Paige. Any questions about the present methodology as described in the plan?

(No response.)

SPEAKER 1: Hearing none, we'll entertain a motion with a second to reaffirm the policies in the plan.

SPEAKER 3: So moved.

SPEAKER 1: Thank you.

SPEAKER 4: Second.

SPEAKER 1: All those in favor, say "aye."

SPEAKERS: Aye.

SPEAKER 1: Thank you. Paige, let's now go on to the change in cardiac catheterization need determination methodology submitted by WakeMed.

SPEAKER 2: Yes, sir. So there was one petition for this and that was WakeMed. There were four comments submitted to the Agency and they were all in opposition to the petition.

The request from the Petitioner is that they requested a methodology for determining need for a cardiac catheterization equipment in North Carolina be revised for the 2016 State Medical Facilities Plan.

A summary of the Agency report. Statewide data indicates cardiac catheterization procedures have been declining and continue to do so as of the 2013 data, which is the year -- the data year for the 2015 State Medical Facilities Plan. Table 1 in the Agency report shows this trend.

There have been five need determinations from 2007 to 2015 as seen in the SMFPs. Two successful petitions requesting adjusted need determinations had an impact on this total, one removed a need determination and another added a need determination.

The current methodology, along with the declining procedure volumes, are currently generating very few need determinations across the state. WakeMed, in their petition, discussed some of the issues from a previous petition that was submitted in 2013 by New Hanover Regional Medical Center which include the capacity of one machine at 1500 weighted procedures is too low and that both diagnostic and interventional procedures do not take as long as assumed in the current methodology.

Discussions about procedure volumes are further complicated by the idea that, despite the methodology, facilities may judge capacity at their respective hospitals differently, depending on the hours

of operation.

Further considerations include the number of cardiac catheterization units at each facility. Raising the threshold or changes in the procedure weighting may have a greater impact on providers with one machine as compared to facilities with several machines. The logic is that facilities with one machine may not be able to build efficiencies of service with the cleaning and turnaround of the room between patients as providers with multiple machines.

Thus, with a higher threshold, facilities with fewer units or procedure volumes may be prevented from generating a need. Any increases in capacity of the equipment would further limit the number of calculated need determinations, which is already fairly low.

Currently, the methodology appears to be working and further restricting the calculation of need determinations did not seem warranted at this time, and facilities in the past have applied for adjusted need determinations which have been successful.

So given that information and the comments that were submitted to the Agency, the Agency recommends denial of this petition.

SPEAKER 1: So I will treat the Agency recommendation as a motion for discussion. Dr. Moore, do

you have any concerns you want to comment on this particular Agency recommendation?

SPEAKER 3: No, sir.

SPEAKER 1: Okay.

SPEAKER 4: I don't think I -- I guess mine's more global. I think their comments hit on something, a more global thing that I'm going to continue to harp on, is looking at the methodologies and some sort of systematic method --

SPEAKER 1: Uh-huh.

SPEAKER 4: -- every five years or so, and if this -- if somebody wants -- you know, if WakeMed wants cardiac cath to be looked at, I think it would be a reasonable place to start on as we systematically move through the methodologies we're reviewing.

So I don't think I have a -- I think I'm okay with the Agency's recommendation, but I think my -- my recommendation would be, okay, this is the first methodology that this committee looks at.

SPEAKER 1: Uh-huh. We'll take that as a separate issue.

SPEAKER 4: Yeah, as a separate issue.

SPEAKER 1: Dr. Akers, no comment?

(No response.)

SPEAKER 1: Well, let's vote on the motion

and then we can return, perhaps briefly, to the methodology review issue, which I know I promised you last year we would undertake. So a vote "aye," a "yes" vote, is to deny the petition as submitted and there is no substitute policy attached to this Agency recommendation, so all those in favor of the Agency recommendation, signify by saying "aye."

SPEAKERS: Aye.

SPEAKER 1: And it is adopted. With regard to your second point, I would prefer to have an offline conversation on prioritization --

SPEAKER 4: Okay.

SPEAKER 1: -- but I will reiterate I'm in favor of doing what you -- what you request. What we'll balance it on is staff time availability and prioritization.

SPEAKER 4: Fair enough.

SPEAKER 1: And, you know, the Gamma Knife one, for instance, I don't think we need to put near the top of the list.

SPEAKER 4: No. Exactly.

SPEAKER 1: And go from there. Okay.

SPEAKER 4: Lithotripsy, I don't -- no.

SPEAKER 1: Well, lithotripsy's interesting this year. So let's review the table very quickly and

adopt it and then we're going to move a little faster through the rest of this.

SPEAKER 2: So I did present to the committee the table -- I'm sorry, Tables 9S, which is the adult diagnostic fixed cardiac cath procedures by facility and aggregate cath totals, 9T, which is the pediatric diagnostic cath procedures, 9U, mobile cardiac cath procedures, 9V, which is percutaneous coronary interventional procedures, and 9W, which is the table where the needs -- where the need determinations are calculated and displayed.

Our preliminary data indicates there is a one draft need for additional cardiac catheterization equipment in Cumberland County. That -- that concludes the data for cardiac cath.

SPEAKER 1: Can I have a motion to approve the tables with the recognition of further amendments as better data becomes available?

SPEAKER: So moved.

SPEAKER 1: Dr. Moore, any questions?

SPEAKER 3: No, sir.

SPEAKER 1: Then we'll -- those who favor, say "aye."

SPEAKERS: Aye.

SPEAKER 1: It is adopted. Thank you very

much. One of the issues, I think, that did come out of this discussion on the petition is this issue of productivity in the small versus large and where do you apportion.

I believe the Petitioner is absolutely correct that in a busy, multi-facility lab we'll probably have assumptions that are too long. However, at the current lower threshold, we're not triggering needs and that's part of the dilemma of what to do.

6/3/2015 - SHCC

45:00 to 53:13

SPEAKER 1: With regard to cardiac catheterization equipment, there was one petition with comments to these petitions received on this section of this chapter. The Petitioner was WakeMed Health and Hospitals. Petitioner requested that the methodology for determining need for cardiac catheterization equipment in North Carolina be revised for the 2016 State Medical Facility Plan.

Four comments were received about this petition. All were in opposition to the proposed change. The committee recognized that there is a variation in practices which may affect the average case times for cardiac catheterization cases across facilities and that

the total number of cases statewide have been declining over a multi-year period.

The requested changes would have the effect of further suppressing need determinations. Since the current methodology produces very few need determinations, and over the years the adjusted need determination process has been used successfully in special situations, the committee recommended denying the submitted petition.

Application of the methodology based on data and information currently available results in one need determination for a fixed cardiac catheterization equipment in Cumberland County at this time. Need determinations are subject to change.

The committee authorized the staff to update all narratives, tables and need determinations for the proposed 2016 plan as new and corrected data are received. That concludes the report of the Technology and Equipment Committee. I need a motion for adoption and a second.

SPEAKER 2: Motion.

SPEAKER 1: Did I see a second?

SPEAKER 3: Second.

SPEAKER 1: Okay. Are there any comments, discussion or concerns about the -- this section of the

proposed plan? Yes, sir.

SPEAKER 4: On the Dosher (phonetic) Memorial, can staff share with me and (indiscernible)? The mobile MRI that's in place right now, is that a part time or is that -- is that in place in their county in their service area on a full-time basis or does it actually move out of there?

SPEAKER 5: That's actually a fixed -- for Dosher, that's actually a fixed -- although it's called mobile, it's actually fixed onsite -- not actually on the site of the hospital, but a couple of miles away. Yes, sir.

SPEAKER 4: And so the -- the request by Dosher after -- as I understand it, after leasing time on this machine for a period of seven years, is based on the fact that the approval would actually give the inventory of MRIs -- it would be in excess of what the majority should be, because we have a mobile that's not really a mobile, a cost that's supposed to go down if it -- if the Dosher approval was -- or Dosher request was approved and a vendor who could move that machine to some other part of the state at this point?

SPEAKER 5: Yes, sir.

SPEAKER 4: Do I understand that correctly?

SPEAKER 5: Yes, sir.

SPEAKER 4: I -- you'd share the technology committee. I'm just -- I'm a little bit baffled that we have -- we've ruined a vendor contract or we've allowed a vendor contract that's expired and been in place for seven years that's really not a mobile, but a fixed, over a machine that probably, more fittingly, belongs at or close to an emergency facility in a county that is growing and serves a different population and a piece of technology that I think has become much more common as opposed to what it was seven years ago when that vendor contract was in place.

SPEAKER 1: I'll respond to that on a couple levels because the committee doesn't disagree with you in principle. What we have is a grandfathered unit that preexisted the law and, therefore, essentially is free to move wherever it wishes, so it's a mobile without the tires on the system.

It's located, I believe, four miles distance from the hospital, which is a logistically poor situation. There are cost issues involved, as well. The proposal required a policy change as the proposed solution which raised a variety of other unintended consequences across the state if we dealt with it as a policy at this time.

We have suggested that a special-need

petition should be considered by the Petitioner, which would be due in the summer. It would be dealt with with this committee at the fall meeting and at our final meeting of the year.

In the meantime, we're happy to consider or keep working on a policy change, but it is a -- it's a problem which crosses a variety of lines and it's very hard to craft a solution. In addition, we cannot pick winners and losers in a given county and the application would have to be a competitive need.

I don't know whether the mobile will pick up and relocate or have sufficient business to stay where it is, but that's not the concern of the CHIC. We have received, over the past several years, several other petitions for a similar single-county -- in this case, it's also not a single county. There are actually two MRs in the county.

We have dealt with a number of other single-provider, critical access hospitals that are only one in the county and have standards in place for that. Dosher does not meet those standards. We have tried to determine whether we should change the standard and, at this point, we don't have enough data, nor have we seen enough problems, where we should take a statewide -- in my personal opinion, a statewide change as opposed to

using the special need petition, which is there to deal with special needs.

SPEAKER 4: I understand, and I agree on not necessarily changing the statewide requirements. The special needs, I think, works and --

SPEAKER 1: Well, we'll --

SPEAKER 4: -- (indiscernible).

SPEAKER 1: I can't predict the success of the petition, but I have urged them to do a well written petition and we'll consider it, as I say, this year for the 2016 plan --

SPEAKER 4: Thank you.

SPEAKER 1: -- if it's submitted. Any other questions or concerns? We've talked a long time. This is an issue of both quality access and of a critical access facility.

SPEAKER 4: Thank you.

SPEAKER 1: (Indiscernible), do you want to say anything?

SPEAKER 6: No.

SPEAKER 1: No?

SPEAKER 6: I think he covered it.

SPEAKER 1: Mr. Bryan, Mr. Beaver, any comments or concerns?

SPEAKER 7: No, none from me.

SPEAKER 8: No comments from me.

SPEAKER 1: Thank you. Seeing no one wishing to speak, a vote "yes" is to adopt the committee report as provided. A vote "no" would be to reject the report.

All those in favor of adopting the report as submitted, signify by saying "aye."

SPEAKERS: Aye.

SPEAKER 1: Two ayes on the phone. It is adopted. Thank you.

9/16/2015 - T & E Digital Recording

28:13 to 55:53

SPEAKER 1: We'll move on to the cardiac catheterization section of Chapter 9. A petition for an adjusted need determination for one fixed cardiac cath unit in Wake County was submitted. Paige will give us the Agency report.

SPEAKER 2: Thank you, Mr. Chairman. One letter of support was received and two letters of opposition were received in regards to this petition. The request is that Rex Healthcare petitions the State Health Coordinating Council to create an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Wake County in the 2016

State Medical Facilities Plan.

The proposed 2016 SMFP provides two standard need determination methodologies for cardiac catheterization equipment. Methodology one is the standard methodology for determining need for additional fixed cardiac catheterization equipment and methodology two is the need determination methodology for shared, fixed cardiac cath -- shared, fixed cardiac catheterization equipment. Application of these methodologies to utilization data does not generate a need determination for a fixed or shared cardiac cath equipment in Wake County.

Wake County has a total of 17 cardiac catheterization machines in the 2016 SMFP. Of those, Rex has a total current inventory of four machines. Using the standard proposed methodology of 80% utilization, the number of machines for Rex would actually calculate to five. Thus, in the proposed 2016 SMFP, Rex has a one-machine deficit.

In Wake County, the last ten years of the data shows an average annual compound annual growth rate of negative 1.76%, a decline, while the North Carolina compound annual growth rate over the same time period had an average decline of negative 1.94%. This indicates a slow and steady reduction in the number of procedures in

both regions with Wake County experiencing slower decline than the state overall.

However, the data provides an opportunity to review the utilization trends on an annual basis. In 2014, the most recent data year, Wake County demonstrates an increase in the annual number of procedures by 3.69%, while the state experienced a steeper decline of negative 3.37%. Thus, Wake County's experiencing a recent unique growth as compared to statewide trends.

Rex's petition suggests that they have unique utilization trends in recent years and cites an increase in procedure volume as a result of a professional -- as the result of the professional affiliation with Wake Heart and Vascular Associates. Rex Hospital is the only provider in Wake County that has shown a consistent increase in the number of procedures over the last five years of data.

More notably, Rex, in the most recent two years, has demonstrated utilization of greater than 80%, the utilization threshold for determining a need for the -- a need in the health service area. Application of the methodology does generate deficits for this facility for both years. However, the 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.

Finally, Rex's utilization has increased from 84% in the last year to 100% in the most current year of the data which, again, it calculus to the equivalent of one machine. The Agency supports the standard methodology for fixed cardiac catheterization equipment, but Wake County and Rex Healthcare are experiencing recent decreases in the utilization at cardiac catheterization laboratories. Given available information in the comments submitted by the August 14th deadline, the Agency recommends approval of the petition.

SPEAKER 1: Thank you, Paige. So, in this case, the Agency is recommending one fixed cardiac cath unit for Wake County be added to the plan as requested. It is a competitive application, not an award to a specific institution. This motion is now open for discussion.

SPEAKER 3: So I'd like to comment based on the comments of those who have opposed it, Duke University, WakeMed, and being someone who practices in Wake County, I'd like our members on the phone to also be aware. There are three institutions in Wake County, Duke, UNC-Rex and WakeMed, and in some of the comments by WakeMed and Duke, we can see that there are other beds in this health service area and county that are grossly

underutilized and, you know, how do we contend with this going forward, because this won't be the only instance in which we have such requests.

This would be going in violation, really, so to speak, it may be a heavy word, but of how we determine the need for a bed for a service area, whether it's an MRI or cardiac cath bed. And secondly, when such petitions are made, whether it's this one or any other, frankly, if the net value or cost goes up, which I surmise it does, knowing the dynamics and costs of this market, then that defeats the purpose of what we are really, you know, obligated to do.

And just three or four years ago, maybe a little longer, we had a quality access value committee led by Don Bradley that was dissolved because of lack of -- you know, enough staff and so on, and such -- such authorizations would go against value and the economic impact should also be taken into consideration if we are to consider any such petition in any of the major counties, whether it be Mecklenburg or Wake. You know, there are only two or three and I would surmise or also put out that we have one million people in Wake County, so this is a big issue.

It's not just, you know, well, we're one of 99 counties. Ten percent of the population resides here,

as it does in Mecklenburg, and if we were to vote in favor, we would be voting without knowing economic impact -- I mean, actually having actual numbers -- with a surplus of beds within, literally, five minutes of this particular institution, WakeMed Cary or WakeMed Raleigh or Duke and so on, and that -- that bothers me because we're supposed to be reducing cost and because of -- somehow -- I mean, somebody's got to have influenced this process because we have never voted this way. You know, the staff has -- as a petition. Special needs, different story. Yes, we have had special needs petitions where, you know, that's a different story, but I think I'd be happy to, you know -- or be interested in hearing comments from, you know, the Chairman or folks on the phone because we're going to -- if we set a precedent, then we're going to have many precedents to come.

SPEAKER 1: Thank you, Dr. Patel (phonetic). These are important questions. I'll entertain other questions before I respond. Trey, did you have a question?

SPEAKER 4: Yeah, and I think I -- it's probably a pro-business, probably being younger, you know, capitalistic nature, I understand Rex -- Rex's issue, and I sympathize with that and get on them for building a fantastic heart program, from what I

understand, and grabbing the best docs in the county.

I guess I'm having a hard time with it from a process standpoint and within the realm of the basic principles governing the plan. I sort of have to put that hat aside and look at what are we supposed to uphold here and we're upholding the basic principles.

To dumb it down a little bit, I think, you know, I think one of the goals is to force providers to play nice and utilize everything in a health system. I mean, the whole point is that we don't have over-capacity.

I understand that capacity shifted. People providing the procedures has shifted, but does that -- are we going against the principles that this whole plan is founded on by approving this?

SPEAKER 1: Good question.

SPEAKER 4: And so I guess that's what I'm struggling with. Is this setting a precedence that theoretically undermines the whole -- one of the basic principles of the reason we're here? So, you know, those are my comments, I think. I don't have any problem -- the future -- the future (indiscernible) of undermining the basic principles of this plan.

SPEAKER 1: Uh-huh. Any concerns or questions on the phone?

SPEAKER 5: No, sir.

SPEAKER 1: Kelly?

SPEAKER 6: Yeah. I kind of agree with the concerns brought by Trey (indiscernible). Looking at Table 2 and the annual change, it seems like these numbers sort of shift wildly from one year to the next, so -- and I urge caution in making decisions based on one year of data, and I recognize that there's a, you know, compounded annual growth rate, as well, but the shift from 2013 to 2014 --

SPEAKER 1: Sure.

SPEAKER 6: (Indiscernible), yes.

SPEAKER 1: I share all those concerns and we've had some discussions about all of those, in terms of trying to settle this out. We have turned down this request previously. Unfortunately, and I live in a market that is divided and consolidated and patients don't really move between providers, regardless of what the capacity is in Provider A versus Provider B because they go where their doctor goes, and what we had was a large shift of physicians who were actively engaged in one institution in the community who chose -- I've heard various terms used about why the choice was made, but who chose to shift their affiliation. That was their business and professional decision, but they've

essentially created an imbalance inside a local market in the process and then they resigned their privileges to provide any service at another underutilized facility as part of that process. I may not have any -- I may not believe that was the world's greatest idea, but I understand why that happened.

At some point -- and I believe the numbers next year will look even more unbalanced than they do this year based on anecdotal inquiries from people in the community. I also recognize that patients who get delayed access because of overcrowding in an institution or having their procedures done very late in the day or into the evening are also suffering in this process, in terms of their personal care, and don't understand why that should occur.

And, in addition, I understand the issue of mergers and acquisitions and hospital versus outpatient charging structures and, as Dr. Patel knows, I can't control that. The market forces are not something that I believe this committee can control, per se, but the market is addressing charging, including, for instance, the move in congress to take the hospital outpatient payment system, which pays more, versus the IDTF and go to what's called single site of service and essentially reduce the (indiscernible) payment, which would address

the cost issue in the process.

It's a judgment call and, while I don't think these come up very often, if you go back and look at our petitions, they do come up, just as the Dosher situation doesn't fit the mold and assumptions of the plan.

At the end of the day, my personal judgment is that at some point I put patients first, in terms of where they are getting their services, and believe the market can address that, but I can't solve that through a CHIC mechanism.

As I noted earlier, the need is not an award to an institution. It is a competitive need, but the data indicates that only one of the competitors in the market is substantially burdened by utilization constraints. So I also -- and I also recognize that if we turn this down waiting to see what the data would look like, would it rebalance, would, in fact, this congestion lead to more patients being cared for in one of those other facilities, and I don't see that happening this year. I don't believe it will happen next year. It doesn't happen in my own community where we have had similar imbalances, but they haven't reached the extreme that we have here, and this is an extreme case of facility imbalance.

So my personal view was that, while it's not something that I'm enthused about, at some point I also -- my heart is with the people who are being cared for, and so I personally support this recommendation on that basis, recognizing the cost issues, recognizing that there, in fact, is a lot of unused capacity at other sites in the county, but I see no mechanism for it to get used that's likely to succeed and relieve that patient burden that is also occurring.

Trey, you look like you're having trouble with my feelings.

SPEAKER 4: I think that, you know, the patient is -- it's not a family practice doctor, I think. Patients have always come first and I probably didn't know my dad as well as a lot of other folks because he was always at the hospital, but -- and that's always a concern to me. I think a lot of the stuff we've done today, forward thinking, helps patients.

I'm concerned -- I mean, is -- is not -- this is more of maybe a philosophical question on the plan and what we're here to protect. Is the plan not designed to enforce the market to absorb this capacity? And, at some point in patient care, I mean, you've got the Hippocratic oath and, you know, you can say all that stuff, but at some point I believe doctors will do the

right thing for their patients, and it is not the purpose of this plan to force the healthcare system to utilize what they have to the best of patients -- to help the healthcare community.

If we do this, I feel like we're sort of undermining, that we're not -- we're not using this to, honestly, force the utilization of the capacity in marketplaces, which -- and it's not a quality issue, as far as I understand, at the other -- at the other hospitals, that there's -- there's good quality care out there and these docs could use other facilities if they were getting backlogged because it's out there.

And I'm more or less concerned about the undermining of the whole system based on approval of this because I think this is conceptually what it was designed for, was to force people to work together and utilize -- and build a strong healthcare community and not these little silos (indiscernible).

I understand the business aspects of it and I sympathize with them. I just personally think that this is a slippery slope (indiscernible) policies.

SPEAKER 7: Mr. Chairman, you know, I respect your comments. I've held you at very high regard over the years I've served and you've been here even way before I got here. We all care about patients. I can

guarantee you that in the United States of America, let alone North Carolina, Wake County, no patient will suffer anything terminal. We all fast for colonoscopies and take preps and cardiac caths and so on, that this plan is designed to compel change amongst hospital and physician behavior to promote quality and to promote competition, not reduce competition and so on.

This, in effort, 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. The teaching does not go on in nine counties that are under the UNC banner. Teaching goes on primarily at UNC-Chapel Hill and that negotiating power is being used to swallow up all kinds of hospitals that raise the cost of healthcare.

It is our duty at the CHIC to stand and be as such and this is not about UNC or Wake. It could be anywhere in the State of North Carolina.

SPEAKER 1: Uh-huh.

SPEAKER 7: When more monies are spent and there are higher deductibles and HSAs and so on, that bounces back to the patient, and clearly, they're -- whenever we are presented with such, in any table that we have, we never have any economics attached to it. We

always have the great things about, you know, patient safety, patient access, but we all tout value, but we never vote in -- vote for value. Value here is a vote no and that is how I will be voting on this.

SPEAKER 1: You should vote no if that's how you feel. That's why we have votes.

SPEAKER 7: I respect you, but this -- this is wrong. There's a precedence. I mean, this is going to create incredible precedence in the state.

SPEAKER 1: Well, I disagree with that, but -- about the precedent, but, you know, inpatient catheterizations are what they are (indiscernible), but I respect your position. I don't like over-consolidation in the market, but this plan doesn't control that, but if you feel -- you know, this is why we have votes.

The committee is not obligated to accept the Agency recommendation, so if -- I sincerely tell you, if those concerns, you believe, are more important than the value and judgment that I personally support, I'm not uncomfortable having you vote no.

SPEAKER 7: Thank you.

SPEAKER 1: That's what the purpose of being here is. This is not a rubber stamp. And -- and I also -- it's a judgment call. I don't believe disaster will strike if this is turned down, but I do think that

patient -- you know, there are certain patient care issues which will be aggravated and I -- you know, so you're living in the community. I live far away and I don't have the same perspective.

I will tell you that in my personal view, if this is a tie vote, I am allowed to vote and I am going to consider whether I'm willing to vote, but if it is a tie and I don't vote, the motion fails as proposed.

So, any further discussion? Kelly? Dr. Moore?

SPEAKER: I would just add, just as my personal perspective with regard to the dynamics of hospital and physician affiliations, it's very complicated. It changes. It is beyond the influence of what we can accomplish, I think, by ruling on this or any other similar CHIC petition, and that we -- I, personally, would prefer to allow those physicians and patients who are working in overburdened facilities to have the advantage of newer and more readily accessible equipment in the venue in which they've chosen to have their care.

SPEAKER 1: Very good. Thank you, Dr. Moore. Kelly, any further concerns or questions?

SPEAKER: No. I think (indiscernible).

SPEAKER 1: I would agree. This is not one

that I think in a muted conversation reflects that. So because this is going to be potentially a head count vote, what I'm probably going to do is we will do a recorded vote so that I actually don't have to guess who says yes and no. So I'll start with Trey.

SPEAKER 4: No.

SPEAKER 1: Vote no.

SPEAKER 4: No.

SPEAKER 1: Kelly?

SPEAKER: I'm going to vote for the recommendation.

SPEAKER 1: Dr. Moore?

SPEAKER: Yes.

SPEAKER 1: Yes. So we have a tie vote. I am not going to vote on this and, as a result of the tie vote, the motion will die.

SPEAKER: Thank you.

SPEAKER 1: I think we also have a second petition for an adjusted need determination for one shared fixed cardiac cath unit in Harnett County. I will ask Paige to present it.

SPEAKER 2: Okay. Thank you, Mr. Chairman. There were nine letters of support received in regard to this petition. Harnett Health requests an adjusted need determination for one unit of shared, fixed cardiac

catheterization equipment for the 20 -- the North Carolina 2016 State Medical Facilities Plan.

The proposed plan provides two standard methodology need determinations for cardiac catheterization equipment. Application of these methodologies does not generate a need for a fixed or shared cardiac catheterization equipment in Harnett County.

Methodology one, as it is written, does not apply to Harnett County as it only addresses facilities that have the cardiac catheterization laboratory. Methodology two provides for the opportunity for a service area that has no fixed laboratory, but instead utilizes a mobile laboratory. Need exists for one unit of shared, fixed equipment, cardiac catheterization equipment, when the number of cardiac catheterization procedures performed on a mobile site exceeds 240 procedures per year.

The petition indicates that Harnett Health has not utilized a mobile cardiac catheterization laboratory as required to generate a need through the methodology two, but transfers cardiac catheterization payments to other facilities in neighboring counties.

Data regarding drive time and distance to both Harnett Health facilities, Betsy Johnson in Dunn and

Central Harnett Health in Lillington, show that the closest facility to either is Johnston Health at 24.5 miles or approximately 37 minutes. The nearest facility affiliated with Harnett Health, Cape Fear Valley Medical Center, is approximately 30 miles and a 40-minute drive. These drive times and distances are important in looking at optimal patient care.

The standard clinical treatment for ST elevation myocardial infarctions, or STEMI, is reprofusion, a procedure performed in the cardiac catheterization laboratory. The 2013 ACCF-AHA guidelines for management of STEMI is the most comprehensive resource for the treatment of patients with a diagnosis of this type of myocardial infarction.

The report endorses goals for STEMI patients with an ideal first medical contact to device time system goal of 90 minutes or less. The data shows that transport of patients from Harnett Health to a hospital that offers interventional cardiac cath procedures would require a third to more than half of the time allotted in the 90-minute -- 90-minute window of treatment.

Furthermore, the North Carolina Office of EMS -- STEMI, EMS, Triage and Destination Plan includes a decision point for transporting patients to the nearest PCI-capable hospital at 30 minutes transport time.

Distance to care is an important component of this discussion, but the volume of patients is another fact to consider.

Data provided in the petition indicates an estimated number of 1,708 of these procedures in 2013 and 2,114 in 2014, Harnett County residents. Other calculations state that 67% of cardiac catheterization procedures for Harnett County residents are diagnostic. Comparatively, the statewide percentage is calculated as 57.

Assuming 50% out migration and using the lower statewide calculation of 57%, in the most recent data year of 2014 the minimum estimated diagnostic procedures would be 603, which is more than double the 240 threshold that would generate a need in methodology two.

Given the available information and the comments submitted by August 14th, the Agency recommends approval of the petition. This concludes the Agency report.

SPEAKER 1: Thank you, Paige. So we have a petition to add one shared, fixed cardiac cath unit in Harnett County now open for discussion. Do any members of the committee have a question or concern about this petition and the recommendation?

SPEAKER: None.

SPEAKER 1: None? Jeff?

SPEAKER: None.

SPEAKER 1: Okay. Dr. Patel, you look quizzical.

SPEAKER: No.

SPEAKER 1: You're fine. Okay. So a vote "yes" is to add the need in Harnett County to the plan for 2016. All those in favor, signify by saying "aye."

SPEAKERS: Aye.

SPEAKER: Aye.

SPEAKER 4: And I refuse.

SPEAKER 1: And Trey refused, so it is adopted. Thank you, sir. We now need a motion to vote and approve the cardiac cath recommendations to the CHIC as a whole. I need a --

SPEAKER: Motion to approve with the exception of the motion that died; is that correct?

SPEAKER 1: Well, that's part of our report.

SPEAKER: Oh, okay. Yes.

SPEAKER: Second.

SPEAKER 1: Second? Any further discussion?

(No response.)

SPEAKER 1: Seeing none, all those in favor, say "aye."

SPEAKERS: Aye.

SPEAKER 1: Thank you.

10/7/2015 - SHCC Recording

50:12 to 1:43:54

SPEAKER 1: We'll now go on to the report of the Technology and Equipment Committee, which I personally chair, as well as chairing the full CHIC. On September 16th, 2015, the Technology and Equipment Committee met to consider the petitions and comments in response to Chapter 9 of the North Carolina proposed 2016 SMFP. The committee makes the following recommendations for consideration by the North Carolina State Health Coordinating Council in preparation for the technology and equipment chapter of the 2016 SMFP. This is Chapter 9 of the plan.

The first section of Chapter 9 that I'll discuss is Magnetic resonance imaging, or MRI, section. The proposed 2016 SMFP showed two need determinations for additional fixed MRI scanners in Lincoln and Mecklenburg Counties.

Over the summer, Health Planning received updated data resulting in corrections to the MRI scanner inventory table. The changes created a need determination for one additional fixed MRI scanner in

Guilford County.

There were two comments regarding the MRI section. The committee received three petitions over the summer for an adjusted need determination in the MRI scanner section of the 2016 SMFP. The first petition was concerning Lincoln County and was filed by Carolinas Healthcare System. The request was for an adjusted need determination to remove the need for one fixed MRI scanner in Lincoln County. No comments were received on this petition.

The committee discussed the petition in the Agency report, which recommended approval of the petition request, which is to remove the need. The concurrence was that Lincoln County does not -- does have unique circumstances, including a potential change to future MRI volume and slow projected growth rate in the county that would probably preclude existing or new providers from meeting the CON standards of a qualified applicant. The committee recommends to the CHIC that the Petitioner request be approved for an adjusted need determination, which is to remove the need.

A second petition was filed in Wake County by Raleigh Radiology. Raleigh Radiology requested an adjusted need determination to add the need for one fixed MRI scanner in Wake County. Two letters of support were

received, two comments in opposition and one general comment concerning this petition.

The committee discussed the petition and Agency report which recommended approval of the petition request. Data presented in the Agency report demonstrated a high weighted procedure average for the last ten years with only one need being generated by the standard methodology. Projections of data indicated a need determination would potentially be generated by the standard methodology in the 2017 plan.

Additional dialogue included the potential for grandfathered mobile MRI machines to suppress need determinations. The committee agreed that the proactive approach to healthcare planning was preferred and recommended to the CHIC that the petition be approved for an adjusted need determination for one fixed MRI in Wake County.

The third petition is from Brunswick County concerning J. Arthur Dosher Memorial Hospital. J. Arthur Dosher Memorial Hospital requested an adjusted need determination to add the need for one fixed MRI scanner in Brunswick County with a lower tiered planning threshold of 1,716 weighted procedures for applicants. The petition received 45 letters of support and one comment in opposition.

The committee discussed the petition and the Agency report which recommended approval of the petition request. The concurrence was that Brunswick County does have unique circumstances, including an MRI that is classified in the SMFP as fixed, but is available for fewer hours than a mobile machine is typically available.

The fixed machine is located four miles from the hospital, which potentially serves as a barrier for inpatient care. The committee recommends to the CHIC that the Petitioner request be approved for an adjusted need determination in Brunswick County.

In the cardiac catheterization equipment section, since the proposed 2016 SMFP there have been no changes in need projections for cardiac catheterization equipment. The proposed 2016 SMFP showed one need determination for fixed cardiac catheterization equipment in Cumberland County. There were no need determinations for shared, fixed cardiac catheterization or mobile cardiac catheterization equipment anywhere in the state.

During the summer, two petitions were received for adjusted need determinations in the cardiac catheterization section of the 2016 SMFP. The first petition was from Wake County filed by Rex Healthcare. Rex Healthcare requested an adjusted need determination for one additional unit of fixed cardiac catheterization

equipment in Wake County in the 2016 SMFP. There were four comments in total, including one from the Petitioner, one in support and two in opposition.

The committee has no recommendation to forward to the CHIC on this petition. The committee vote resulted in a tie and the motion died at that time. No additional motions were made concerning this petition. This is essentially a denial of the petition as it currently sits.

A second petition came from Harnett County from Harnett Healthcare. Harnett Health requested an adjusted need determination for one additional unit of shared, fixed cardiac catheterization equipment in Harnett County in the 2016 SMFP. Nine letters of support were received. The committee discussed the petition and the Agency report which recommended approval of this request.

Based on the data presented in the Agency report, the committee agreed that Harnett County has the volume of cardiac catheterization to support a shared, fixed machine. In addition, the current driving miles to the nearest cardiac catheterization lab is potentially outside of the current clinical recommendation for ST elevated myocardial infarction patients. The committee recommends to the CHIC that the petition request be

approved for an adjusted need determination for one unit of shared, fixed cardiac catheterization equipment in Harnett County.

In the positron emission tomography section, there has been no change in the need projections for PET scanners. These are really PET/CT scanners, in reality. There is no need determination for an additional fixed or mobile PET scanner anywhere in the state. The committee received one petition regarding PET scanners.

The petition, which was a statewide request, came from Alliance Healthcare Services. They requested an adjusted need determination for zero conversions pursuant to Policy TE-1, fixed and mobile PET scanners in the 2016 SMFP. Two comments were received in opposition. The petition and the Agency report, which recommended denial of the petition request, were discussed by the committee.

The consensus was that the potential changes in the next few years in mobile PET indicate the possibility of needing more capacity than is currently existing or even proposed. The Agency report indicated the division of health services regulation will continue to monitor and reevaluate annually applicants for Policy TE-1, PET utilization and the site distribution of these units. The committee recommends to the CHIC denial of

this petition. The effect of this is to leave Policy TE-1 to function as written.

Lithotripsy section. Since the proposed 2016 SMFP, there have been no changes in the need projections for lithotripsy. There is a statewide need determination identified for one lithotripter. The committee received no petitions or comments over the summer regarding the lithotripsy section of the proposed 2016 SMFP.

Linear accelerator section. Since the proposed 2016 SMFP, there have been no changes in need projections for linear accelerators. There is no need indicated anywhere in the state for additional linear accelerators. The committee received no petitions and only one comment regarding linear accelerators.

Gamma Knife section. The proposed 2016 SMFP shows no changes in need projections for Gamma Knife. There is no need for Gamma Knives anywhere in the state at this time. The committee received no petitions or comments over the summer regarding the Gamma Knife section of the proposed 2016 SMFP.

The committee recommends to the State Health Coordinating Council approval of Chapter 9, Technology and Equipment, with the understanding that staff is authorized to continue making necessary updates to the

narratives, tables and need determinations as indicated.

Do I have a motion for that?

SPEAKER 2: Moved.

SPEAKER 1: Thank you. And a second?

SPEAKER 3: Second.

SPEAKER 1: I heard second. Okay. This is now open for discussion. Dr. Green?

SPEAKER 4: Just a clarification. On the cardiac cath equipment section, the petition from Rex Healthcare for an adjusted need determination, where you ended up in this report is you were recommending not to approve that; is that correct?

SPEAKER 1: The committee effectively voted denial --

SPEAKER 4: Okay. Thank you.

SPEAKER 1: -- in its present form because it didn't act to approve the petition.

SPEAKER 4: Okay. Thank you.

SPEAKER 1: That's the current status. Yes, sir.

SPEAKER 5: I had previously recused myself on the MRI discussion for Dosher. Do I need to re-recuse myself or does that kind of carry through?

SPEAKER 1: So noted, but the public record does show a prior recusal.

SPEAKER 5: Perfect. Thanks.

SPEAKER 1: Mr. Bergot (phonetic)?

SPEAKER 6: Mr. Chair, can we extract the Rex Healthcare discussion and discuss that as a board?

SPEAKER 1: Certainly, we can discuss it and act on it prior to voting on the entire -- the entire proposal. This is the area of discussion, so --

SPEAKER 6: Go ahead?

SPEAKER 1: Well, unless there are other -- the way I'll probably treat that is as a motion issue and --

SPEAKER 6: Make a new motion?

SPEAKER 1: -- and we'll go from there. So Mr. Bergot proposes to extract the Rex Healthcare petition for further discussion and review by the entire committee. Do I hear a second for that?

SPEAKER 7: Second.

SPEAKER 1: There's a second from Dr. Parik. If you -- we will not discuss the motion. If we choose to vote "yes," it means that you desire to have a further discussion about that petition. If you vote "no," you are essentially voting to deny the petition in the form that it is currently, and it can be a little confusing, so I want people to know what they're voting on.

SPEAKER 6: Say it one more time.

SPEAKER 1: You have moved to extract the Rex petition section of the report for review by the entire council. That was seconded, so I'm going to treat that as a motion requiring a vote. If you vote "yes," we will take that petition and discuss it and come to a vote on that, the specifics of that petition and the committee can either approve it or reject the -- the recommendation, and the staff, I think, will -- I'll probably have them recap the Agency report on this if we move ahead.

If you vote "no," you essentially are satisfied with what is there and we'll save a whole bunch of time, but I'm not telling -- that's just basically how it will play out because I expect there to be a fair discussion if it's extracted, which is fine.

So all of those in favor of extracting the Rex petition for further consideration -- individual consideration, signify by saying "aye."

SPEAKERS: Aye.

SPEAKER 1: All of those who are opposed?

SPEAKERS: No.

SPEAKER 1: Okay. I'm going to need a show of hands. I won't depend on voice volume at my desk. I also will go through the phone. Why don't we do the phone first? Kurt, do you have a vote, yea or nay?

SPEAKER 8: Yea.

SPEAKER 1: Yea, you would like it extracted. Mr. Lambeth, are you on the phone?

(No response.)

SPEAKER 1: No? Denise (indiscernible)?

SPEAKER 9: I vote nay.

SPEAKER 1: You vote no?

SPEAKER 9: Yes, sir.

SPEAKER 1: And Steve Lawler?

SPEAKER 10: I vote yea.

SPEAKER 1: Yea. So I've got two yeas and one nay on the phone. Okay. Now, all of those who are in the room where I can count -- or maybe I'll have the staff count hands because I can't see everybody, so I'm going to designate Kelly to count for me.

All of those in favor of further discussion of the Rex petition, please raise their hand, high enough so we can see it. I don't want a miscount.

SPEAKER 11: I see seven.

SPEAKER 1: You see seven. Okay. All of those opposed to extraction, raise their hand.

SPEAKER 11: Seven.

SPEAKER 1: Seven. And we had -- so by a margin of one vote, we will extract this for further discussion.

Here's how -- here is how we will do this, and I want to start out by saying that I am not pro-Rex, I am not pro-Wake, nor am I anti the two involved organizations.

For those of you -- I hope everyone has read the petition, but I will put a little bit of a framework around the petition and then we'll start comments.

This is one in a series of petitions we have received that are related to an economic situation in Wake County that has resulted in a substantial patient shift in the county. You can have your view of whether that was a good idea, bad idea, but that's what happened and we've had a variety of petitions trying to address one or the other viewpoint of, you know, how that plays out.

I don't think there is a right or wrong here. This is a question of judgment about where you draw lines, and the Agency report, which the Agency worked on has drawn the line in a certain place which I would say is related to the impact on the least represented group at this table, which are the patients, and it's based on a utilization model.

I can fully understand those who want to support the methodology, which clearly shows there is a surplus of equipment in the -- in the service area, and

there will continue to be a surplus whichever way this is voted.

There's a substantial unused capacity in the county. It's not distributed to where the patients are, and I'm not telling anyone how to vote, but I do want people to understand that's why we take votes. We're not obligated to accept the Agency's, you know, attempt to find the Gordian knot solution, but it is -- it is our responsibility as representatives of the people of the state, as it says under Executive Order 46, to act in our best judgment and I don't know what the best judgment is, but I think there are sincere beliefs on both sides of the issue.

So --

SPEAKER 10: (Indiscernible.)

SPEAKER 1: Yeah.

SPEAKER 10: Steve Lawler.

SPEAKER 1: Yeah, Steve.

SPEAKER 10: First of all, I admire you for your Solomon-like approach to this.

SPEAKER 1: I didn't do the --

SPEAKER 10: (Indiscernible) this up was just to make sure that I, myself, and perhaps the rest of the group had a greater understanding of, you know, how the methodology set the stage and drove the discussion

for the committee and then how the committee, you know, came to a split decision, as do you.

I mean, I -- you know, I'm kind of ambivalent in regards to supporting one side to the other. I do support, you know, the idea that all patients should have access to the right care as close to home as possible and, you know, this -- what's going on in Wake County, as far as, you know, I can tell is, you know, it's a tale of physician alignment that kind of moved and shifted patients from one location to another, but had little impact at all in regards to total demand within that service area.

So, you know, my interest was really just getting a deeper understanding from the staff in regards to methodology and maybe some insight into the conversation that the -- that your committee had.

SPEAKER 1: I'll ask Paige to review the Agency report based on that.

SPEAKER 12: Thank you, Mr. Chair. So as we all know, the request was from Rex Healthcare and they requested an adjusted need determination for an additional fixed unit of cardiac catheterization in Wake County.

Application of the methodologies, the utilization data and the proposed 2016 State Medical

Facilities Plan did not generate a need determination for fixed or shared cardiac catheterization equipment in Wake County.

Rex was requesting the adjusted need determination based on the unique utilization trends faced by Rex. Rex currently has a total inventory of four machines. Using the standard methodology of 80% utilization, the number of machines for Wake County and Rex is 12.33 and 5, respectively.

In the face of steady increases and aging population, the cardiac cath -- catheterization has remained fairly stable over the last decade. Data that was presented in the Agency report illustrates that the compound annual growth rate and overall change in the weighted procedures for both Wake County and North Carolina from 2005 to 2014.

In Wake County in the last ten years, the data shows an average annual change of negative 1.76, a decline, while the North Carolina compound annual growth over the same time period had an average annual decline of negative 1.94. These indicate a slow and steady reduction in the number of procedures in both regions, with Wake County experiencing a slower decline than the state overall.

However, data also presented in the Agency

report shows the opportunity to review the utilization trends on an annual basis. In the most -- in 2014, the most recent data year, Wake County demonstrates an increase in annual number of procedures by 3.69%, while the state experienced a steeper decline of negative 3.37%. Thus, Wake County is experiencing recent unique growth as compared to statewide trends.

Rex's petition suggests that they have unique utilization trends in the three years and they cite the professional affiliation with Wake Heart and Vascular Associates.

Rex Hospital is the only provider in Wake County that has shown a consistent increase in the number of procedures over the last five years of data.

More notably, Rex, in the most recent two years, has demonstrated utilization greater than 80%, which is the utilization threshold for determining a need in the health service area. However, application of the methodology does generate needs for the facilities for both years, but considers procedure volume and number of machines in the entire service area, so Rex's deficit is offset by the surplus of machines in Wake County as a whole.

Finally, Rex's utilization has increased from 84% last year to 100% in the most current year,

which calculates to the equivalent of one full machine. And with that, the Agency recommended approving the petition.

SPEAKER 1: Thank you, Paige. Any questions for Paige about the Agency report before we go to other discussion?

SPEAKER: Yes, I have a question.

SPEAKER 1: Yes, sir.

SPEAKER: I noted that while -- while Wake had an increase, it was not uncommon in the period that you've shown on Table 2, back in 2008, Wake also showed an increase. The state showed a larger increase and, yet, in the following three years, the actual requirement decreased. So is the 3.69% increase an aberration? Is it something that's just going to happen once or is it an ongoing trend? And, at least according to the Table 2 here, it may only be a one-year influx.

SPEAKER 12: Well, I think that you make an excellent point. The data -- obviously, anything can happen. If you look at the trends over the last ten years, there are certainly times where there have been increases for a couple years and then decreases for a couple years, so I think it would be difficult to project what will be happening next year, except to say that Rex now has had two years of unique utilization with that

only increasing.

SPEAKER: If I may?

SPEAKER 1: Sure.

SPEAKER: Isn't the charge of the committee and of the staff in this to look at the lines that were drawn? If we want to change the lines, then shouldn't we recommend a change in lines and have the Petitioner request under the basis of a change in the lines drawn? So would we not have to change the -- the basis for coming up -- if you will, the population basis for coming up with the change that's being requested?

SPEAKER 12: I'm not sure I quite understand your question.

SPEAKER: You used Wake County.

SPEAKER 12: Yes, sir.

SPEAKER: Okay. If you're looking at Rex alone, then you have to change the lines of -- of what -- where the population is counted.

SPEAKER 1: Mr. Lewis, I appreciate that comment and I think the -- that gets back to whether you redraw the statewide methodology for a unique circumstance in one county or whether you attempt to address that unique circumstance with a petition model that keeps the methodology in place statewide.

There is no question that the overall

utilization of cardiac cath services is falling and has done so for more than five years statewide. What you have here is a market share and distribution issue unique to one county, and I think that's the -- that's the question we wrestle with. Should we change the methodology and overhaul it?

The vast majority of opinion we have is that the methodology's got it right. We don't need any more facilities statewide. This gets back to the judgment do you make an adjustment in a -- in a circumstance in one area either to endorse the methodology as is or grant an exception to that methodology and that's what we're having our discussion over.

SPEAKER: Okay. So the other issue that comes in the discussion between Wake and Rex is the -- the very providers, very physician group, that drove -- that drove -- drives the need at Rex was originally aligned with Wake, so why would that tell us -- and I don't know the answer to this, but why would that tell us that the population is now in the Rex area as opposed to the Wake area? And again, it goes back to the issue of methodology for the county and for the state.

SPEAKER 1: Uh-huh.

SPEAKER: Mr. Chairman?

SPEAKER 1: Just a second. Yeah. Paige, I

think -- do you have any further comment on that last question? And then we'll -- everyone will be heard before we do anything.

SPEAKER 12: No, sir. I mean, I understand your point, but we go based on the way the methodology currently works and evaluated it based on the Petitioner's request for their utilization -- their specific utilization trends.

SPEAKER: I understand.

SPEAKER 1: Yeah.

SPEAKER: Thank you.

SPEAKER 1: And I think at the end of the day it's a constrained market, not a free market. Yes, sir.

SPEAKER: I want to apologize because I'm on that committee and I was not there that day at the meeting, and if I had been it wouldn't be three-three. It wouldn't have been, so a lot of this is because I just couldn't make that meeting, but if I had been there, I would have voted in favor for Rex.

SPEAKER 1: Uh-huh. Yeah, it would have been an unusual one-vote margin, but, you know, the amazing thing is we usually reach consensus. This was in a situation where we did not reach consensus in the committee and I respect the viewpoints of people on both

sides.

SPEAKER: Mr. Chairman, can Paige tell us how many excess cardiac cath beds are -- there are in this health service area? And secondly, how far a distance WakeMed Cary and WakeMed Raleigh are from Rex, time-wise?

SPEAKER 12: Well, I think there's approximately seven bed -- or 12 -- what did I say, 12.33 machines and 5 machines, so I think there's a seven-bed surplus. And distance from WakeMed Raleigh to Rex, I mean, they're probably not more than 15 or 20 minutes apart.

SPEAKER: And does WakeMed Cary have cardiac cath services that you're aware of?

SPEAKER 12: WakeMed Cary does have cardiac cath services.

SPEAKER: Okay.

SPEAKER 12: Yes, sir.

SPEAKER: Thank you.

SPEAKER 1: Yeah. You know, not everybody knows the geography of Wake County and I'm not an expert on it, you know, quite honestly. Mr. Bergot, you made the motion. Do you have anything to offer in terms of your viewpoint?

SPEAKER 6: When I read the staff's

recommendation and started reading the different information and saw the vote, you know, I started going back and just reading through things and some of the things I noted was the heart is still the number-one killer in Wake County. It's one of the fastest growing counties in the state, over a million in population. It's going to continue to grow. Probably is going to be accelerated from all the economic stuff that I look at and it's all about patient care.

I mean, if you've got a facility that is 100% utilized -- now, I look at it from a business point. I've got numerous businesses. We're building and adding to businesses where there's businesses across the road that are declining, but that's because of great service and all the other things that we try to do.

So, you know, I want us to be proactive and be ahead of the curve rather than reactive, and I think this is a proactive move.

SPEAKER: But if you could get that facility at a cheaper price, wouldn't you go that instead of buying -- taking new capital and getting a new facility?

SPEAKER 6: If it met my needs and it could be at a cheaper price.

SPEAKER: And I think that's what the committee really thought should happen here. There are

numerous facilities available and they're going unused because Rex refuses to compromise.

SPEAKER: Well, couldn't the two -- is one willing to sell to another?

SPEAKER: I think they are.

SPEAKER: (Indiscernible). I have one more question. Do we know if the physicians at Rex also have admitting and clinical privileges at the other -- you know, at WakeMed and vice versa?

SPEAKER 1: The only piece of data I have is that I believe the physician group resigned their WakeMed privileges at the end of last year.

SPEAKER: Can I ask another question?

SPEAKER 1: Yeah.

SPEAKER: What would keep Wake from hiring more physicians?

SPEAKER 1: Well, they would have to do that.

SPEAKER: I mean, if you --

SPEAKER 1: And on the cost point-of-view -- on the cost point-of-view, there is the cost of the equipment. The cost of the procedures for these are all hospital-based and are basically set by Medicare or negotiations and these patients are going to get done, so there is a small macroeconomic adjustment for the

capital, but I'm not sure there's a big gradient. There's no outpatient imaging center equivalent pricing model for cardiac catheterization that I'm aware of anywhere in the state.

Now, in defference that Dr. Parik made a fairly impassioned discussion about that lack of price competition in markets and I think I offered the return that this committee can't solve that, but I understand the concern as someone who's been through the healthcare system on both inpatient and outpatient sides in the last 12 months.

Any other viewpoints? Kurt, on the phone, or Denise, either of you have a question, comment, observation?

SPEAKER: No, sir. Just listening.

SPEAKER 1: Thank you. Kurt?

SPEAKER: No. I'm fine, thank you.

SPEAKER 1: Kelly? Trey?

SPEAKER: I guess since I've already fallen on this knife, for purposes of transparency to the group and why I voted no on the petition, Mr. Bergot's point, to a certain point, I mean, being a more capitalistic nature. This tugs on my heartstrings a little bit. Good on Rex for offering these docs a place to go.

My concern, today's environment, based on

this, the plan as it stands and our role to operate within the ream of this plan and protect it, I feel like approving this petition is probably bad precedence for the plan in general. This -- and my opinion is one of the glaring reasons the CON process was developed, in general.

You've got a big area, a big county with a lot of resources and the purpose of this plan and the access, the value, is to force collaboration and force folks to use -- to utilize all the resources.

Now, I think there are certain aspects in this -- in this plan where it may limit quality care, that it inhibits people's ability to come in and provide a quality service.

I don't think that Duke and WakeMed, if patients went there, would be receiving poor care. Before the case, I probably would have voted the other way. I think there needs to be the opportunity for these hospitals to come together and figure out how to utilize all of the resources in the county first.

I think at the end of the day, Dr. (Indiscernible) point, at the end of the day, the patients are who we are looking out for.

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, and that's -- that's why I voted no.

SPEAKER: Can I ask a question?

SPEAKER 1: So I assume you're still speaking against the petition?

SPEAKER: Yes.

SPEAKER 1: Okay. Yes, sir.

SPEAKER: If we don't vote "yes" -- I mean, if we vote "yes," then there is an incentive for them to talk. If we vote "no," there's no incentive for them to talk and do anything. They just stay at odds.

SPEAKER: Well, I think it's something -- I think you would hope --

SPEAKER: You don't think so? If I had -- if I owned a business across the street and somebody said, "Well, they're --" and say CON applied to car

dealerships and somebody said, "Well, now we're going to let you approve (indiscernible)," and I'd say, "Well, let me go talk to them and see if I can buy that one first before they put another one in."

SPEAKER: WakeMed has about 20 cardiologists. Your question about whether they can hire cardiologists. The cardiology groups exist there and they have privileges, meaning, you know, those that are not employed by WakeMed. There are employee cardiologists.

SPEAKER: Staff cardiologists?

SPEAKER: Yeah, staff and they have Cary Cardiology, which is another major group that are affiliated and they do cardiographs, they do intervention, and it was only as of January 1st, 2015 that Wake Heart and Vascular pulled its privileges voluntarily. That should tell you something. That should tell all of us something, voluntarily. WakeMed would like those docs back. They were coming to both facilities despite having an affiliation with Rex.

And before, they were situated at WakeMed, at WakeMed Raleigh. So it's not a question of whether there are enough cardiologists at WakeMed currently. They both do cardiographs. It was a voluntary exit and this is the same surface area, which is about five

minutes away and this would be an enormous precedent in the whole state. Forget about Wake County. I'm not worried about Wake County, even though I practice here. It could be Charlotte, it could be anywhere. It could be any of the large counties. You know, whatever happens in large counties will potentially start happening in many of the other large counties.

SPEAKER: I still think it's a customer service issue, you know. Customers choose -- the patients choose to go to a certain facility or certain doctors to be provided a service.

SPEAKER: I would disagree with that. I think -- I came at this as, also, an agnostic. I didn't even know where the hospitals were and so I spent time looking at where they were and then I actually spoke to a board member for Rex this week and I became convinced that approving the petition was the wrong route.

You know, there's a line in the movie "Cold Mountain" with Renee Zellweger before she got a facelift and she says --

SPEAKER 1: Strike that from the minutes.

SPEAKER: -- all of this -- all of this is manmade, and I'll clean it up (indiscernible). All of this was manmade. This war is a cloud over the land, but they made the weather and now they're complaining because

they're getting wet. Okay?

Rex made this and Wake Cardiology or Heart, they made this and when they moved and then resigned their -- their positions at Wake, they required their patients -- or they didn't require, but they basically forced their patients to move to Rex. The patients don't have a choice.

SPEAKER 1: Uh-huh. It's a constrained mark at the end of the -- a constrained market.

SPEAKER: Exactly.

SPEAKER 1: Jim, from a functional point-of-view, if you have Trey's opinion, which is you'd like people to be nice in the sandbox, then you should vote to deny the petition because once you have the need in hand, the leverage to bargain, you know, with somebody else goes away.

SPEAKER: Well, my point, though, is before I would go build a new facility, if I could buy a facility at a lower price, I would make (indiscernible) decision. I mean, I do that with buildings all the time.

SPEAKER 1: Yeah.

SPEAKER: I look at the cost of the new construction, the cost of renovation, and if I can make it work, I do the renovation because I make more money.

SPEAKER 1: That's assuming the product's

available, so --

SPEAKER: So I'm not sure I --

SPEAKER 1: (Indiscernible.)

SPEAKER: I'm not sure I do understand what that tells me about the WakeMed Cardiology (indiscernible). Can you (indiscernible) how that happened? I don't know what it's about.

SPEAKER: So -- so what happened is Wake Heart and Vascular --

SPEAKER 1: Hope nobody gets slandered in the process.

SPEAKER: -- (indiscernible) but because of --

SPEAKER 1: Do you have anything you want to say? You okay?

SPEAKER: -- stress (indiscernible) for Medicare, cuts the ultrasounds to Medicare, which is (indiscernible) business and then also what happens is the private insurance industry (indiscernible). They have to make decisions and (indiscernible). That's the bottom line. The electives are no longer there. I mean, that's what happened. I mean, you know, people need to know the real story.

I'm not for one or the other. I just want people to know that should we set a precedent in Wake

County, that's my concern because it'll impact 99 other counties. That's the real concern. It's not about just one petition. It's about Mecklenburg, Forsyth, whatever, any high-populated area, and, guess what, to your, you know, issue -- or not issue, but the mention of you buying the existing facility, 140 or 50 million dollars in bond money has been raised for the new North Carolina Heart and Vascular Center by Rex.

Yet, a seven- or eight-story hospital (indiscernible) in Raleigh and another four-story, three floors and a basement, sits in Cary. It's operational. It's not hurting or anything like that, and that hurts because it hurts business. Higher copays, higher, you know, health savings accounts. It's not about just servicing -- services (indiscernible) and you pay 20, 30% more.

Cardiac cath is bread and butter, as in diabetes care. I mean, yes, you need good docs, don't get me wrong, but it's really bread and butter for them. I can't (indiscernible), but for those who do it, it's bread and butter. It could raise the cost of small business, too.

SPEAKER 1: Sandra?

SPEAKER: Mr. Chairman --

SPEAKER: And again, it's a precedent

setting thing. I mean, because you know one of the things set aside was a second linear accelerator that Duke asked for in Wake County that we approved and that was the reason cited in their petition, to approve their petition because precedent was already set.

A second linear accelerator, this one was on the books for (indiscernible).

SPEAKER: Mr. Chairman --

SPEAKER 1: Sandra?

SPEAKER: -- I would like to call the question and I'm trying to figure out what the question is.

SPEAKER 1: Well, I will frame the question.

SPEAKER: All right. You frame the question. I'm calling the question.

SPEAKER 1: Call the question is a primary motion which means that debate is now -- the discussion is now halted on this and we go to a vote. But I think the way to handle this is that we voted to extract this. What we need, I believe the motion will be intrinsic in that is if you -- the Agency recommendation was to grant the need. If you vote "yes" to support the Agency recommendation, you are voting to add the need.

If you vote "no," it is to deny the petition and, therefore, there will not be a need in the 2016

SMFP. Once we settle that unresolved -- because it was a tie. You can look at it. It's unresolved. Once that's settled, we will return to the original motion to vote on the committee report as amended or supported. So I need a motion to adopt the Agency recommendation.

SPEAKER: Could I make a --

SPEAKER 1: Yeah. Please do.

SPEAKER: -- suggestion? It might be clearer if we -- if we made the motion around the actual petition because that's what we have to ultimately vote on. We don't have to vote on the Agency report.

SPEAKER 1: That's fair. We could do it that way.

SPEAKER: So could I move that we deny the petition from Rex?

SPEAKER 1: Do I hear a second for that?

SPEAKER: Second.

SPEAKER 1: Okay. So the Rex petition was to add a need and so --

SPEAKER: Motion to deny.

SPEAKER: Motion to deny.

SPEAKER 1: So she has a motion to deny, so if you vote "yes," you are voting to deny the petition.

SPEAKER: It's turned around.

SPEAKER: That just flipped it?

SPEAKER 1: That's correct. I want everybody to be clear what we're going to vote on. She -- the suggestion from Dr. Green is that a motion be made to deny the Rex petition, which is the flipside of the Agency, which I was trying to use previously.

SPEAKER: I think it's clear.

SPEAKER: It's clear.

SPEAKER: It's clear.

SPEAKER 1: So which way would you like me to phrase it? Can we vote to deny --

SPEAKER: The motion is to deny.

SPEAKER 1: -- or should we vote the Agency petition -- recommendation?

SPEAKER: We need to -- we need --

SPEAKER: Vote to deny.

SPEAKER 1: Okay. So what the motion is, and I assume we have a second for that --

SPEAKER: I did second.

SPEAKER 1: The motion is to deny the request for an additional cardiac catheterization need in Wake County. Bear in mind that while Rex made the petition, the need would be county-wide, so I think it's appropriate -- in the plan it will be listed as a Wake County need.

SPEAKER: Okay.

SPEAKER 1: So the motion is to deny the addition of a need in Wake County, so if you vote "yes," you are saying no new capacity.

SPEAKER: Yes.

SPEAKER 1: If you vote "no," then we will have to return to approving the need, potentially.

SPEAKER 1: So -- huh? Have I got it -- have it got it completely confused?

SPEAKER: You got it.

SPEAKER: You got it.

SPEAKER: A no means --

SPEAKER 1: The motion was for denial.

SPEAKER: The motion is to deny.

SPEAKER: Deny. Yes is a deny?

SPEAKER: Yes.

SPEAKER 1: So if you vote "yes," you are -- I want everybody to be clear because this is important. We had a one-vote margin to extract this for discussion and I want to make sure that everyone is clear, when they cast their vote, what the meaning of this vote is going to be because it may be a one-vote margin again or maybe two votes. I don't know what it'll be. It may be five, hopefully, but we'll see.

So the motion was made to deny. The petition was to add a cardiac cath need in Wake County,

at its essence. The motion is to deny the adjusted need request, so if you vote "yes" to the motion, you are voting to deny or not put a need in the plan in Wake County.

If you vote "no," then we will have to re-discuss or re-vote on whether or not we will then add a need in the plan if someone were to make that motion.

So this is a petition to deny. Now, because it was close, I'm going to actually ask for a show of hands and an indication of the individuals on the phone and so I'm going to start with our phone folks. Kurt, what is your vote?

SPEAKER: No.

SPEAKER 1: Donnie Wembeth, are you on the phone?

(No response.)

SPEAKER 1: Denise (Indiscernible)?

SPEAKER: I vote yes.

SPEAKER 1: Steve Lawler:

SPEAKER: Yes.

SPEAKER 1: All right. That's the phone group. Now, all of those who want to vote "yes," which, again, is to deny -- not to put a need in the plan, please raise your hand, and you count. Do we agree on the number? You can put your hands down.

All of those who vote "no" on the motion, please raise their hand. Okay. What is our summary, Kelly?

SPEAKER: Twelve yeses and five nos.

SPEAKER 1: So the motion to deny the need carries and there will be no need in the 2016 SMFP in Wake County.

We had no other extractions from the committee report, so I will return now to the committee report as amended by this council. And by the way, I think this is a healthy discussion and that's why we hold votes. We're not here just to, you know, to raise hands and rubber stamp things, so I'm actually delighted that we went through this process, even though it's run a little bit longer than planned.

So we have a motion on the table to approve the Technology and Equipment Committee report. All those in favor, signify by saying "aye."

SPEAKERS: Aye.

SPEAKER 1: It is adopted. That was easy, wasn't it?

All right. Now, the next item on the agenda is what I term a clarification of language to Policy TE-2 to the dental OR demonstration project and the need determination in Brunswick County. In the course of a

variety of discussions, there was an identification of a implicit aspect of these proposals, which have now all been adopted.

I'm going to ask Martha Frazzoni to briefly present and -- which I believe actually expresses the intent of the committee, but spells it out. Could you give Martha the microphone? You can sit there, but the --

SPEAKER: Hopefully, you don't -- can y'all hear me?

SPEAKER 1: Yeah.

SPEAKER: Okay. Ordinarily, in the CON review there are performance standard rules that would apply and those performance standard rules are usually based on the methodologies adopted by the CHIC and approved by the governor.

It became clear to us, however, that for the Brunswick MRI need determination, the dental ambulatory surgical center demonstration projects and probably Policy TE-2, that it is the implicit intent of the CHIC that a different standard would apply in the review.

So if you look at the language of the dental demonstration project, which I believe is in your packet of materials, there were 11 criteria that Dr. Green reviewed.

We are suggesting and asking that the CHIC include a twelfth criteria for that that would make it explicit, that the performance standard rules in the OR rules would not apply.

I don't believe that the applicants would be able to meet those performance standards which would necessitate us denying an otherwise approvable application, which I don't believe is the intent of the CHIC.

The same is also true in the MRI rules. The need determination itself says that the threshold for this MRI scanner would be at the lowest threshold. However, based on the standard methodology and the standard -- performance standard rules, a much higher threshold would apply and it's believed that, you know, no one would be able to successfully be approved for that, and if some of that same logic was applied in basically adjusting the need determination in Lincoln County and removing the need determination because it was felt that an applicant would not be able to meet the performance standards.

With regard to policy TE-2, we looked at it and realized that there's no language at all that addresses the utilization of an intraoperative MRI scanner. I know I'm asking to go back to the spring for

this.

This is not something that's been discussed recently, but the threshold that an applicant would have to meet, given some of the criteria, I imagine it would end up being in the larger areas, such as Mecklenburg or Wake, where they would have to show as much as 4800 or more weighted MRI scans, and this type of machine which is limited by the language of the policy to inpatients only and cannot be used for anything but the surgical patients, and we don't want to be in the position of having to apply a rule that would basically nullify the need determination.

So what we are asking for is the addition to each of those of a single sentence, and it will vary a little bit, for the adjusted MRI scanner need in Brunswick County and Policy TE-2. The sentence that we're asking that you approve is to add the sentence, "The performance standards in 10(a) NCAC 14(c) 2703 would not be applicable." The same sentence would be added as the new criteria 12 for the OR demonstration project. The only difference is it would state that the performance standards in 10(a) NCAC 14(c) 2103 would not be applicable because the qualification is in a different rule for OR than for MRI. Any questions?

(No response.)

SPEAKER 1: Rob?

SPEAKER: Motion to approve.

SPEAKER 1: Is that because it's clear as mud? Martha, thank you for your report. As I said, I believe this is a clarification which expresses our intention in an explicit fashion and removes uncertainty later, so any discuss -- did I hear a second, by the way, to Rob's motion?

SPEAKER: Second.

SPEAKER 1: Got a second. Open for discussion. Any discussion about adding this language to those three proposals?

(No response.)

SPEAKER 1: Hearing none, all those in favor, signify by saying "aye."

SPEAKERS: Aye.

SPEAKER 1: It is approved.

3/30/2016 - T&E Recording

10:49 to 25:30

SPEAKER 1: We will now look at Chapter 9, cardiac catheterization. We will hear from Paige Bennett on the review of the policies and the need methodologies for cardiac catheterization. Now, my -- it says here that I need a motion for that discussion approval.

SPEAKER 2: After.

SPEAKER 1: But we'll do that afterwards.

SPEAKER 2: Thank you, Mr. Chair. The cardiac catheterization equipment planning areas are the same as the acute care bed service areas as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.

The cardiac catheterization equipment service area is a single county unless there is no licensed acute care hospital located within the county and those counties are then grouped with the single county where the largest proportion of patients received inpatient, acute care services.

These service areas are reviewed every three years and this year they will be reviewed again and preliminary data analysis indicates there will be minor changes which will be discussed at the second meeting of this committee.

There are two standard need determination methodologies for cardiac catheterization equipment. Methodology one is the standard methodology for determining need for additional fixed cardiac catheterization equipment and methodology two is for shared, fixed cardiac catheterization equipment.

Steps one on methodology part one. For fixed cardiac catheterization equipment, procedures are

weighted based on complexity as described on page 179 of the 2016 SMFP. The State Health Coordinating Council defines capacity as 1500 diagnostic equivalent procedures per year.

The number of fixed cardiac catheterization equipment required is determined by dividing the number of weighted or diagnostic equivalent procedures performed at each facility by 1200 procedures, which is 80% of the 1500 capacity. The calculated number of required units of equipment is compared with the current inventory to determine if there is a need.

Steps two, methodology part two. If no unit of fixed cardiac catheterization equipment is located in a service area, a need exists for one shared, fixed cardiac catheterization equipment when the number of mobile procedures done in the service area exceeds 240 or 80% of 300 capacity per year for eight hours per week in operation at that site. And with that, that concludes the review of Chapter 9, cardiac catheterization need methodology.

SPEAKER 1: Thank you, Paige. Does anyone have a question about the methodologies currently outlined in the plan?

(No response.)

SPEAKER 1: Let's move on, then, to the

petition to change the cardiac catheterization need determination methodology submitted by Rex Healthcare. Paige, if you could do the Agency review.

SPEAKER 2: Yes, sir. So the Petitioner was Rex Hospital and we received two comments, which were in opposition to the petition. The request was the Petitioner requests that the methodology for determining need for cardiac catheterization equipment in North Carolina be revised for the 2017 State Medical Facilities Plan.

Specifically, the Petitioner requests changes to step five and six of the cardiac catheterization methodology so that the number of units of fixed cardiac catheterization equipment needed is calculated for each hospital and a need determination is generated irrespective of surpluses at other hospitals in the service area with the exception of hospitals under common ownership where the surpluses and deficits would be totaled.

In Table 1 in the Agency report is a review of the statewide data. It indicates a continued decrease in the number of procedures in 2014, the data year of the 2016 State Medical Facilities Plan.

The current methodology, along with the declining procedure volumes are currently generating very

few need determinations across the state. This year, there was one need determination in Cumberland County generated by the standard methodology for fixed cardiac catheterization equipment.

Applying the proposed methodology to data drawn from the 2016 SMFP, which is the most recent full data set we have available, generates need determinations in Cumberland and Wake Counties. Under the proposed methodology, Wake County would be the only affected county since the existing approved methodology generated a need in Cumberland County.

Also, the Petitioner in the current written request, and at the March 2nd, 2016 public hearing, indicated that there would be a meeting between WakeMed and Rex Hospital which would be -- take place in the coming weeks to discuss collaboration on the issues as discussed in the petition. The Agency is interested to see if a mutual, agreeable resolution may be reached.

The limitations of the methodology as cited in the Petitioner's request and the outcome of the proposed methodology are evident only in Wake County. Data shows a continued decline in cardiac catheterization procedures and relatively few need determinations generated by the current methodology. In the future, any broad examination of the cardiac cath methodology should

include questions brought forth in this petition.

Given the available information and comments submitted by March 18th, the Agency recommends denial of the petition. This concludes the presentation.

SPEAKER 1: Thank you, Paige. I have traditionally treated the Agency recommendation as a -- as a motion, as a basis of discussion, so the proposal is to deny the petition as submitted. It is now open for discussion.

Trey, did you have anything you wanted to offer on this?

SPEAKER 3: I would be curious to know if anybody's heard about the meeting from WakeMed or Rex, if there's been any update on a collegial understanding of how to possibly make this work like we asked them to do last year, and if we could get an update on that from either party.

SPEAKER 1: To the best of my knowledge, I'm not aware that we have that information at this point, but it's an area that we will remain interested in without question. Yes, sir.

SPEAKER 4: I have a question, Dr. (Indiscernible). Is there -- is there another facility or another way, rather than changing the entire policy for this particular -- across the state, for them to

petition or for this to work?

SPEAKER 1: Yes. They could -- they could decide to file what's called a Special Need Petition, which would have a filing date in late July or early August. I haven't looked it up. I think it's early August, typically, and then we consider that at the fall meeting of this committee before the plan. They submitted a request through this mechanism unsuccessfully in the past. That doesn't mean that the next, you know, request will or will not be denied. It has to stand on its own merits.

So implicit in the Agency analysis is that the Special Need Petition channel remains available for local needs, and what that's designed to do is to get away from the one size fits all issue, recognizing you can't write a rule that fits every -- every space.

That Special Needs Petition process is meant to identify where adjustments need to be made based on local conditions that don't fit the assumptions of the methodology.

So the answer is there are other -- there are other channels, and a local agreement could also be a solution in the process.

Dr. Patel, anything you would like to offer on this or --

SPEAKER 5: An amicable solution would be great. I mean, the physicians at Rex, one of them who is here, they do phenomenal work. They're very well trained. They do unique things. An amicable solution would be wonderful.

There's amicable time slots available at, really, hospitals in the vicinity, so -- but that's between UNC and Rex. I mean, and so I agree with Trey. It would be great to have a update.

SPEAKER 1: We will do our best to obtain one as we get closer to the next meeting. That would, of course, impact -- if they come to an agreement, there will be no Special Need Petition necessary in the August filing, if a mutual solution can be found.

I'll also emphasize that -- and you have heard me say this before, that as we have the capacity to do so, we will, as long as I'm chair, we will go through methodology reviews to look at what revisions or changes or what's working and what's not working and this type of a request would be included in that review as to whether or not a facility-based model might be a better model than a county or health service area model going forward, but we don't have the -- you can't make that kind of a review in this short time cycle and have the input you need to have, so we will put that in the, if you want, in

the file folder for when we have the opportunity to undertake that.

SPEAKER 5: One of the questions I would have is are the cardiac catheterizations decreasing nationwide or -- I mean, I would assume we're not any different in North Carolina, but I don't know. I don't want to assume.

SPEAKER 1: I don't have data personally that I -- you know, that I'm familiar with, but I think the trend reflects a national trend based on comments that have been offered by others.

I also am very cognizant of the physician comments at the first meeting of the full committee about late cases, night call, bumping cases. That is not the way any facility wants to operate and I'm very empathetic to that because I've lived that life, but the problem is to find an equitable solution that helps ameliorate that situation, which I stated last time, was a result of conscious, voluntary decisions by the parties involved, sort of a market competitive thing in a way, but that's what -- that's the outcome of it.

So, as I said, if we have the opportunity to form a work group on the entire need methodology, this certainly would be an issue that would be brought back to that discussion going forward, but that's not what we're

capable of doing in this immediate review cycle.

Jeff, anything you want to add or --

SPEAKER 6: I would just add that the landscape of medicine has changed dramatically since these rules were --

SPEAKER 1: Uh-huh.

SPEAKER 6: -- enacted and the application of the methodologies that we're currently using, I think in the present and the future, need to be revised for just such reasons as this. Business follows quality and cost and it's ever more increasingly the cost that matters, not only to the consumer, the end consumer, but the intermediaries, the insurance companies, the federal government, and the distribution of assets, both human and equipment, is following a pattern that I think has changed in the last 20 years, certainly.

SPEAKER 1: Uh-huh.

SPEAKER 6: So I would really suspect that we should visit those rules sooner rather than later.

SPEAKER 1: Yes. I made a -- I agree with you. You know, the assumptions that underline the methodology, which includes sort of free movement of physicians and patients, that marketplace is different now and we need to think through that very carefully.

SPEAKER 6: Uh-huh.

SPEAKER 1: On the phone, Kelly, Valerie?

SPEAKER: I don't have anything further to add. I'd be interested in seeing if we can -- we can put a working group together to -- to reevaluate the methodology.

SPEAKER 1: So noted.

SPEAKER: This is Valerie. I don't have anything further to add, either, other than what's already been said.

SPEAKER 1: Great. Okay. If there are no further items of discussion or viewpoints that have not been expressed, and I'm happy to hear more, a vote "yes" will be to adopt the Agency recommendation, which is to deny the petition, so a yes is for denial of the petition because that's what the recommendation is.

So all of those who are going to vote yes, please signify by saying "aye."

SPEAKERS: Aye.

SPEAKER 1: Are there any --

SPEAKER: Aye.

SPEAKER 1: Aye, okay. The other phone? I only heard one --

SPEAKER: Aye.

SPEAKER 1: Aye. Anyone, no?

(No response.)

SPEAKER 1: So the vote is unanimous to adopt the Agency recommendation.

We now need a motion to adopt the cardiac catheterization section for -- that we have reviewed.

SPEAKER: Motion.

SPEAKER 1: Trey? I'll let Brian be the second.

Now, a vote for yes is to indicate that, basically, the first past review, including the decision on the petition, is our -- is the outcome of this discussion, so all those voting yes, say "aye."

SPEAKERS: Aye.

SPEAKER 1: It's unanimous.

5/25/2016 - SHCC Recording

43:29 to 1:21:35

SPEAKER 1: The final report on the committee side is the Technology and Equipment Committee and, as chairman of that committee, I will give the report to the council.

The Technology and Equipment Committee met on 30 March, 2016 and 27 April, 2016. Topics reviewed and discussed included current policies, assumptions and methodologies for lithotripsy, Gamma Knife, linear accelerators, positron emission tomography, PET scanners,

magnetic resonance imaging scanners, cardiac catheterization equipment for the proposed 2017 SMFP.

Preliminary drafts of need projections generated by the standard methodologies were reviewed. One petition requesting a new policy for MRI scanners was reviewed and voted on. One petition requesting changes to the methodology for cardiac catheterization was reviewed and voted on. One petition requesting changes in the methodology for lithotripsy was reviewed and voted on. Policy TE-3, a plan exemption for fixed magnetic resonance scanners, was also examined.

The following is an overview of the committee's recommendations for consideration by the North Carolina State Health Coordinating Council in preparation of Chapter 9, Technology and Equipment, for the proposed 2017 plan. The report is organized by the equipment sections of Chapter 9.

Chapter 9 lithotripsy, there is one petition and three comments on this section of the chapter. The Petitioner was Hampton Roads Lithotripsy, Incorporated, or LLC. The request was for Hampton Roads Lithotripsy, LLC, that the North Carolina 2017 State Medical Facilities Plan include a new policy regarding lithotripsy. There were three comments in opposition and no supporting comments.

A discussion during the committee meeting included lithotripter inventory, capacity and this year's need determination as detailed in the 2016 SMFP. The members also discussed geographical distribution of sites as outlined in the Agency's report. The committee voted unanimously to recommend denying this petition.

Application of the methodology based on data and information currently available results in no need determination for lithotripsy services in the statewide service area at this time.

Chapter 9, Gamma Knife. There were no petitions or comments on this section of the chapter. Based on the data and information currently available, no draft need determinations have been identified at this time.

Chapter 9, linear accelerators. There were no petitions or comments on this section of the chapter. Applications of the methodology based on data and information currently available result in no draft need determinations at this time.

Chapter 9, positron emission tomography scanners. There were no petitions or comments for this section of the chapter. Application of the methodology based on data and information currently available results in one draft need determination for HSA 4.

This is an update from the information initially presented at the April 27th committee meeting. Duke Raleigh Hospital, with four linear accelerators, exceeding 12,500 ESTV procedures generated a need through the methodology part two.

Chapter 9, magnetic resonance imaging scanners. There was one petition on this section of the chapter. Petitioner was Cape Fear Valley Health System. Cape Fear Valley Health System requested the CHIC to continue its discussion regarding fixed MRI in community hospitals and requested that a new policy, TE-3, fixed MRI scanners in community hospitals, be included in the 2017 State Medical Facilities Plan.

Four comments were received on this petition. Members of the committee acknowledged the recent history of petitions related to MRI capacity for small hospitals located in counties without fixed MRI scanners. Discussions included the number of procedures required to break even on a machine, the need for MRI capabilities for emergency services and the development of additional service lines requiring MRI scans.

There was a consensus that the methodology provided a barrier to obtaining MRI scanners. Members suggested the threshold may be too high for small counties. The committee voted unanimously to recommend

to deny the petition. Dr. Ulrich, the chair of the committee, requested staff develop a policy to present at the second committee meeting on April 27th.

New policy TE-3, plan exemption for fixed magnetic resonance imaging scanners. Qualified applicants may apply for a fixed magnetic resonance imaging scanner. To qualify, the health service facility proposing to acquire the fixed MRI scanner shall demonstrate in its certificate of need application that it is a licensed North Carolina acute care hospital with emergency care coverage 24 hours a day, seven days a week and is located in a county that does not currently have an existing or approved fixed MRI scanner as reflected in the inventory in the applicable State Medical Facilities Plan.

The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year. The performance standards listed in 10(a) NCAC 14(c).2703 would not be applicable. The fixed MRI scanner must be located on the hospital's main campus as defined in 131(e)-176-(14n)A.

I don't know that any of us actually know what those regulations are by that identifier, but these are technical, related to the standards under which they

have to be operated to be a successful applicant.

SPEAKER: And Dr. Ulrich -- did the 850 threshold, did that change or is that the same standard as before?

SPEAKER 1: The prior standard for a single county was 1716 scans. That was derived in 2003 when operating costs were higher. The policy was developed by the staff at the request of the Technology and Equipment Committee and was presented at the April 27 committee meeting. The committee recommends the following.

The committee discussed the 850 threshold and had further conversation about the break even for a machine. Members expressed support of counties with no fixed MRI scanner, obtaining the equipment through a policy. The committee recommends including Policy TE-3 in the proposed 2017 plan.

Let me also say that this is voluntary and not required. It is an opportunity. It will allow these institutions to apply for a CON without a Special Need Petition.

We have entertained, I believe, five similar petitions over a period of years and this will reduce the cost for those small institutions to pursue this, should they deem it necessary.

Similarly, if they're satisfied with their

current service, that arrangement can be maintained or improved as time evolves, so it's an opportunity, not a requirement and it sets the threshold that based on the data numbers submitted in several of the applications is an achievable number for an institution.

Again, the adoption of this by the committee was unanimous. The application of the methodology based on data and information currently available results in two need determinations for fixed MRI scanners in Lincoln and Mecklenburg Counties at this time.

There was one petition with two comments to this petition received on the cardiac catheterization equipment section. The Petitioner was UNC Rex Healthcare. The Petitioner requested that the methodology for determining need for cardiac catheterization equipment in North Carolina be revised for the 2017 State Medical Facilities Plan.

Specifically, the Petitioner requests changes to steps five and six of the cardiac catheterization methodology one so that, in quotations, "The number of units of fixed cardiac catheterization equipment needed is calculated for each hospital and the need determination is generated irrespective of surpluses at other hospitals in the service area," closed quotes, with the exception of hospitals under common ownership

where the "surpluses," again in quotations, "and deficits would be totaled," close quotes. Two comments were received about this petition. Both were in opposition.

The committee discussed the recent history of the petitions for both methodology changes and adjusted need determinations. Using data from the most recent SMFP, changes to the methodology as outlined in the petition would impact only Rex Healthcare, the Petitioner.

Since the current methodology produces very few need determinations, and over the years the adjusted need determinations process has been used successfully in special situations, the committee unanimously recommended denying this specific petition.

The application and the methodology based on data and information currently available results in one need determination for fixed cardiac catheterization equipment in Cumberland County at this time.

Recommendations. The committee recommends the current assumptions methodologies and draft tables for lithotripsy, Gamma Knife, linear accelerators, PET scanners, MRI scanners and cardiac catheterization equipment be accepted for the proposed 2017 plan.

References to dates will be advanced one year as appropriate. The committee authorizes the staff

to update all narratives, tables and need determinations for the proposed 2017 plan as new and corrected data are received. Need determinations, as always, are subject to change.

So the recommendation to adapt the committee report in total needs a motion and then a second and then we can discuss it.

SPEAKER: So moved.

SPEAKER: Second.

SPEAKER 1: Seconded. It is now open for discussion. Rob?

SPEAKER: I read the -- this TE-3, comments from Triangle, you know, where they pointed out that the CMS reimbursement from Medicare for MRIs is 12 and a half percent higher at the hospital and 52% higher with commercial insurance if done at the hospital versus, you know, a private, you know, provider who might want to --

SPEAKER 1: Uh-huh.

SPEAKER: -- offer the same services. What was the discussion on that?

SPEAKER 1: If this were a statewide methodology change, that concern would be more pertinent. In these small counties with a single provider hospital, and the coverage -- basically, acute critical access hospitals in a limited number of counties, the

possibility of opening a separate facility is virtually -- financially, virtually nil.

So that -- and, in fact, the current mobile service has the same, you know, gradient issue in terms of payments. Volumes are very low. So there is virtually no -- in my opinion, virtually no possibility of creating a lower cost, if you will, entry point unless that hospital chose to create a freestanding facility.

However, the petitioner needs in multiple petitions was for access for acute evaluation of emergency room and inpatient emergencies related to stroke and several other conditions, so that I think the committee felt fairly strongly that whatever installation is made, it had to be not only on the campus, but connected to the existing facility so that inpatient access was facilitated without requiring transportation.

SPEAKER: So do any of these facilities now have mobile scanners that just come like a certain day of the week? Is that the problem?

SPEAKER 1: That's -- well, it's not a problem, but it's a -- it's -- these are long-standing -- yeah. There is limited availability in terms of a 24/7/365.

We've had a number of petitions, some accepted, some not, which indicated that they had trouble

sustaining their orthopedic surgery practice with the limited service available in a mobile. They could not recruit oncologists or some other specialty line to the community that required MR as a basic, you know, function, and they had this emergency need where they could not adequately evaluate an admittedly low number of patients, but ones with a very acute and potentially catastrophic health condition.

And this revolves around the Dosher petition, the Person petition, et cetera, et cetera, and so it's a very limited solution. What it really does, Rob, is get us out of having to -- these hospitals go through special need determinations by creating a very narrow, voluntary exception or voluntary pathway through this policy, and my guess is only a couple are likely to even take advantage, that in many cases they're satisfied with their current arrangements or don't want to take on the financial burden of changing those arrangements, but it will be a voluntary business decision and, you know, we can go from there.

We did not have a discussion about changing the current need methodology for MR scanners in the rest of the state at this time. I'll make the observation that the need in Mecklenburg County did not draw a physician group applicant this year, but it was

available.

SPEAKER: We missed that one.

SPEAKER 1: I expected you to be there, but it -- I understand, and there will be -- currently, there's one in the plan for next year again, but I think people are making judgments about what five and seven years later in the healthcare system looks like in the crystal ball. I think you'd agree with me, it is a little cloudy.

SPEAKER: To say the least.

SPEAKER 1: So in any event, it was a very limited discussion at a very targeted subgroup of hospitals that have a very challenged financial environment, but are critical to those communities having access to care, and that's all it will effect.

SPEAKER: I understand. Thank you.

SPEAKER 1: Yeah. Any other questions? That was an excellent question and I was happy to discuss it, but are there any other concerns about any of the items in that report?

(No response.)

SPEAKER 1: Seeing no one holding their hand up, we will move to voting on the -- the committee report for adoption for the proposed plan, recognizing we still have a comment period that people can help us with. All

those in favor of adopting the acute -- or the Technology and Equipment Committee report signify by saying "aye."

SPEAKERS: Aye.

SPEAKER 1: Admitted. Thank you. It is adopted unanimously.

Now, we have as our usual duty another two votes related to formal adoption of the proposed 2017 SMFP as accepted by committee report. We need to adopt the entire plan so that it can be posted and go out for public comment. The approved recommendations of the three standing committees are another step in the development of the 2017 SMFP. I need a motion to adopt the entire proposed 2017 SMFP.

SPEAKER: Motion.

SPEAKER 1: And a second, please?

SPEAKER: Second.

SPEAKER 1: All of those in favor of adopting the plan as currently constructed, signify by saying "aye."

SPEAKERS: Aye.

SPEAKER 1: Any opposed?

(No response.)

SPEAKER 1: Kurt, did you vote?

SPEAKER: Yes.

SPEAKER 1: Good. It's unanimous. We need

a second vote to direct the health planning staff to continue to update tables, narratives and need determinations for the proposed 2017 SMFP as new and corrected data is received. Motion, please?

SPEAKER: So moved.

SPEAKER 1: Moved. Second?

SPEAKER: Second.

SPEAKER 1: Sandra. A vote "yes" is to essentially allow the process of continuing data integrity and table correction. All those in favor, signify by saying "aye."

SPEAKERS: Aye.

SPEAKER 1: Any opposed?

(No response.)

SPEAKER 1: It's unanimous. We will now review the public hearing schedule, which will be provided by Mr. Mark Payne, the assistant secretary for audit and health service regulation. Mark?

SPEAKER: Thank you, Mr. Chairman. We have scheduled six public hearings. The first is in Greensboro on Tuesday, July 12th from 1:30 to 2:30 at the Women's Hospital. The second is in Asheville on Friday, July 15th from 1:30 to 2:30 at Mountain Area Health Educational Center. The third is in Greenville on Tuesday, July 19th from 1:30 to 2:30 at the Pitt County

office building, Commissioner's Auditorium. The next is in Wilmington on Friday, July 22nd, 2016 from 1:30 to 2:30 at the New Hanover County Public Library. The next is in Concord on Monday, July 25th from 1:30 to 2:30 in the CMC Northeast Campus Medical Arts Classroom 1, 2 and 3, and then the final meeting will be here in this room on Thursday, July 28th from 1:30 to 2:30.

Copies of the list of public hearings are available at the sign-in table and also we request that people who will be speaking provide a written copy of their comments.

SPEAKER 1: Thank you, Mr. Secretary. Again, I urge CHIC members to try to make an effort. Yes, Mark?

SPEAKER: I believe on the sign-up sheet for the Concord it says it's on Wednesday. It's just an error there on the sign-up sheet.

SPEAKER 1: And what is the correct --

SPEAKER: It's on Monday, I believe, Monday the 25th. It says Wednesday, the 25th, I think.

SPEAKER: Monday, the 25th, I believe is correct.

SPEAKER 1: I appreciate that updated data.

SPEAKER: I would have shown up late two days.

SPEAKER 1: Yeah, but I might have come two days late. Again, it's important for the CHIC members to try to attend one or more of these meetings if feasible. I got -- I have one of the two sign-up sheets back. I'm not sure where the other one is. Kelly's already got it? Miss Kelly collects those and she will give me a summary. I will typically designate a member of the council to be the chair of a particular public hearing based on who signed up and the staff will be there to support you.

You will be given a set of instructions about how to do it, so you will not be alone as you go through that process. I have always found the hearings to be both informative and amicable, in terms of the attitude in the room.

Rob, you look like you have a question.

SPEAKER: I have some more business I wanted to bring up.

SPEAKER 1: Well, we'll get there.

SPEAKER: All right.

SPEAKER 1: The -- where am I here? Okay. Now, also, before we get to the old business, I will briefly review the remaining committee and full council meeting dates for this year. For the entire State Healthcare Coordinating Council, which is the meeting we have today, there will be a meeting on September 7th,

2016 which is required by the executive order to be held quarterly.

We have done this as a telephone conference call. There will be no substantive votes taken at that meeting, but we will provide information on the petitions which were filed, comments that may have been made that were perhaps previously unheard by the committee and other information items. My expectation is that that conference call would be unlikely to extend beyond one hour, but we need to have that meeting and record it to stay within our charter.

The last business meeting of the year will be October 5th in this room. At that time, we will have the committee reports on the Special Need Petitions and other actions of our three committee and we will adopt a revised SMFP for 2017 that will be submitted to the governor for his review and ultimate signature, and that will conclude our formal cycle for planning for this year.

The committee meetings for -- that precede that final October meeting are the Acute Care Services Committee, which is September 13, 2016 in this room, the Long-term and Behavioral Health Committee, which is September 9th in this room, and Technology and Equipment Committee meeting September 14th, 2016 in this room. Are

there any questions about the committee or the council meetings?

(No response.)

SPEAKER 1: Good. Is there any old business that the CHIC needs to address? Dr. McBride?

SPEAKER: Yes, sir. So three times this year Mr. Lawler has brought up in here, twice in the CHIC and once with the Acute Care Services Committee, that the CHIC should consider instituting a financial penalty or sending a CON for the (indiscernible) demonstration projects if any of the projects did not reach their 7% charity care. In fact, Dr. Green put that on the agenda for the September meeting.

So -- and I'm not worried about it from our demonstration part. I think we have over 7% in our report, but I -- so I wondered -- the question is does the CHIC actually have the authority to do any of those two things, and so I called a bunch of people who I thought might know the answer to that, including the medical society, who didn't know the answer, a CON consultant that we've used who didn't know the answer, and somebody who had served on the CHIC for a long period of time and did not know the answer, either.

So -- but I was able to get to the bottom of it and hopefully either Ms. Ferrell or Ms. Bergen from

the attorney general's office will confirm what I'm going to tell you.

The imposition of a financial penalty is at the authority of the general assembly, and so the State Medical Facilities Plan, of course, is the governor's plan. If a financial penalty was put into it, it would be void because we don't really have the authority to do that.

The other has to do with rescinding a CON. The CHIC does not issue CONs because the CHIC does not have the authority to rescind CONs, and I know you know that lies solely with the authority of the CON section.

And if you read the 2010 State Medical Facility Plan, which I've done and it's easy to pull up, although it's really thick, of course, there's clear language and direction given to the CON section should any of those things happen, either the demonstration projects don't report as they're supposed to or don't reach their targets, their action and authority given to them is what they're supposed to do.

So it would be my -- my opinion, hopefully the attorney general's office, that the CON does not have the authority to do any of those two things and doesn't really need to because the 2010 CHIC already put that language in there.

SPEAKER: And what does the language say that can --

SPEAKER: The language directs them to take any of the demonstration projects to the -- well, they direct them to the Wake County Court, Alice --

SPEAKER: Okay.

SPEAKER: -- or the county that they live in to force them to do those things is what it says.

They also interestingly had language in there that says after five years of collection data, which will be next year, that we're supposed to potentially create a task force to review that data and look at potentially putting demonstration projects elsewhere in the state, so in a year from now, I would guess that that's what we should do.

SPEAKER: Mr. Chairman, just a point of clarity. So, first of all, I appreciate my colleague's comments and my intent in regards to just asking the question was not, you know, to break out a legislative stick.

I mean, the intent of asking the question is, you know, what process do we have in place once we grant a pilot to monitor how that pilot is being successful because, in fact, you know what we're doing is we're saying that in exchange for the opportunity to test

a theory that people are going to get better care, cheaper care or we're going to create greater access points to the people of the state, in exchange for that there are certain benchmarks and certain gates that, you know, those organizations that are participating in the pilot are saying that they're going to meet.

So my question really was directed toward, you know, what's the process that we go through or use, you know, to either provide oversight or to help coach organizations up that may not be hitting those thresholds? You know, there are certainly, you know, legislative or other rules or regs that kind of oversight -- you know, provide oversight to all of that, but, you know, the reason that you have a pilot is to satisfy either an assertion or, you know, an experiment to say by doing this and doing something differently, it provides greater benefit for the folks that we're serving.

So, you know, my suggestion was not a stick suggestion. It was, you know, how are we involved in providing oversight, support and encouragement to hit those targets that are outlined in that pilot.

SPEAKER: Thank you.

SPEAKER 1: All right. My intention has been to take those demonstration projects and have periodic reviews of the data probably through the

committee process. The creation of a taskforce will be discussable when we reach that point. It's going to depend on bandwidth and a number of other things, but I'm not opposed to having that discussion.

There are a number of other unresolved issues, including what happens when a pilot really fails. Secondly, if you look in the tables, there are a number of older pilots which have run well past five years and that don't really have an upgrade path or, you know, a longer term placeholder in the plan that we have never really, forthrightly dealt with or, you know -- you know, what do you do if you -- if the idea no longer works?

SPEAKER: But, you know, when we created the dental projects just recently, I had, personally, a concern that they had a business plan that was going to succeed, so that would certainly be one that we want to keep a close eye on.

SPEAKER 1: Sure. Sure, and I don't -- I have not asked for an update. When's our first application date, Martha, for the dental --

SPEAKER: We've already had that deadline.

SPEAKER 1: And who --

SPEAKER: We received three applications.

SPEAKER 1: Three applications. And who were they? Can you name the applicants by memory?

SPEAKER: No. Actually, we've had two of the need determinations. We have the -- the analysts are doing reviews in the room. We have two applications for both of them, I think, so there's a competing one in Greenville and that's competing with one in Fayetteville, and then we have two proposals here in Wake County --

SPEAKER 1: Okay.

SPEAKER: -- one in Garner, one in Raleigh.

SPEAKER 1: Good. And the second tier of applications for the other HSAs?

SPEAKER: Those are July --

SPEAKER 1: July?

SPEAKER: -- reviews, so they'll be due in June, so they're due fairly soon.

SPEAKER 1: Okay. So then there's the question we've talked about before of what I call zombie CONs where people have one and don't act on it. Some people might characterize it as a form of cyber squatting, but those, I think, have largely diminished as people have taken seriously that those need to be acted on and there have been some discussion, both in the Agency and in this committee in the past, about that.

We have never set a time limit, a dead end -- you know, kind of a drop dead limit to act in the Agency or in the -- but they have to keep filing updates

and then the Agency -- correct me if I'm wrong, but my understanding is basically they have to keep filing updates and the Agency can approve those and go forward and, you know, try to get them to the end point.

The problem with some of them are they're in the -- they get in the plan as a denominator, but there's no -- there's no volume and then they become a suppression, you know, in how we calculate data, so that's not fair to other people, either, so there's got to be a happy medium in there somewhere.

SPEAKER: Perhaps some folks might have a thought because Dr. McBride triggered something in regards to what happened recently is we had approved a linear accelerator for a private urology group and I'm not sure what happened. And I was in support of it, in general, but we approved it and they were waiting to get it online.

I think they got it online and then I'm not sure what happened, but it's very interesting that that CON was approved and was sold to the highest bidder in Wake County, and the highest bidder is not always the best valued institution.

In this county, we had three institutions and the bid was lost to the highest bidder, and the highest bids often have to do with which hospital in a

multi-hospital county gets the most money or has the most money, and I don't think that would be our objective, although I have a solution to deal with that, but it raises the fact that when a CON is provided or, in this case, linear accelerator for treating prostate cancer and if somebody goes under -- it's not about going under and having to unleash their equipment and get back what they invested. The issue at hand is when you sell it to the highest bidder, if that highest bidder gets more money from the insurance industry, that doesn't serve anybody, really, very well in this county or many other counties were patients will be coming to this county for that kind of care.

I don't have the answer to how we -- at no fault of our own, just tremendously increase the cost of care because even if that institution got a direct CON, it still did not have served well, and I spoke to the CEO of another hospital who lost out on the bid and they said, "We just couldn't match the bid," and I'd love to hear thoughts on something like that because that's very interesting.

SPEAKER 1: Well, I wasn't going to discuss the -- the purchaser is Rex Healthcare.

SPEAKER: Oh, I don't -- I don't care for the bid.

SPEAKER 1: But it's a process and --

SPEAKER: (Indiscernible) proposition.

SPEAKER 1: -- they are, as far as I can tell, still bound by the demonstration project requirements as the new -- the new operator of that CON.

This is not a CHIC-specific issue, per se. If you go back and look at the prior cycle of outpatient surgery centers that were established in the 1990s, virtually all of them were subsequently sold to either third-party operators or hospitals, whether it was on a bid basis or just a direct approach for purchase.

They did not stay in the hands of the original applicant. Some operated for a number of years. Some had a shorter life span before change and arrangement. I think Rob's agreeing with me on that.

SPEAKER: Yes, he is (indiscernible) several (indiscernible).

SPEAKER 1: Right. And in different parts of the state there were other purchasers, but we actually had a very similar sort of a cycle, but it was under standard CON arrangements rather than a -- than a demonstration project.

I found this whole episode to be an unhappy moment, to put it nicely. Somebody's chuckling on my other side here. Especially after all the work that went

into that.

And so, you know, my -- the only thing I can say is that I'm certainly going to watch and see that the demonstration project is fulfilled by the new owner as part of their obligation. I believe they want to be compliant and we'll just, you know -- the rest of the process.

SPEAKER: I would like to clarify that once there's an existing facility, that the CON law requires us to exempt the acquisition if we are given prior written notice by a buyer. We do not have any statutory authority to deny that. There are no criteria.

SPEAKER 1: Right.

SPEAKER: As long as it's an existing facility and the buyer gives us prior written notice, it's exempt from CON.

SPEAKER 1: Correct, and we're not empowered to really alter that, but I think -- am I correct, Martha, they have to live up to the demonstration project requirements?

SPEAKER: Yes. Anyone who subsequently acquires a health service facility that did obtain certificates of need, even if it was 20 or 30 years ago, they are required to comply with the material representation. So whoever ends up acquiring a

demonstration project must comply with the representations made in that application regarding the demonstration project.

SPEAKER 1: Right. Interesting -- you know, these are -- these are more about long-term financial arrangements and market forces.

Anyone else have a question? I will -- while people are thinking about whether they want to question, I will ambush my advisor at the attorney general's office to make sure that we have not overstepped or misrepresented the legal situation that this discussion kind of worked around.

SPEAKER: I haven't heard anything that's concerned me.

SPEAKER 1: Good. Good. I don't want to be doing depositions.

SPEAKER: I'll represent you well if you have to.

SPEAKER 1: I'm confident that that will be taken care of, but I still have to make the afternoon off. Rob, is there any action item or --

SPEAKER: No, sir.

SPEAKER 1: I appreciated the research. There are a number of those kind of murky areas about, you know, where do you go and what do you do.

SPEAKER: I thought Martha probably knew the answer, but I was afraid to ask her based on the statement you read at the beginning of each one of these meetings.

SPEAKER: It's not under review.

SPEAKER 1: And my understanding, Martha, is that the notice does not require a disclosure of the arrangements, only that there's a change of ownership?

SPEAKER: That is correct.

SPEAKER 1: So that's where we are, but I was disappointed that it's taken that course and I hope that the new owner vigorously pursues the demonstration project as intended and we'll see what happens.

SPEAKER: They're required to.

SPEAKER 1: Yeah. Well, you can do it with enthusiasm or to the letter, but, in any event, it's there and I think that was a good discussion.

Any additional old business or topics that any member of the council believes should be addressed that we're not addressing at this time?

(No response.)

SPEAKER 1: Good. We have reached the point where I need a motion for adjournment.

SPEAKER: So moved.

SPEAKER 1: Seconded by somebody?

SPEAKER: Second.

SPEAKER 1: Good. All those in favor, say "aye."

SPEAKERS: Aye.

SPEAKER 1: Thank you, Kurt, for being on the phone.

SPEAKER: All right. Thank you.

SPEAKER 1: Thank you everyone and this meeting is officially adjourned.

CERTIFICATE OF NOTARY - COURT REPORTER

STATE OF NORTH CAROLINA)
COUNTY OF WAKE)

I, Lindsey D'Anne Cline, Certified Court Reporter, Notary Public in and for the above county and state, do hereby certify that the above proceedings were transcribed by me at the time and place hereinbefore set forth, under my direction and supervision, and that this is, to the best of my knowledge and belief, a true and correct transcript.

I further certify that I am neither of counsel to either party nor interested in the event of this case.

IN WITNESS WHEREOF, I have hereto set my hand this the 15th day of July, 2016.

_____
Lindsey D'Anne Cline, CVR,
Notary Public, Wake County,
North Carolina
Notary No. 20002130221

Exhibit 3

UNC REX HEALTHCARE

March 28, 2016

Mr. Donald Gintzig, President and CEO
WakeMed Health & Hospitals
3000 New Bern Avenue
Raleigh, NC 27610

Dear Donald:

Thank you and Drs. Sinden and Silver for visiting with Drs. Zidar, Sachar and me recently. We appreciated the opportunity to learn more about your desires and interests in heart and vascular care, and in particular, your opposition to UNC REX's petition to change one or more existing vascular rooms into cardiac catheterization labs at little to no cost. This flexibility would allow for better utilization of UNC Rex's already well utilized rooms. As you know, the equipment for a vascular lab is essentially identical to a cardiac catheterization lab. We're simply asking to use our rooms for multi-purposes rather than a single purpose, just like WakeMed.

Below is a summary of the ideas that were discussed in our meeting:

1. 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?
2. UNC REX suggested leasing or purchasing one or two cardiac catheterization lab CONs from WakeMed at a fair market price. If WakeMed is amenable to this idea, please send us the price and terms of such an arrangement.
3. We believe collaboration on interventional stroke has the potential to provide the greatest impact for the community. Currently, all three Wake County hospitals are building interventional stroke programs independently. We would like to have further discussion with you and Duke Raleigh around what we could accomplish together and how we would structure sharing interventional neurologists. Wake County EMS could continue to take patients to the closest facility and we could share the program costs and data on patients. It would represent substantial savings to the community. This seems manageable with the small number of physicians who would be required.

Steve W. Burriss
President
4420 Lake Boone Trail
Raleigh, NC 27607-6599
(919)784-7264
rexhealth.com

I would like to reiterate a point from our meeting that UNC REX could operate an additional cath lab today, at no cost, in an existing lab if we had a state license. Like WakeMed, we continue to believe in the importance of maintaining the status of CON in North Carolina. We do not need to give opponents of CON examples for their arguments. Allowing for flexible rooms allows for higher utilization of expensive resources and is in the best interest of hospitals and the public.

Thanks again for your time in meeting with us. I look forward to your response on the above questions.

Sincerely,

Steve Burriss
President

cc: Christopher G. Ullrich, MD, Chairman, State Health Coordinating Council

UNC REX HEALTHCARE

February 3, 2016

Mr. Donald Gintzig, President and CEO
WakeMed Health & Hospitals
3000 New Bern Avenue
Raleigh, NC 27610

Dear Donald,

Thank you for your letter regarding the North Carolina State Health Coordinating Council's ("SHCC") recent decision on Rex's petition for one new cardiac catheterization unit in Wake County in the 2016 State Medical Facilities Plan. We were certainly disappointed by the Council's decision and we continue to believe we have a strong and compelling case for the unit that we requested. However, we respect the Council's position and their desire to make sure that the existing cath labs are being utilized to the fullest extent possible. We have been and continue to be open to meetings to discuss ideas for collaboration and cooperation. Accordingly, I will have Julie Molgaard contact your office to schedule such a meeting.

As you prepare for our visit, please understand the significant facilities challenges that we face. We are seeing a significant increase in the volume of heart and vascular patients being treated at UNC REX. We currently operate four cardiac cath labs that are running 24/7 for emergencies. These labs also operate well into the evening for scheduled cases, and on weekends due to the heavy volume of patients who desire to be seen by North Carolina Heart & Vascular and our other leading UNC REX specialty practices.

In addition to our busy cath labs, we have vascular labs whose software could easily be upgraded to perform cardiac procedures for approximately $30,000. Instead we have expensive rooms in which only limited types of procedures can be performed, staff working well into the evening and patients having to wait for care because of your organization's opposition to this software upgrade. To accommodate the volume, we have even resorted to paying $16,000 per month for access to a mobile lab for 3 days each week. The SHCC, employers, payors and the public expect common sense solutions to the high cost of health care. This is an example of where the CON rules have not kept pace with the evolution of the treatment of cardiovascular disease. I think any rational business would choose a one-time upgrade of $30,000 instead of a monthly expense of $16,000.

According to the most recent data your organization supplied to EMMA, UNC REX now performs the most heart and vascular procedures in Wake County, while constrained by half the number of cath labs WakeMed utilizes. UNC REX performed the first Trans Aortic Valve Replacement (TAVR) in Wake County and continues to have the highest volume of procedures. In addition, our peripheral vascular program provides services not being offered anywhere else in Wake County. Because of the growing reputation of our heart and vascular program, UNC REX now receives 300 transfer patients per month from other parts of our

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rexhealth.com

state; these are primarily patients with significant heart issues from eastern North Carolina. This has created further capacity constraints.

We congratulate you on the accolades listed in your letter. Our community can feel comfortable knowing there are three quality hospitals to care for them. We too are recognized by many of the same organizations, but in addition, UNC REX is the only North Carolina hospital to receive national distinction for patient care and safety by The Leapfrog Group with its 2015 Top Hospital Award, all while receiving Medicare reimbursement that is 25.7% lower than WakeMed. It is unfortunate that the incidence of heart and vascular disease continues to be one of the highest causes of mortality in our state. We understand that prevention needs to be as much as if not more of our focus as treatment of the disease, and that's why the North Carolina Heart & Vascular Hospital will have a full demonstration kitchen to help educate our community about heart healthy cooking. We also are helping to train physicians from across North Carolina, the nation and the world by transmitting cases locally and globally and teaching teams of physicians traveling to UNC REX. Prevention and education are two ways to reduce the cost of health care, and might provide a partnership opportunity for us to further explore.

I always welcome the opportunity to discuss how we can work together to improve the health of the people in our region. I look forward to our meeting to speak in more detail about possible partnership opportunities.

Sincerely,

Steve Burriss
President

cc: Members of the North Carolina State Health Coordinating Council

file

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

January 5, 2016

Mr. Steve Burris, President
UNC REX Healthcare
4420 Lake Boone Trail
Raleigh, NC 27507

Dear Steve,

On October 7, 2015, the North Carolina State Health Coordinating Council voted to deny a petition filed by Rex Healthcare for one new unit of cardiac catheterization equipment in Wake County in the 2016 State Medical Facilities Plan. The Council cited the surplus of existing cardiac cath labs already located in Wake County as the primary reason behind its decision. The Council encouraged hospital leaders to enter into a dialogue regarding more effective use of the county's cardiac cath equipment, rather than to continue to add capacity, to meet the needs of the community and region.

This purpose of this letter is to begin that discussion. WakeMed would very much welcome the opportunity to meet with UNC REX Healthcare, and its affiliated physicians, to identify potential innovative partnerships to best meet the cardiovascular needs of our community and state.

As a leading regional cardiac referral center, our cardiology team performs more than tens of thousands of procedures a year. Patients come from all 100 North Carolina counties, and out of state, to access WakeMed heart services. BlueCross BlueShield of North Carolina recognizes WakeMed as a Blue Distinction Center for Cardiac Care for its focus on quality, patient safety, clinical outcomes and affordability. The WakeMed Raleigh Campus and Cary Hospital are both certified Chest Pain Centers and accredited in Heart Failure care. WakeMed's cardiovascular program continues to receive high honors by the American College of Cardiology, the American Heart Association and the Society of Thoracic Surgeons National Database.

These accolades are a direct reflection of the years of commitment, dating back to 1968, which WakeMed has made by employing exceptional talent, building state-of-the-art facilities and purchasing cutting-edge technology and equipment. We made these tremendous investments because the residents of Wake County, our region and the state deserve the best when it comes to caring for their hearts.

Currently WakeMed operates 10 cardiac catheterization labs – nine on the Raleigh Campus and one at Cary Hospital. The nine cath labs on the Raleigh Campus are staffed 24/7, ready to respond to a heart attack around the clock. Additionally, the Raleigh campus is home to the Heart Center Inn with 38 rooms specifically designed for heart patients' families. Your physicians are extremely familiar with the WakeMed heart team and facilities.

While WakeMed fully recognizes UNC REX Healthcare's plans to develop a second heart center in Raleigh, we also appreciate the NC SHCC's guidance and encouragement of our organizations to avoid expensive and unnecessary duplication of resources resulting in higher

medical costs. Policy makers at national, state and local levels all agree and have communicated clearly that health care cost too much. Let's prove to them that we can still compete, 10-miles away from one another, while working to identify ways to apply common sense, maximize existing capacity and help make healthcare more affordable. WakeMed accepts this challenge because it is in the best interest of the residents of Wake County and beyond.

We hope to meet with you and your senior leadership to discuss how we can foster a mutually beneficial relationship, one that improves the provision of patient care and that ensures the optimal utilization of health care resources in Wake County. Let's set the example for our colleagues around the state.

Please feel free to contact me at 919-350-8112 at your earliest convenience to discuss this matter. Thank you for your consideration.

Very Respectfully,

Happy 2016

Donald R. Gintzig
President & CEO

cc: Members of the North Carolina State Health Coordinating Council

Exhibit 4

Received 3-2-16
DHHS-DHSR
Healthcare Planning

PETITION

Petition for Change to Cardiac Catheterization Need Determination Methodology

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

INTRODUCTION

UNC REX Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to change the Cardiac Catheterization Need Determination Methodology in the *2017 State Medical Facilities Plan* (*2017 SMFP*). This request is the most recent in a series of 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 be able 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 means that its labs are operating at 116 percent of capacity. While there are significant operational and logistical challenges to operating at these utilization levels, Rex would encourage the SHCC to consider that these challenges also impact the lives of patients. 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. In addition, while the SHCC may view this issue as being limited to cardiac catheterization equipment, and certainly that is the scope of Rex's petition, it is important to understand that cardiac care for even a single patient is rarely limited to cardiac catheterization procedures, as explained in further detail below. Cardiac catheterization is part of

comprehensive cardiac care which rarely starts and ends in the cath lab. Thus, delays in providing cardiac catheterization services has negative effects on multiple other services, impacting additional patients, families, physicians and staff.

As the SHCC is aware, WakeMed's CEO, Donald Gintzig, sent a letter to Rex to discuss collaboration on these issues and copied each member of the council. Rex responded and has begun the process of setting up a meeting between the two parties. Rex welcomes the opportunity to meet with WakeMed and determine a positive solution. However, 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 is submitting the proposed petition and strongly encourages the SHCC to consider it on its merits and to also not assume that the discussions with WakeMed will correct the imbalance in the allocation of cardiac catheterization equipment in Wake County.

In particular, 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: 2016 Hospital License Renewal Applications.

Thus, even if WakeMed were to agree to sell Rex two of its excess machines, Duke Raleigh's sizable surplus could soon become an obstacle to the ability to develop new capacity. 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 specifics of Rex's current petition are provided later in this document, but first, this document will address several issues raised during deliberations of the SHCC on previous Rex petitions for this service. While Rex believes that approving its petitions are the best thing for patients, and though Rex's petitions are consistent with the Basic Principles of the *SMFP*, it is clear that Rex's opponents have attempted to politicize the petition process, providing some SHCC members with incorrect information that has surfaced in the SHCC meetings. Rex does not believe that providing such misinformation, particularly outside of public forums, is helpful to the patients it serves and would urge the SHCC to focus on the salient facts before it. However, given that some SHCC members have raised secondary issues, Rex believes that these should be addressed. As detailed below, Rex believes that approval of its petitions would be:

1. Similar to past SHCC actions and not precedent-setting;
2. A positive impact on the cost of care based on independent reimbursement data and other factors; and,
3. The most effective solution given physician privileges and the need to provide access across the region.

Each of these issues is addressed below.

Precedent

In opposing Rex's petitions, several SHCC members have stated that an approval would be precedent-setting. 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*. 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 expressly designed to allow for changes outside of the standard methodologies or changes to the methodology. 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. 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 so that it could end a business relationship with Alliance for the lease of its existing unit. 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.

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. Rex believes just the opposite for several reasons.

Contrary to the statements made by some SHCC members, 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[1], 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	
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	

1 In arguing against Rex's petition, one SHCC member cited the development the Rex-Raleigh Orthopaedic Clinic joint venture ambulatory surgery center (ASC), Raleigh Orthopaedic Surgery Center (ROSC). Contrary to those statements, ROSC is a freestanding ASC which provides a low-cost surgical alternative to existing hospital-based options in Wake County. The Rex-Raleigh Orthopaedic Clinic relationship is a mutually beneficial partnership that provides significant value to patients.

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

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 for the complete data available from Blue Cross Blue Shield of North Carolina tool. *Only data for "Left heart cath" and "coronary bypass with cardiac cath" is provided by the Blue Cross Blue Shield of North Carolina tool for cardiac catheterization services. Left and right heart catheterization costs are not available.

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 providers 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

Finally, 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 solution would be a one-time upgrade for $30,000 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.

Physician Privileges

In the SHCC's prior discussions of Rex's petitions, 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, 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.

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 between physicians, staff, and hospital. Patients are choosing North Carolina Heart & Vascular and Rex due to this offering. 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.

STATEMENT OF THE PROPOSED CHANGE

Rex requests that the threshold for additional cardiac catheterization equipment in the Cardiac Catheterization Need Determination Methodology be applied to

each hospital, or in the case of hospitals under common ownership in the same service area, to each group of commonly-owned hospitals. Need determinations would be granted once equipment is appropriately utilized irrespective of the utilization of other hospitals in the same service area. Rex proposes the changes described below to Chapter 9: Cardiac Catheterization Need Determination Methodology, Methodology 1 (Fixed Cardiac Catheterization Equipment). Please note the Steps 1 to 4 remain unchanged.

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

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

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

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

a) For each facility, the number of units of fixed cardiac catheterization equipment needed is equal to the deficit as calculated in Step 5 rounded to nearest whole number. If a facility has a surplus, there is no resulting need determination.

b) The number of units of fixed cardiac catheterization equipment needed is calculated for each hospital, and a need determination is generated irrespective of surpluses at other hospitals in the service area, unless there are other hospitals in the service area under common ownership.

c) If two or more hospitals in the same service area are under common ownership, the surpluses and deficits for those hospitals are totaled as calculated in Step 5. The number of units of fixed cardiac catheterization equipment needed for hospitals under common ownership is equal to the summed total deficit rounded to nearest whole number. If hospitals under common ownership have a surplus in total, there is no resulting need determination.

d) The projected need determinations of all facilities and owners in the service area will be summed to determine the total number of units of fixed cardiac catheterization equipment needed in the service area. Any pending CONs in the service area should be subtracted from the total number of units needed.

IMPACT OF THE PROPOSED CHANGE

Based on Rex's review of the 2016 Hospital License Renewal Applications and Inventory of Medical Equipment Forms, the impact of the proposed change is limited to Wake County, in which a need determination for two units of fixed cardiac catheterization equipment for the *2017 SMFP* would be generated. Both of these units would be based on the utilization at Rex, which currently shows a deficit of 1.78 units. Please note that Rex's proposed change, while having an immediate impact in only Wake County, would only ever have the possbililty of impacting six counties statewide where there are two or more providers of cardiac catheterization services not under common ownership. For example, the proposed change would have no impact on the projected need determination in Cumberland County, where Cape Fear Valley Medical Center will generate a need with or without Rex's proposed change. Please see Attachment 2 for detailed tables comparing the results of the current methodology and the proposed methodology for the six impacted counties. As discussed below, Rex believes the proposed change is needed in order to provide access to cardiac

catheterization services, and that it will not have adverse effects on providers or consumers, will not result in unnecessary duplication, and is consistent with the Basic Principles of the *SMFP*.

BACKGROUND

The various methodologies in the *SMFP* generally consider need based either on the entire service area or each individual provider. The current cardiac catheterization methodology determines need based on the entire service area, and as a result, individual providers may have a significant deficit, but no need is determined to exist in the area because of the surplus at other providers.

A service area approach for allocating capacity may be reasonable for certain services, particularly those for which the service is merely one adjunct to the overall diagnostic process and treatment plan. For example, a patient needing an MRI scan to support a diagnosis may choose an MRI provider separate from his physician or hospital, without it negatively impacting his diagnosis or treatment, particularly on an outpatient basis, as the vast majority of MRI scans are provided.

Other services, however, are much more central to the overall process of diagnosis and treatment, require a physician present to perform the procedure, and may be performed more often on an inpatient basis than other procedures. Such is the case for cardiac catheterization services. The cardiology practice, which is comprised a team of providers, including medical, invasive, interventional and surgical cardiologists, has been chosen by the patient to provide his or her care. This team is central to the diagnosis and treatment, and the interventional cardiologist is directly involved with performing the procedure on the patient. Since those physicians have been chosen by the patient to provide his or her care, the notion of the physician referring the patient to a physician at another facility, just because there may be more cardiac catheterization capacity available there, is extraordinarily unlikely, as well as being disruptive to the continuity of care. Although cardiologists may be privileged at multiple hospitals, they typically choose a single facility at which to perform most of their procedural work for efficiency, as discussed above with regard to North Carolina Heart & Vascular. The utilization of a particular facility is thus driven primarily by physician and patient preference, not the deficit or surplus at a facility. Therefore, a facility-specific methodology for cardiac catheterization is more appropriate than a service area-based methodology.

As noted above, other methodologies within the *SMFP* use a facility-specific approach, consistent with the proposed change, including the methodologies for acute care beds and PET scanners. In contrast, the existing fixed cardiac catheterization need determination methodology calculates projected need based on the aggregate need within each service area. However, since cardiac catheterization services are limited to hospital providers, and since most service areas include only one hospital, the vast majority of facilities have a need methodology that is, in essence, facility-based. Specifically, in the 39 cardiac catheterization service areas, all but seven (7) of them have only one fixed cardiac catheterization provider. In each of these service areas, the need methodology bases its calculation on the utilization of a single facility, and so the methodology is effectively facility-specific for the majority of state. In the remaining seven service areas in which there are two or more providers of fixed cardiac catheterization services, the need methodology calculates projected need based on the aggregate need of all providers in the service area. As such, the utilization of a single facility is subordinate to overall utilization. Please note, however, that the Durham/Caswell Service Area includes two hospitals under the common ownership of Duke University Health System; thus, as a result, the proposed methodology will have no impact on this service area.[3] Therefore, only six (6) service areas would ever be affected by the proposed change in the methodology.

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

Although Rex believes the proposed change is important, and though it will change the methodology statewide, it does not believe it will have a far-reaching impact. As the SHCC is aware, since 2003, cardiac catheterization volume has

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

decreased statewide, although it does appear to have stabilized in recent years. Given this trend, it is unlikely that many providers will generate a need in the near future. However, Rex believes the methodology should evolve to reflect changes in healthcare, including the increasing alignment between physicians and hospitals in single systems of care, which has led to substantial shifts of patients among providers. In this context, the cardiac catheterization methodology must be more flexible in responding to the needs of specific facilities and the patients and physicians who choose to utilize them.

Prior Responses from the SHCC and the Medical Facilities Planning Section

Rex proposed changes to the cardiac catheterization methodology in its 2014 methodology change petition. The SHCC denied that petition following the recommendation of the Medical Facilities Planning Section in its Agency Report. Rex believes that the following discussion responds to the issues raised by the Medical Facilities Planning staff in recommending denial of Rex's 2014 methodology change petition.

The Agency Report for Rex's 2014 methodology change petition stated that "[w]*hile the petitioner's proposed methodology change did not make specific changes to Step 1 of the methodology, the proposal would have an impact on pending CONs . . .* [u]*nder the suggested methodology change it would be possible for a need determination to be generated without regard to a pending CON review.*" In order to remedy this potential issue, Rex has added language to Step 6d indicating that pending CONs be subtracted for the need determination calculation for the service area. Please note that acute care bed methodology has historically managed pending CON awards in this manner with success.

The Agency Report for Rex's 2014 methodology change petition stated that "*there is the potential for one facility in a service area to generate a need but the CON is awarded to a different facility in the service area. Thus, additional need determinations for the service area could again be generated the next year due to the procedures performed at the facility that initially generated the need. This would increase the service area's capacity unnecessarily but would not benefit the facility that triggered the need. Seven service areas in the state have multiple cardiac catheterization service providers that could generate this scenario.*"

First, Rex believes it is important to note that this hypothetical scenario would not be unique to cardiac catheterization equipment. A repeated need determination, as suggested in this example, is possible for all multi-provider service areas under the acute care bed and PET methodologies, as a need determination could be generated by one facility and awarded to a different

facility with the original facility generating another need in subsequent years. In practice, this scenario would occur very infrequently and only as a result of unique circumstances because the different facility would need to demonstrate to the CON Section why the need for additional capacity is located at its facility rather than the facility that generated the need.

Further, unlike acute care beds, cardiac catheterization has special CON rules that only allow for the approval of providers that have historically operated their cardiac catheterization equipment at 80 percent of capacity. The acute care bed rules have no historic performance standard, thus, a historically underutilized provider could be approved to add capacity. Finally, an applicant proposing to add cardiac catheterization capacity must demonstrate to the CON Section that the projected utilization of its existing and proposed equipment will be 60 percent of equipment. Specifically, 10A NCAC 14C . 1603 states, as excerpted below:

(a) An applicant proposing to acquire cardiac catheterization equipment shall demonstrate that the project is capable of meeting the following standards:

(1) each proposed item of cardiac catheterization equipment, including mobile equipment but excluding shared fixed cardiac catheterization equipment, shall be utilized at an annual rate of at least 60 percent of capacity excluding procedures not defined as cardiac catheterization procedures in 10A NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of the project;

(c) An applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac catheterization shall:

(1) demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, located in the proposed cardiac catheterization service area operated at an average of at least 80 percent of capacity during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Health Service Regulation;

(2) demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the fourth quarter of the third year following completion of the project; and

Thus, if one facility in a service area generates a cardiac catheterization need, the CON could only be awarded to a different facility in the service area, if that different facility demonstrates to the CON Section that its historical and projected utilization meets these performance standards.

The 2014 Agency Report stated that "*a facility specific calculation is used for acute care bed needs. However, in determining need for acute beds (both licensed and pending) all projected deficits and surpluses for each facility are total for the service area and can offset each other.*" The Agency Report was mistaken in this statement. Under the acute care bed methodology, the projected deficits and surpluses for each facility under common ownership are totaled and can offset one another. However, the total deficit for one group of facilities under common ownership creates a need determination regardless of any other facilities in the service area. Please see the Mecklenburg County service area in the *2013 SMFP* as an example where the Carolinas HealthCare System deficit of 40 beds (identified as Carolinas Medical Center Total) resulted in a need determination without regard for Novant Health's surplus of 44 beds (identified as Presbyterian Hospital Total). Similar examples exist in the Wake County service area in the *2011 SMFP* and the Mecklenburg County service area in both the *2008* and *2009 SMFPs*.

The 2014 Agency Report stated that under Rex's proposal "*need is generated at a considerably lower threshold than with the current methodology.*" Rex now proposes to leave that threshold unchanged at a deficit of 0.5 units, rounded to the nearest whole number.

The 2014 Agency Report noted that "*the total volume of cardiac catheterization procedures performed with fixed equipment in North Carolina has declined steadily since 2005*" and suggests that the proposed change is unnecessary in light of this decline and could result in the over-projection of need. It is Rex's belief that the proposed change is necessary due to the nature of cardiac catheterization services. Specifically, cardiac catheterization is central to the overall process of diagnosis and treatment. Please see the discussion above for greater detail on the reasons why the need for cardiac catheterization should be evaluated by facility rather than across a service area. In this context, Rex does not believe the statewide trend is relevant in evaluating its proposed methodology change. The SHCC should not ignore potential improvements to the *SMFP* if volume trends suggest that they are unlikely to impact a significant number of providers.

REASON FOR THE REQUESTED ADJUSTMENT

Rex believes that the cardiac catheterization methodology should determine need on a facility-specific basis, which would provide an equitable approach and only impact a minority of the hospitals across the state. Highly utilized providers would be able to generate need determinations, regardless of underutilized providers in the same service area. It should be noted any need determination generated under the proposed change would still be subject to Certificate of

Need review, whereby any qualified provider could apply for, and demonstrate the need to acquire, additional cardiac catheterization equipment. Underutilized providers could not be approved to develop capacity created by these need determinations as they would not meet the historical performance standards in the special CON rules.

The proposed change will further the efforts of those healthcare systems that are working to improve their quality and continuity of care. As noted above, Rex also believes this change would be consistent with other recommendations from the SHCC delineated above.

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

The benefits of a change in the need methodology are evident in considering Rex's growing need for capacity. In 2015, Rex's cardiac catheterization utilization indicated a deficit of one unit of equipment. While the Agency Report recommended approval of a special need adjustment for the one unit requested by Rex, the SHCC ultimately failed to approve the petition. One year later, Rex's cardiac catheterization utilization indicates a deficit of two units of equipment, so that even if the previous special need adjustment had been approved, Rex would face a deficit of another unit and another capacity need. A revised methodology would have appropriately allocated additional capacity as Rex's volume has grown.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

As noted above, the current fixed cardiac catheterization need determination methodology can perpetuate imbalances between highly utilized and underutilized providers in the same service area. An underutilized provider diminishes the need demonstrated by a highly utilized provider. A provider could operate above the utilization standards indefinitely and not be able to acquire additional capacity, if another provider in its community was sufficiently underutilized. There is no remedy for the patients, physicians, and providers in such a situation for cardiac catheterization services outside of a methodology change, as proposed, or a special need adjustment.

As a result, the greatest adverse effect of the failure to approve the petition is the negative impacts that continuing capacity constraints have on patient safety,

quality, and convenience. As volume continues to increase at highly utilized providers, the *SMFP* methodology will not provide additional capacity. The ability to provide timely emergency procedures, high quality and convenient outpatient diagnostic procedures, and seamless care within a system of care will increasingly be more challenging.

ALTERNATIVES CONSIDERED

File a Petition for a Special Need Adjustment

As noted above, Rex has chosen this alternative in 2014 and 2015 and was denied by the SHCC. One of the reasons provided by a SHCC member for voting against the most recent petition is that the current SMFP methodology for cardiac catheterization addresses need for all providers, not just a single facility. Notwithstanding the fact that the SHCC has approved petitions in similar circumstances many times, Rex is proposing to change the methodology in light of the SHCC member's suggestion that the methodology should be changed before a need is generated in Wake County. Regardless, the current cardiac catheterization methodology is unequitable and perpetuates imbalances between providers. A petition in the summer for a special need adjustment would, at best, result in a one-time allocation and would fail to address the problematic aspects of the current methodology. While Rex believes a special need determination can remedy the growing issues for cardiac catheterization capacity in Wake County, it would not address potential issues in other counties or issues that arise in future years. Again, Rex's recent experience demonstrates, a provider experiencing continuing growth could result in repetitive special need adjustments without the proposed change to the methodology.

Exclude Chronically Underutilized Facilities

The operating room methodology excludes chronically underutilized facilities in order to remedy the imbalances between highly utilized and underutilized providers. Rex does not believe this approach is appropriate for the cardiac catheterization methodology for several reasons. First, there is no consensus around an appropriate definition of a chronically underutilized cardiac catheterization provider. Such a definition would need to account for the emergency, life-saving nature of the service and its subsequent vital importance in many communities, regardless of utilization. More importantly, the majority of the state is already treated with a facility-specific methodology, effectively, and an extension of that approach to the remainder of the state would provide the needed remedy. Finally, the number of cardiac catheterization units in each

service area is much lower than the number of operating rooms, and most providers have at least modest utilization levels. Thus, the exclusion of chronically underutilized facilities would not be as useful for this methodology. It should be noted, however, that in Wake County, if the 40 percent underutilization threshold were applied to cardiac catheterization as it is to operating rooms, four of the 17 units in Wake County (nearly one-quarter) would be excluded: three at Duke Raleigh Hospital and one at WakeMed Cary. Such a step would still not correct the imbalance in the county; however, it demonstrates that the issues concerning cardiac catheterization in Wake County go beyond just Rex and WakeMed's main campus.

UNNECESSARY DUPLICATION

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

BASIC PRINCIPLES

If the SHCC is committed to developing an *SMFP* in accordance with the Basic Principles of Safety and Quality, Access, and Value, then it must recognize that the status quo fails to meet the needs of the citizens of North Carolina under these standards, and it should therefore approve Rex's petition, which would positively impact these principles.

Safety and Quality

The proposed methodology change will provide a process for facilities to generate cardiac catheterization capacity regardless of the utilization of other providers. Without this methodology change, a provider could indefinitely operate its cardiac catheterization equipment at high levels of utilization without any possibility of acquiring additional capacity through the current methodology. In such a situation, a facility may not be able to provide optimal safety and quality of care. Cardiac catheterization services must be available

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

Access

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

More specifically, the SHCC's denial of Rex's petitions limits access to Rex's patient who have chosen to receive care at Rex. 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 & Vascular physicians see patients in 15 offices in nine counties. Increasing these physicians' access to cardiac catheterization capacity at Rex, rather than duplicating coverage at WakeMed, allows them to continue providing access for these patients across a large region, including areas where no interventional cardiac catheterization

capacity exists . For example, patients in Franklin, Harnett, and Sampson counties who see North Carolina Heart & Vascular physicians in local offices will have greater access to cardiac catheterization services which are not available in their home county. Instead of expanding access, the suggestion by some SHCC members that North Carolina Heart & Vascular begin practicing at WakeMed would result in duplicating coverage at WakeMed, forcing the physicians to reduce access in these suburban counties.

Value

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

In the specific circumstances of Wake County, 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.

CONCLUSION

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

Thank you for your consideration.

Attachment 1

NC

Estimated Treatment Cost Results

Coronary bypass with cardiac cath, 10 miles from raleigh, nc - Modify Your Search

Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits.

Rex Hospital

4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$54,998

Blue Options, Blue Advantage
$66,975

Wakemed Raleigh Campus

3000 New Bern Ave
Raleigh, NC 27610

Blue Value
$63,963

Blue Options, Blue Advantage
$84,706

Data last Updated [illegible]

Sort By:

Cost

Sort

IMPORTANT INFORMATION: The information provided in this tool is **FOR INFORMATIONAL PURPOSES ONLY**. The estimates listed are averages and your actual costs may be different based on factors such as your health plan design, deductibles/co-insurance and out-of-pocket limits.

Please note that many providers practice at multiple locations, and your costs can vary based on the location where you receive service. We cannot guarantee that a provider listed in this tool at the time of your search will be in network at the time you receive service. This is because we regularly add providers to our network – and occasionally providers decide to leave our network.

For questions about how much you will actually pay for a health care service, please contact your insurer. If you are currently a BCBSNC member, please login to our Member Services portal and use our cost estimator tool for members, which will provide a more customized estimate based on your actual benefits.

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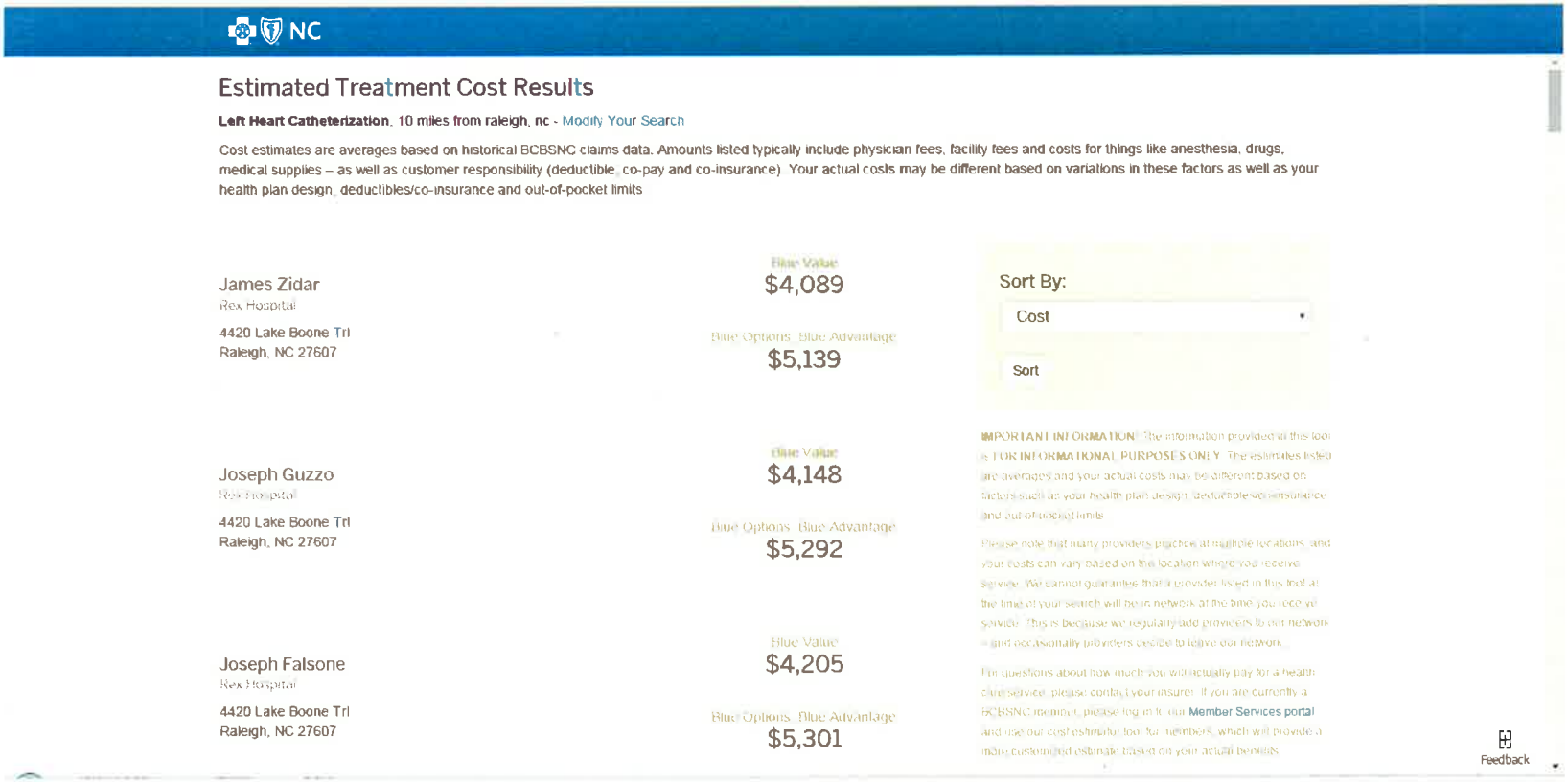
Feedback


NC
Estimated Treatment Cost Results
Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search
Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits
James Zidar
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607
Blue Value
$4,089
Blue Options Blue Advantage
$5,139
Joseph Guzzo
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607
Blue Value
$4,148
Blue Options Blue Advantage
$5,292
Joseph Falsone
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607
Blue Value
$4,205
Blue Options Blue Advantage
$5,301
Sort By:
Cost
Sort
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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Robert Bruner Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,294 Blue Options, Blue Advantage $5,478	Sort By: Cost Sort
George Adams Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,333 Blue Options, Blue Advantage $5,454	
Bruce Usher Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,508 Blue Options, Blue Advantage $5,677	

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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Deepak Pasi Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,515 Blue Options, Blue Advantage $5,692	
James Scanlan Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,521 Blue Options, Blue Advantage $5,722	
Mateen Akhtar Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,535 Blue Options, Blue Advantage $5,709	

Sort By:

Cost

Sort

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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Rex Hospital

4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,555

Blue Options, Blue Advantage
$5,747

Matthew Hook

Rex Hospital

4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,577

Blue Options, Blue Advantage
$5,784

Mohit Pasi

Rex Hospital

4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,586

Blue Options, Blue Advantage
$5,793

Sort By:

Cost

Sort

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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Sameh Mobarek
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,633

Blue Options, Blue Advantage
$5,810

Gregory Rose
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,633

Blue Options, Blue Advantage
$5,816

Robert Jobe
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,652

Blue Options, Blue Advantage
$5,870

Sort By:

Cost

Sort

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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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David Walker Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,774 Blue Options, Blue Advantage $6,030	Sort By: Cost Sort
William Newman Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,832 Blue Options, Blue Advantage $6,099	
Ravish Sachar Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,845 Blue Options, Blue Advantage $6,092	

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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits

Sagir Ahmed Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $5,054 Blue Options, Blue Advantage $6,461	
Willis Wu Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $5,121 Blue Options, Blue Advantage $6,490	
Benjamin Atkeson Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $5,360 Blue Options, Blue Advantage $6,795	

Sort By:

Cost

Sort

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[+] Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Joel Schneider
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$5,510

Blue Options: Blue Advantage
$6,969

J. Richard Daw
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options: Blue Advantage
$7,968

Maitreya Thakkar
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options: Blue Advantage
$8,022

Jimmy Locklear
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options: Blue Advantage
$8,237

Sort By:

Cost

Sort

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[+]
Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits.

Siddhartha Rao
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,274

Pratik Desai
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,294

Franklin Wefald
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,294

Islam Othman
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,297

James Nutt

Blue Options, Blue Advantage

Sort By:

Cost

Sort

IMPORTANT INFORMATION: The information provided in this tool is FOR INFORMATIONAL PURPOSES ONLY. The assembled/estimated prices and your actual costs may be different based on factors such as your health plan design, deductibles/co-insurance, and out-of-pocket limits.

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[+] Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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James Nutt WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,378
Robert Jobe WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,407
Virgil Wynia WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,434
John Kelley WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,437
Joel Schneider		

Sort By:

Cost

Sort

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[–]
Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization 10 miles from raleigh, nc - Modify Your Search

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Joel Schneider
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,465

Dhirenkumar Shah
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,481

Shalendra Varma
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,499

Matthew Hook
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,554

WakeMed

Blue Options, Blue Advantage

Sort By:

Cost

Sort

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[+] Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,560

Willis Wu
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,572

Sumeet Subherwal
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,653

Mateen Akhtar
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,677

Jack Noneman
WakeMed
3000 New Bern Ave

Blue Options, Blue Advantage
$8,787

Sort By:
Cost
Sort

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[+] Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization 10 miles from raleigh, nc - Modify Your Search

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Jack Noneman WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,787
Pavlo Netrebko WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,836
Amarendra Reddy WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,879
Rama Garimella WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,917
Priyavadan Shah	Blue Options, Blue Advantage	

Sort By:

Cost

Sort

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[–]
Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Priyavadan Shah WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$10,013
Mark Leithe Duke Raleigh Hospital 3400 Wake Forest Rd Raleigh, NC 27609	Blue Options, Blue Advantage	$10,468
Duke Raleigh Hospital 3400 Wake Forest Rd Raleigh, NC 27609	Blue Options, Blue Advantage	$10,883
James Mills Duke Raleigh Hospital 3400 Wake Forest Rd Raleigh, NC 27609	Blue Options, Blue Advantage	$12,114
John Sinden WakeMed	Blue Options, Blue Advantage	[illegible]

Sort By:

Cost

Sort

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[+] Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits.

Duke Raleigh Hospital
3400 Wake Forest Rd
Raleigh, NC 27609

Blue Options, Blue Advantage
$10,883

James Mills
Duke Raleigh Hospital
3400 Wake Forest Rd
Raleigh, NC 27609

Blue Options, Blue Advantage
$12,114

John Sinden
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$12,160

Brian Go
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$12,247

Data Last Updated 07/23/2015

Sort By:
Cost
Sort

IMPORTANT INFORMATION: The information provided in this tool is **FOR INFORMATIONAL PURPOSES ONLY**. The estimates listed are averages and your actual costs may be different based on factors such as your health plan design, deductibles/co-insurance and out-of-pocket limits.

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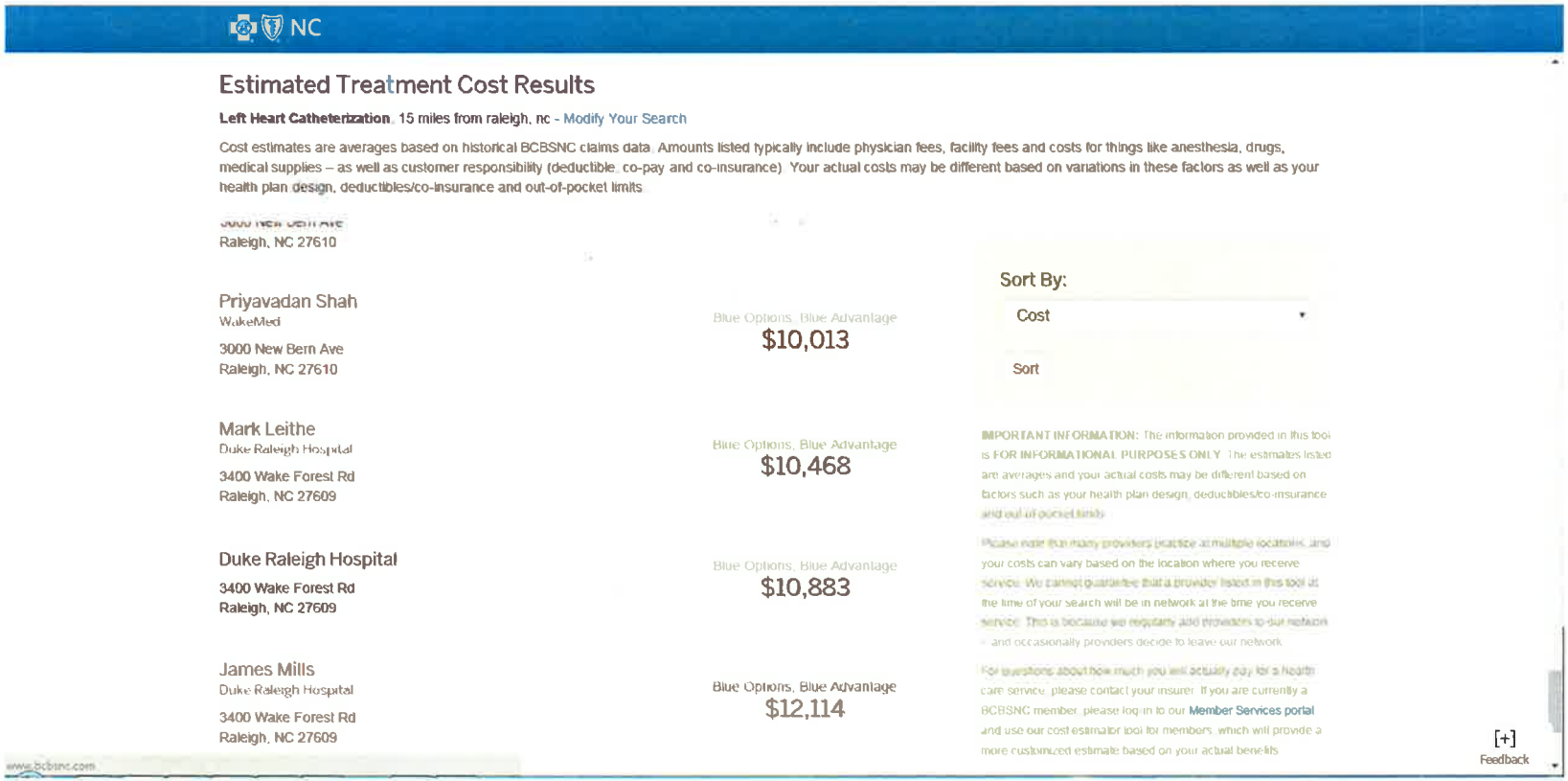
[+] Feedback


NC
Estimated Treatment Cost Results
Left Heart Catheterization, 15 miles from raleigh, nc - Modify Your Search
Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits.
Raleigh, NC 27610
Priyavadan Shah
WakeMed
3000 New Bern Ave
Raleigh, NC 27610
Blue Options, Blue Advantage
$10,013
Mark Leithe
Duke Raleigh Hospital
3400 Wake Forest Rd
Raleigh, NC 27609
Blue Options, Blue Advantage
$10,468
Duke Raleigh Hospital
3400 Wake Forest Rd
Raleigh, NC 27609
Blue Options, Blue Advantage
$10,883
James Mills
Duke Raleigh Hospital
3400 Wake Forest Rd
Raleigh, NC 27609
Blue Options, Blue Advantage
$12,114
Sort By:
Cost
Sort
IMPORTANT INFORMATION: The information provided in this tool is FOR INFORMATIONAL PURPOSES ONLY. The estimates listed are averages and your actual costs may be different based on factors such as your health plan design, deductibles/co-insurance and out-of-pocket limits.
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[+]
Feedback
www.bcbsnc.com

Attachment 2

Cardiac Catheterization Equipment Service Areas	Facility	Total Planning Inventory	2015 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed
Catawba	Catawba Valley Medical Center	1	1,108	0.92	0	
	Frye Regional Medical Center	4	3,026	2.52	0	
	TOTAL	**5**		**3**		**0**
Forsyth	Novant Health Forsyth Medical Center	8	4,730	3.94	0	
	N.C. Baptist Hospital	5	3,775	3.15	0	
	TOTAL	**13**		**7**		**0**
Guilford	High Point Regional Health System	4	3,124	2.60	0	
	Cone Health	7	4,987	4.16	0	
	The Cardiovascular Diagnostic Center*	1	661	0.55	0	
	TOTAL	**12**		**7**		**0**
Iredell	Iredell Memorial Hospital	1	982	0.82	0	
	Davis Regional Medical Center	1	462	0.38	0	
	Lake Norman Regional Medical Center*	1	63	0.05	0	
	TOTAL	**3**		**1**		**0**
Mecklenburg	Carolinas Medical Center/Mercy	8	6,846	5.71	0	
	CHS Pineville	3	2,642	2.20	0	
	Novant Health Presbyterian Medical Center	4	2,933	2.44	0	
	Carolinas Medical Center-University	1	34	0.03	0	
	Novant Health Matthews Medical Center	1	1,156	0.96	0	
	TOTAL	**17**		**11**		**0**
Wake	Rex Hospital	4	6,934	5.78	2	
	WakeMed	9	7,567	6.31	0	
	WakeMed Cary	1	205	0.17	0	
	Duke Raleigh Hospital	3	463	0.39	0	
	TOTAL	**17**		**13**		**0**

*2014 data was utilized as the 2016 License Renewal Applications for these facilities could not be obtained.

Grey colored cells indicate changes from current methodology

Cardiac Catheterization Equipment Service Areas	Facility	Total Planning Inventory	2013 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed	Need Determinations
Catawba	Catawba Valley Medical Center	1	1,108	0.92	(0.08)	0	
	Frye Regional Medical Center	4	3,026	2.52	(1.48)	0	
	TOTAL	**5**					**0**
Forsyth	N.C. Baptist Hospital	5	3,775	3.15	(1.85)	0	
	Novant Health Forsyth Medical Center	8	4,730	3.94	(4.06)	0	
	TOTAL						**0**
Guilford	The Cardiovascular Diagnostic Center*	1	661	0.55	(0.45)		
	Cone Health	7	4,987	4.16	(2.84)		
	Cone Health Total				***(3.29)***	***0***	
	High Point Regional Health System	4	3,124	2.60	(1.40)	0	
	TOTAL						**0**
Iredell	Davis Regional Medical Center	1	462	0.38	(0.62)	0	
	Iredell Memorial Hospital	1	982	0.82	(0.18)	0	
	Lake Norman Regional Medical Center*	1	63	0.05	(0.95)	0	
	TOTAL						**0**
Mecklenburg	Carolinas Medical Center/Mercy	8	6,846	5.71	(2.29)		
	CHS Pineville	3	2,642	2.20	(0.80)		
	Carolinas Medical Center-University	1	34	0.03	(0.97)		
	Carolinas HealthCare System Total				***(4.07)***	***0***	
	Novant Health Matthews Medical Center	1	1,156	0.96	(0.04)		
	Novant Health Presbyterian Medical Center	4	2,933	2.44	(1.56)		
	Novant Health Total				***(1.59)***	***0***	
	TOTAL			**11**			**0**
Wake	WakeMed	9	7,567	6.31	(2.69)		
	WakeMed Cary	1	205	0.17	(0.83)		
	WakeMed Total				***(3.52)***	***0***	
	Duke Raleigh Hospital	3	463	0.39	(2.61)	0	
	Rex Hospital	4	6,934	5.78	1.78	2	
	TOTAL						**2**

*2014 data was utilized as the 2016 License Renewal Applications for these facilities could not be obtained.

Received 3-2-16
DHHS-DHSR
Healthcare Planning

PETITION

Petition for Change to Cardiac Catheterization Need Determination Methodology

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

INTRODUCTION

UNC REX Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to change the Cardiac Catheterization Need Determination Methodology in the *2017 State Medical Facilities Plan* (*2017 SMFP*). This request is the most recent in a series of 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 be able 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 means that its labs are operating at 116 percent of capacity. While there are significant operational and logistical challenges to operating at these utilization levels, Rex would encourage the SHCC to consider that these challenges also impact the lives of patients. 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. In addition, while the SHCC may view this issue as being limited to cardiac catheterization equipment, and certainly that is the scope of Rex's petition, it is important to understand that cardiac care for even a single patient is rarely limited to cardiac catheterization procedures, as explained in further detail below. Cardiac catheterization is part of

comprehensive cardiac care which rarely starts and ends in the cath lab. Thus, delays in providing cardiac catheterization services has negative effects on multiple other services, impacting additional patients, families, physicians and staff.

As the SHCC is aware, WakeMed's CEO, Donald Gintzig, sent a letter to Rex to discuss collaboration on these issues and copied each member of the council. Rex responded and has begun the process of setting up a meeting between the two parties. Rex welcomes the opportunity to meet with WakeMed and determine a positive solution. However, 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 is submitting the proposed petition and strongly encourages the SHCC to consider it on its merits and to also not assume that the discussions with WakeMed will correct the imbalance in the allocation of cardiac catheterization equipment in Wake County.

In particular, 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: 2016 Hospital License Renewal Applications.

Thus, even if WakeMed were to agree to sell Rex two of its excess machines, Duke Raleigh's sizable surplus could soon become an obstacle to the ability to develop new capacity. 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 specifics of Rex's current petition are provided later in this document, but first, this document will address several issues raised during deliberations of the SHCC on previous Rex petitions for this service. While Rex believes that approving its petitions are the best thing for patients, and though Rex's petitions are consistent with the Basic Principles of the *SMFP*, it is clear that Rex's opponents have attempted to politicize the petition process, providing some SHCC members with incorrect information that has surfaced in the SHCC meetings. Rex does not believe that providing such misinformation, particularly outside of public forums, is helpful to the patients it serves and would urge the SHCC to focus on the salient facts before it. However, given that some SHCC members have raised secondary issues, Rex believes that these should be addressed. As detailed below, Rex believes that approval of its petitions would be:

1. Similar to past SHCC actions and not precedent-setting;
2. A positive impact on the cost of care based on independent reimbursement data and other factors; and,
3. The most effective solution given physician privileges and the need to provide access across the region.

Each of these issues is addressed below.

Precedent

In opposing Rex's petitions, several SHCC members have stated that an approval would be precedent-setting. 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*. 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 expressly designed to allow for changes outside of the standard methodologies or changes to the methodology. 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. 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 so that it could end a business relationship with Alliance for the lease of its existing unit. 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.

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. Rex believes just the opposite for several reasons.

Contrary to the statements made by some SHCC members, 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[1], 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	
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	

1 In arguing against Rex's petition, one SHCC member cited the development the Rex-Raleigh Orthopaedic Clinic joint venture ambulatory surgery center (ASC), Raleigh Orthopaedic Surgery Center (ROSC). Contrary to those statements, ROSC is a freestanding ASC which provides a low-cost surgical alternative to existing hospital-based options in Wake County. The Rex-Raleigh Orthopaedic Clinic relationship is a mutually beneficial partnership that provides significant value to patients.

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

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 for the complete data available from Blue Cross Blue Shield of North Carolina tool. *Only data for "Left heart cath" and "coronary bypass with cardiac cath" is provided by the Blue Cross Blue Shield of North Carolina tool for cardiac catheterization services. Left and right heart catheterization costs are not available.

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 providers 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

Finally, 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 solution would be a one-time upgrade for $30,000 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.

Physician Privileges

In the SHCC's prior discussions of Rex's petitions, 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, 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.

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 between physicians, staff, and hospital. Patients are choosing North Carolina Heart & Vascular and Rex due to this offering. 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.

STATEMENT OF THE PROPOSED CHANGE

Rex requests that the threshold for additional cardiac catheterization equipment in the Cardiac Catheterization Need Determination Methodology be applied to

each hospital, or in the case of hospitals under common ownership in the same service area, to each group of commonly-owned hospitals. Need determinations would be granted once equipment is appropriately utilized irrespective of the utilization of other hospitals in the same service area. Rex proposes the changes described below to Chapter 9: Cardiac Catheterization Need Determination Methodology, Methodology 1 (Fixed Cardiac Catheterization Equipment). Please note the Steps 1 to 4 remain unchanged.

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

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

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

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

a) For each facility, the number of units of fixed cardiac catheterization equipment needed is equal to the deficit as calculated in Step 5 rounded to nearest whole number. If a facility has a surplus, there is no resulting need determination.

b) The number of units of fixed cardiac catheterization equipment needed is calculated for each hospital, and a need determination is generated irrespective of surpluses at other hospitals in the service area, unless there are other hospitals in the service area under common ownership.

c) If two or more hospitals in the same service area are under common ownership, the surpluses and deficits for those hospitals are totaled as calculated in Step 5. The number of units of fixed cardiac catheterization equipment needed for hospitals under common ownership is equal to the summed total deficit rounded to nearest whole number. If hospitals under common ownership have a surplus in total, there is no resulting need determination.

d) The projected need determinations of all facilities and owners in the service area will be summed to determine the total number of units of fixed cardiac catheterization equipment needed in the service area. Any pending CONs in the service area should be subtracted from the total number of units needed.

IMPACT OF THE PROPOSED CHANGE

Based on Rex's review of the 2016 Hospital License Renewal Applications and Inventory of Medical Equipment Forms, the impact of the proposed change is limited to Wake County, in which a need determination for two units of fixed cardiac catheterization equipment for the *2017 SMFP* would be generated. Both of these units would be based on the utilization at Rex, which currently shows a deficit of 1.78 units. Please note that Rex's proposed change, while having an immediate impact in only Wake County, would only ever have the possbililty of impacting six counties statewide where there are two or more providers of cardiac catheterization services not under common ownership. For example, the proposed change would have no impact on the projected need determination in Cumberland County, where Cape Fear Valley Medical Center will generate a need with or without Rex's proposed change. Please see Attachment 2 for detailed tables comparing the results of the current methodology and the proposed methodology for the six impacted counties. As discussed below, Rex believes the proposed change is needed in order to provide access to cardiac

catheterization services, and that it will not have adverse effects on providers or consumers, will not result in unnecessary duplication, and is consistent with the Basic Principles of the *SMFP*.

BACKGROUND

The various methodologies in the *SMFP* generally consider need based either on the entire service area or each individual provider. The current cardiac catheterization methodology determines need based on the entire service area, and as a result, individual providers may have a significant deficit, but no need is determined to exist in the area because of the surplus at other providers.

A service area approach for allocating capacity may be reasonable for certain services, particularly those for which the service is merely one adjunct to the overall diagnostic process and treatment plan. For example, a patient needing an MRI scan to support a diagnosis may choose an MRI provider separate from his physician or hospital, without it negatively impacting his diagnosis or treatment, particularly on an outpatient basis, as the vast majority of MRI scans are provided.

Other services, however, are much more central to the overall process of diagnosis and treatment, require a physician present to perform the procedure, and may be performed more often on an inpatient basis than other procedures. Such is the case for cardiac catheterization services. The cardiology practice, which is comprised a team of providers, including medical, invasive, interventional and surgical cardiologists, has been chosen by the patient to provide his or her care. This team is central to the diagnosis and treatment, and the interventional cardiologist is directly involved with performing the procedure on the patient. Since those physicians have been chosen by the patient to provide his or her care, the notion of the physician referring the patient to a physician at another facility, just because there may be more cardiac catheterization capacity available there, is extraordinarily unlikely, as well as being disruptive to the continuity of care. Although cardiologists may be privileged at multiple hospitals, they typically choose a single facility at which to perform most of their procedural work for efficiency, as discussed above with regard to North Carolina Heart & Vascular. The utilization of a particular facility is thus driven primarily by physician and patient preference, not the deficit or surplus at a facility. Therefore, a facility-specific methodology for cardiac catheterization is more appropriate than a service area-based methodology.

As noted above, other methodologies within the *SMFP* use a facility-specific approach, consistent with the proposed change, including the methodologies for acute care beds and PET scanners. In contrast, the existing fixed cardiac catheterization need determination methodology calculates projected need based on the aggregate need within each service area. However, since cardiac catheterization services are limited to hospital providers, and since most service areas include only one hospital, the vast majority of facilities have a need methodology that is, in essence, facility-based. Specifically, in the 39 cardiac catheterization service areas, all but seven (7) of them have only one fixed cardiac catheterization provider. In each of these service areas, the need methodology bases its calculation on the utilization of a single facility, and so the methodology is effectively facility-specific for the majority of state. In the remaining seven service areas in which there are two or more providers of fixed cardiac catheterization services, the need methodology calculates projected need based on the aggregate need of all providers in the service area. As such, the utilization of a single facility is subordinate to overall utilization. Please note, however, that the Durham/Caswell Service Area includes two hospitals under the common ownership of Duke University Health System; thus, as a result, the proposed methodology will have no impact on this service area.[3] Therefore, only six (6) service areas would ever be affected by the proposed change in the methodology.

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

Although Rex believes the proposed change is important, and though it will change the methodology statewide, it does not believe it will have a far-reaching impact. As the SHCC is aware, since 2003, cardiac catheterization volume has

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

decreased statewide, although it does appear to have stabilized in recent years. Given this trend, it is unlikely that many providers will generate a need in the near future. However, Rex believes the methodology should evolve to reflect changes in healthcare, including the increasing alignment between physicians and hospitals in single systems of care, which has led to substantial shifts of patients among providers. In this context, the cardiac catheterization methodology must be more flexible in responding to the needs of specific facilities and the patients and physicians who choose to utilize them.

Prior Responses from the SHCC and the Medical Facilities Planning Section

Rex proposed changes to the cardiac catheterization methodology in its 2014 methodology change petition. The SHCC denied that petition following the recommendation of the Medical Facilities Planning Section in its Agency Report. Rex believes that the following discussion responds to the issues raised by the Medical Facilities Planning staff in recommending denial of Rex's 2014 methodology change petition.

The Agency Report for Rex's 2014 methodology change petition stated that "[w]*hile the petitioner's proposed methodology change did not make specific changes to Step 1 of the methodology, the proposal would have an impact on pending CONs . . .* [u]*nder the suggested methodology change it would be possible for a need determination to be generated without regard to a pending CON review.*" In order to remedy this potential issue, Rex has added language to Step 6d indicating that pending CONs be subtracted for the need determination calculation for the service area. Please note that acute care bed methodology has historically managed pending CON awards in this manner with success.

The Agency Report for Rex's 2014 methodology change petition stated that "*there is the potential for one facility in a service area to generate a need but the CON is awarded to a different facility in the service area. Thus, additional need determinations for the service area could again be generated the next year due to the procedures performed at the facility that initially generated the need. This would increase the service area's capacity unnecessarily but would not benefit the facility that triggered the need. Seven service areas in the state have multiple cardiac catheterization service providers that could generate this scenario.*"

First, Rex believes it is important to note that this hypothetical scenario would not be unique to cardiac catheterization equipment. A repeated need determination, as suggested in this example, is possible for all multi-provider service areas under the acute care bed and PET methodologies, as a need determination could be generated by one facility and awarded to a different

facility with the original facility generating another need in subsequent years. In practice, this scenario would occur very infrequently and only as a result of unique circumstances because the different facility would need to demonstrate to the CON Section why the need for additional capacity is located at its facility rather than the facility that generated the need.

Further, unlike acute care beds, cardiac catheterization has special CON rules that only allow for the approval of providers that have historically operated their cardiac catheterization equipment at 80 percent of capacity. The acute care bed rules have no historic performance standard, thus, a historically underutilized provider could be approved to add capacity. Finally, an applicant proposing to add cardiac catheterization capacity must demonstrate to the CON Section that the projected utilization of its existing and proposed equipment will be 60 percent of equipment. Specifically, 10A NCAC 14C . 1603 states, as excerpted below:

(a) An applicant proposing to acquire cardiac catheterization equipment shall demonstrate that the project is capable of meeting the following standards:

(1) each proposed item of cardiac catheterization equipment, including mobile equipment but excluding shared fixed cardiac catheterization equipment, shall be utilized at an annual rate of at least 60 percent of capacity excluding procedures not defined as cardiac catheterization procedures in 10A NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of the project;

(c) An applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac catheterization shall:

(1) demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, located in the proposed cardiac catheterization service area operated at an average of at least 80 percent of capacity during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Health Service Regulation;

(2) demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the fourth quarter of the third year following completion of the project; and

Thus, if one facility in a service area generates a cardiac catheterization need, the CON could only be awarded to a different facility in the service area, if that different facility demonstrates to the CON Section that its historical and projected utilization meets these performance standards.

The 2014 Agency Report stated that "*a facility specific calculation is used for acute care bed needs. However, in determining need for acute beds (both licensed and pending) all projected deficits and surpluses for each facility are total for the service area and can offset each other.*" The Agency Report was mistaken in this statement. Under the acute care bed methodology, the projected deficits and surpluses for each facility under common ownership are totaled and can offset one another. However, the total deficit for one group of facilities under common ownership creates a need determination regardless of any other facilities in the service area. Please see the Mecklenburg County service area in the *2013 SMFP* as an example where the Carolinas HealthCare System deficit of 40 beds (identified as Carolinas Medical Center Total) resulted in a need determination without regard for Novant Health's surplus of 44 beds (identified as Presbyterian Hospital Total). Similar examples exist in the Wake County service area in the *2011 SMFP* and the Mecklenburg County service area in both the *2008* and *2009 SMFPs*.

The 2014 Agency Report stated that under Rex's proposal "*need is generated at a considerably lower threshold than with the current methodology.*" Rex now proposes to leave that threshold unchanged at a deficit of 0.5 units, rounded to the nearest whole number.

The 2014 Agency Report noted that "*the total volume of cardiac catheterization procedures performed with fixed equipment in North Carolina has declined steadily since 2005*" and suggests that the proposed change is unnecessary in light of this decline and could result in the over-projection of need. It is Rex's belief that the proposed change is necessary due to the nature of cardiac catheterization services. Specifically, cardiac catheterization is central to the overall process of diagnosis and treatment. Please see the discussion above for greater detail on the reasons why the need for cardiac catheterization should be evaluated by facility rather than across a service area. In this context, Rex does not believe the statewide trend is relevant in evaluating its proposed methodology change. The SHCC should not ignore potential improvements to the *SMFP* if volume trends suggest that they are unlikely to impact a significant number of providers.

REASON FOR THE REQUESTED ADJUSTMENT

Rex believes that the cardiac catheterization methodology should determine need on a facility-specific basis, which would provide an equitable approach and only impact a minority of the hospitals across the state. Highly utilized providers would be able to generate need determinations, regardless of underutilized providers in the same service area. It should be noted any need determination generated under the proposed change would still be subject to Certificate of

Need review, whereby any qualified provider could apply for, and demonstrate the need to acquire, additional cardiac catheterization equipment. Underutilized providers could not be approved to develop capacity created by these need determinations as they would not meet the historical performance standards in the special CON rules.

The proposed change will further the efforts of those healthcare systems that are working to improve their quality and continuity of care. As noted above, Rex also believes this change would be consistent with other recommendations from the SHCC delineated above.

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

The benefits of a change in the need methodology are evident in considering Rex's growing need for capacity. In 2015, Rex's cardiac catheterization utilization indicated a deficit of one unit of equipment. While the Agency Report recommended approval of a special need adjustment for the one unit requested by Rex, the SHCC ultimately failed to approve the petition. One year later, Rex's cardiac catheterization utilization indicates a deficit of two units of equipment, so that even if the previous special need adjustment had been approved, Rex would face a deficit of another unit and another capacity need. A revised methodology would have appropriately allocated additional capacity as Rex's volume has grown.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

As noted above, the current fixed cardiac catheterization need determination methodology can perpetuate imbalances between highly utilized and underutilized providers in the same service area. An underutilized provider diminishes the need demonstrated by a highly utilized provider. A provider could operate above the utilization standards indefinitely and not be able to acquire additional capacity, if another provider in its community was sufficiently underutilized. There is no remedy for the patients, physicians, and providers in such a situation for cardiac catheterization services outside of a methodology change, as proposed, or a special need adjustment.

As a result, the greatest adverse effect of the failure to approve the petition is the negative impacts that continuing capacity constraints have on patient safety,

quality, and convenience. As volume continues to increase at highly utilized providers, the *SMFP* methodology will not provide additional capacity. The ability to provide timely emergency procedures, high quality and convenient outpatient diagnostic procedures, and seamless care within a system of care will increasingly be more challenging.

ALTERNATIVES CONSIDERED

File a Petition for a Special Need Adjustment

As noted above, Rex has chosen this alternative in 2014 and 2015 and was denied by the SHCC. One of the reasons provided by a SHCC member for voting against the most recent petition is that the current SMFP methodology for cardiac catheterization addresses need for all providers, not just a single facility. Notwithstanding the fact that the SHCC has approved petitions in similar circumstances many times, Rex is proposing to change the methodology in light of the SHCC member's suggestion that the methodology should be changed before a need is generated in Wake County. Regardless, the current cardiac catheterization methodology is unequitable and perpetuates imbalances between providers. A petition in the summer for a special need adjustment would, at best, result in a one-time allocation and would fail to address the problematic aspects of the current methodology. While Rex believes a special need determination can remedy the growing issues for cardiac catheterization capacity in Wake County, it would not address potential issues in other counties or issues that arise in future years. Again, Rex's recent experience demonstrates, a provider experiencing continuing growth could result in repetitive special need adjustments without the proposed change to the methodology.

Exclude Chronically Underutilized Facilities

The operating room methodology excludes chronically underutilized facilities in order to remedy the imbalances between highly utilized and underutilized providers. Rex does not believe this approach is appropriate for the cardiac catheterization methodology for several reasons. First, there is no consensus around an appropriate definition of a chronically underutilized cardiac catheterization provider. Such a definition would need to account for the emergency, life-saving nature of the service and its subsequent vital importance in many communities, regardless of utilization. More importantly, the majority of the state is already treated with a facility-specific methodology, effectively, and an extension of that approach to the remainder of the state would provide the needed remedy. Finally, the number of cardiac catheterization units in each

service area is much lower than the number of operating rooms, and most providers have at least modest utilization levels. Thus, the exclusion of chronically underutilized facilities would not be as useful for this methodology. It should be noted, however, that in Wake County, if the 40 percent underutilization threshold were applied to cardiac catheterization as it is to operating rooms, four of the 17 units in Wake County (nearly one-quarter) would be excluded: three at Duke Raleigh Hospital and one at WakeMed Cary. Such a step would still not correct the imbalance in the county; however, it demonstrates that the issues concerning cardiac catheterization in Wake County go beyond just Rex and WakeMed's main campus.

UNNECESSARY DUPLICATION

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

BASIC PRINCIPLES

If the SHCC is committed to developing an *SMFP* in accordance with the Basic Principles of Safety and Quality, Access, and Value, then it must recognize that the status quo fails to meet the needs of the citizens of North Carolina under these standards, and it should therefore approve Rex's petition, which would positively impact these principles.

Safety and Quality

The proposed methodology change will provide a process for facilities to generate cardiac catheterization capacity regardless of the utilization of other providers. Without this methodology change, a provider could indefinitely operate its cardiac catheterization equipment at high levels of utilization without any possibility of acquiring additional capacity through the current methodology. In such a situation, a facility may not be able to provide optimal safety and quality of care. Cardiac catheterization services must be available

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

Access

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

More specifically, the SHCC's denial of Rex's petitions limits access to Rex's patient who have chosen to receive care at Rex. 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 & Vascular physicians see patients in 15 offices in nine counties. Increasing these physicians' access to cardiac catheterization capacity at Rex, rather than duplicating coverage at WakeMed, allows them to continue providing access for these patients across a large region, including areas where no interventional cardiac catheterization

capacity exists . For example, patients in Franklin, Harnett, and Sampson counties who see North Carolina Heart & Vascular physicians in local offices will have greater access to cardiac catheterization services which are not available in their home county. Instead of expanding access, the suggestion by some SHCC members that North Carolina Heart & Vascular begin practicing at WakeMed would result in duplicating coverage at WakeMed, forcing the physicians to reduce access in these suburban counties.

Value

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

In the specific circumstances of Wake County, 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.

CONCLUSION

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

Thank you for your consideration.

Attachment 1

NC

Estimated Treatment Cost Results

Coronary bypass with cardiac cath, 10 miles from raleigh, nc - Modify Your Search

Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits.

Rex Hospital

4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$54,998

Blue Options, Blue Advantage
$66,975

Wakemed Raleigh Campus

3000 New Bern Ave
Raleigh, NC 27610

Blue Value
$63,963

Blue Options, Blue Advantage
$84,706

Data last Updated [illegible]

Sort By:

Cost

Sort

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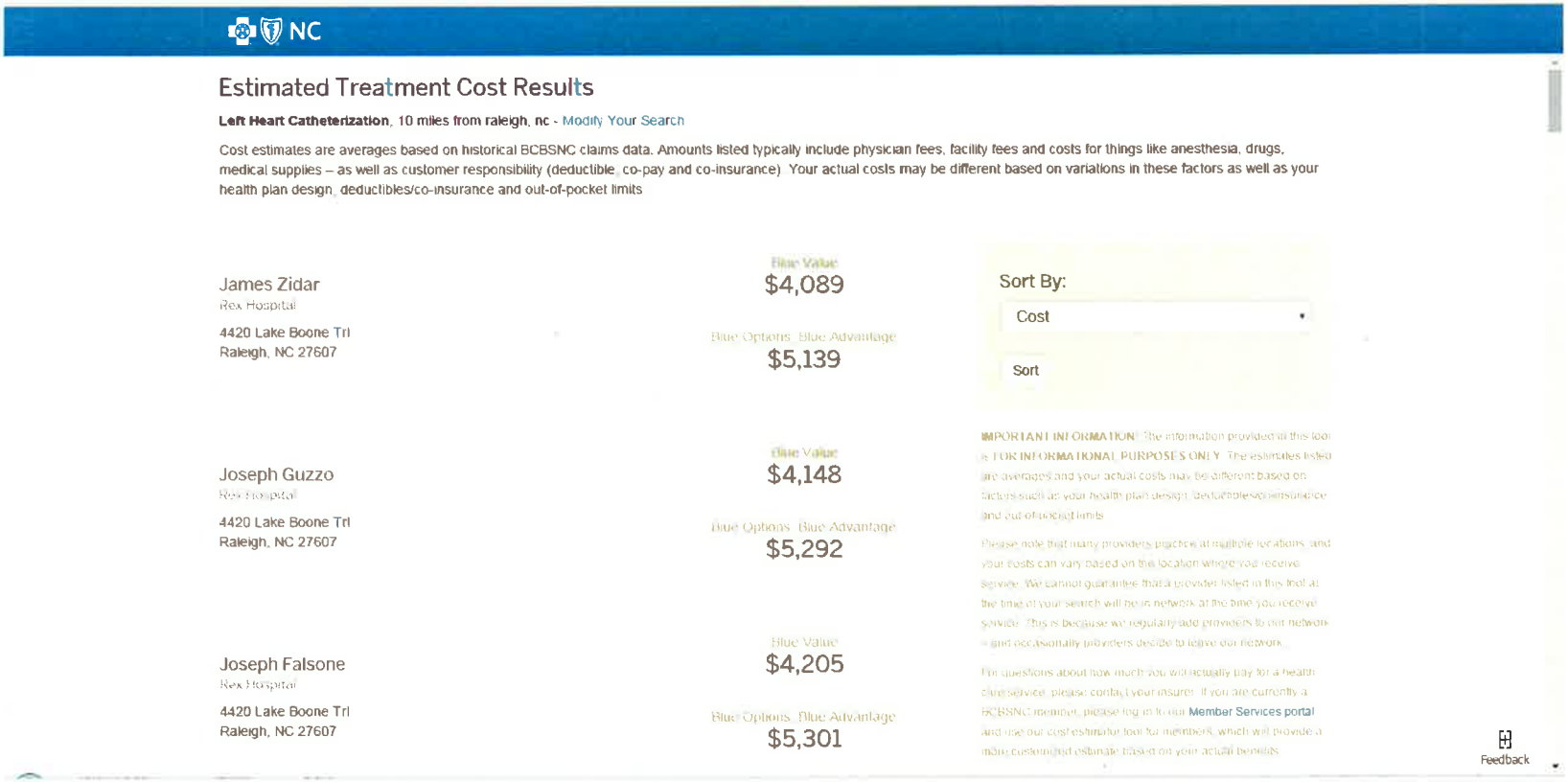
Feedback


NC
Estimated Treatment Cost Results
Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search
Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits
James Zidar
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607
Blue Value
$4,089
Blue Options Blue Advantage
$5,139
Joseph Guzzo
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607
Blue Value
$4,148
Blue Options Blue Advantage
$5,292
Joseph Falsone
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607
Blue Value
$4,205
Blue Options Blue Advantage
$5,301
Sort By:
Cost
Sort
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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Robert Bruner Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,294 Blue Options, Blue Advantage $5,478	Sort By: Cost Sort
George Adams Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,333 Blue Options, Blue Advantage $5,454	
Bruce Usher Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,508 Blue Options, Blue Advantage $5,677	

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[–]
Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Deepak Pasi Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,515 Blue Options, Blue Advantage $5,692	
James Scanlan Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,521 Blue Options, Blue Advantage $5,722	
Mateen Akhtar Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,535 Blue Options, Blue Advantage $5,709	

Sort By:

Cost

Sort

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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Rex Hospital

4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,555

Blue Options, Blue Advantage
$5,747

Matthew Hook

Rex Hospital

4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,577

Blue Options, Blue Advantage
$5,784

Mohit Pasi

Rex Hospital

4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,586

Blue Options, Blue Advantage
$5,793

Sort By:

Cost

Sort

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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Sameh Mobarek
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,633

Blue Options, Blue Advantage
$5,810

Gregory Rose
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,633

Blue Options, Blue Advantage
$5,816

Robert Jobe
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$4,652

Blue Options, Blue Advantage
$5,870

Sort By:

Cost

Sort

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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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David Walker Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,774 Blue Options, Blue Advantage $6,030	Sort By: Cost Sort
William Newman Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,832 Blue Options, Blue Advantage $6,099	
Ravish Sachar Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $4,845 Blue Options, Blue Advantage $6,092	

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Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Sagir Ahmed Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $5,054 Blue Options, Blue Advantage $6,461	
Willis Wu Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $5,121 Blue Options, Blue Advantage $6,490	
Benjamin Atkeson Rex Hospital 4420 Lake Boone Trl Raleigh, NC 27607	Blue Value $5,360 Blue Options, Blue Advantage $6,795	

Sort By:

Cost

Sort

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[+] Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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Joel Schneider
Rex Hospital
4420 Lake Boone Trl
Raleigh, NC 27607

Blue Value
$5,510

Blue Options: Blue Advantage
$6,969

J. Richard Daw
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options: Blue Advantage
$7,968

Maitreya Thakkar
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options: Blue Advantage
$8,022

Jimmy Locklear
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options: Blue Advantage
$8,237

Sort By:

Cost

Sort

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Feedback

NC

Estimated Treatment Cost Results

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Siddhartha Rao
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,274

Pratik Desai
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,294

Franklin Wefald
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,294

Islam Othman
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,297

James Nutt

Blue Options, Blue Advantage

Sort By:

Cost

Sort

IMPORTANT INFORMATION: The information provided in this tool is FOR INFORMATIONAL PURPOSES ONLY. The assembled/estimated prices and your actual costs may be different based on factors such as your health plan design, deductibles/co-insurance, and out-of-pocket limits.

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NC

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James Nutt WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,378
Robert Jobe WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,407
Virgil Wynia WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,434
John Kelley WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,437
Joel Schneider		

Sort By:

Cost

Sort

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[–]
Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization 10 miles from raleigh, nc - Modify Your Search

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Joel Schneider
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,465

Dhirenkumar Shah
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,481

Shalendra Varma
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,499

Matthew Hook
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,554

WakeMed

Blue Options, Blue Advantage

Sort By:

Cost

Sort

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[+] Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

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WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,560

Willis Wu
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,572

Sumeet Subherwal
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,653

Mateen Akhtar
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$8,677

Jack Noneman
WakeMed
3000 New Bern Ave

Blue Options, Blue Advantage
$8,787

Sort By:
Cost
Sort

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[+] Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization 10 miles from raleigh, nc - Modify Your Search

Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits.

Jack Noneman WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,787
Pavlo Netrebko WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,836
Amarendra Reddy WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,879
Rama Garimella WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$8,917
Priyavadan Shah	Blue Options, Blue Advantage	

Sort By:

Cost

Sort

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[–]
Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits.

Priyavadan Shah WakeMed 3000 New Bern Ave Raleigh, NC 27610	Blue Options, Blue Advantage	$10,013
Mark Leithe Duke Raleigh Hospital 3400 Wake Forest Rd Raleigh, NC 27609	Blue Options, Blue Advantage	$10,468
Duke Raleigh Hospital 3400 Wake Forest Rd Raleigh, NC 27609	Blue Options, Blue Advantage	$10,883
James Mills Duke Raleigh Hospital 3400 Wake Forest Rd Raleigh, NC 27609	Blue Options, Blue Advantage	$12,114
John Sinden WakeMed	Blue Options, Blue Advantage	[illegible]

Sort By:

Cost

Sort

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[+] Feedback

NC

Estimated Treatment Cost Results

Left Heart Catheterization, 10 miles from raleigh, nc - Modify Your Search

Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits.

Duke Raleigh Hospital
3400 Wake Forest Rd
Raleigh, NC 27609

Blue Options, Blue Advantage
$10,883

James Mills
Duke Raleigh Hospital
3400 Wake Forest Rd
Raleigh, NC 27609

Blue Options, Blue Advantage
$12,114

John Sinden
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$12,160

Brian Go
WakeMed
3000 New Bern Ave
Raleigh, NC 27610

Blue Options, Blue Advantage
$12,247

Data Last Updated 07/23/2015

Sort By:
Cost
Sort

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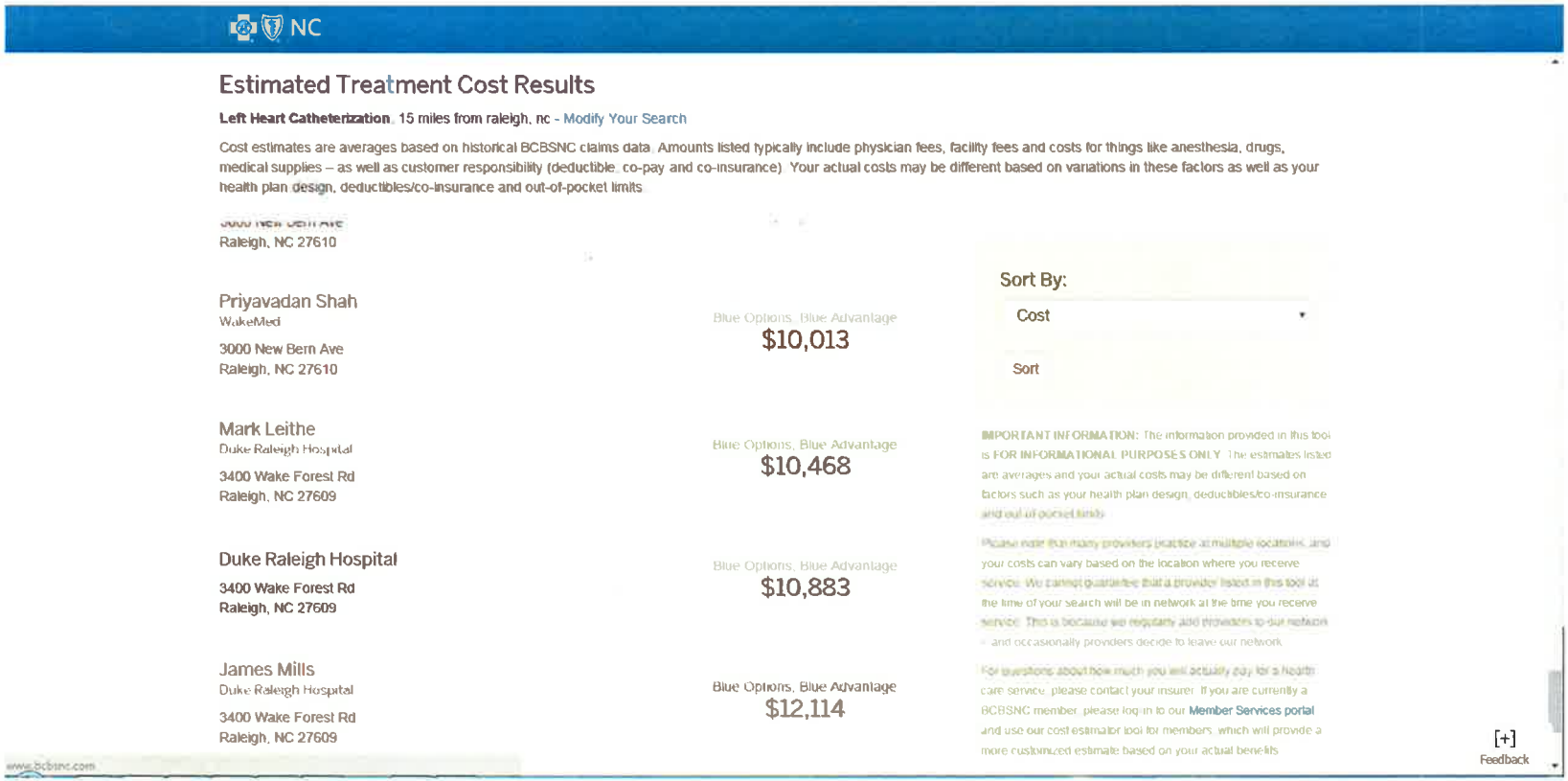
[+] Feedback


NC
Estimated Treatment Cost Results
Left Heart Catheterization, 15 miles from raleigh, nc - Modify Your Search
Cost estimates are averages based on historical BCBSNC claims data. Amounts listed typically include physician fees, facility fees and costs for things like anesthesia, drugs, medical supplies – as well as customer responsibility (deductible, co-pay and co-insurance). Your actual costs may be different based on variations in these factors as well as your health plan design, deductibles/co-insurance and out-of-pocket limits.
Raleigh, NC 27610
Priyavadan Shah
WakeMed
3000 New Bern Ave
Raleigh, NC 27610
Blue Options, Blue Advantage
$10,013
Mark Leithe
Duke Raleigh Hospital
3400 Wake Forest Rd
Raleigh, NC 27609
Blue Options, Blue Advantage
$10,468
Duke Raleigh Hospital
3400 Wake Forest Rd
Raleigh, NC 27609
Blue Options, Blue Advantage
$10,883
James Mills
Duke Raleigh Hospital
3400 Wake Forest Rd
Raleigh, NC 27609
Blue Options, Blue Advantage
$12,114
Sort By:
Cost
Sort
IMPORTANT INFORMATION: The information provided in this tool is FOR INFORMATIONAL PURPOSES ONLY. The estimates listed are averages and your actual costs may be different based on factors such as your health plan design, deductibles/co-insurance and out-of-pocket limits.
Please note that many providers practice at multiple locations, and your costs can vary based on the location where you receive service. We cannot guarantee that a provider listed in this tool at the time of your search will be in network at the time you receive service. This is because we regularly add providers to our network – and occasionally providers decide to leave our network.
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Attachment 2

Cardiac Catheterization Equipment Service Areas	Facility	Total Planning Inventory	2015 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed
Catawba	Catawba Valley Medical Center	1	1,108	0.92	0	
	Frye Regional Medical Center	4	3,026	2.52	0	
	TOTAL	**5**		**3**		**0**
Forsyth	Novant Health Forsyth Medical Center	8	4,730	3.94	0	
	N.C. Baptist Hospital	5	3,775	3.15	0	
	TOTAL	**13**		**7**		**0**
Guilford	High Point Regional Health System	4	3,124	2.60	0	
	Cone Health	7	4,987	4.16	0	
	The Cardiovascular Diagnostic Center*	1	661	0.55	0	
	TOTAL	**12**		**7**		**0**
Iredell	Iredell Memorial Hospital	1	982	0.82	0	
	Davis Regional Medical Center	1	462	0.38	0	
	Lake Norman Regional Medical Center*	1	63	0.05	0	
	TOTAL	**3**		**1**		**0**
Mecklenburg	Carolinas Medical Center/Mercy	8	6,846	5.71	0	
	CHS Pineville	3	2,642	2.20	0	
	Novant Health Presbyterian Medical Center	4	2,933	2.44	0	
	Carolinas Medical Center-University	1	34	0.03	0	
	Novant Health Matthews Medical Center	1	1,156	0.96	0	
	TOTAL	**17**		**11**		**0**
Wake	Rex Hospital	4	6,934	5.78	2	
	WakeMed	9	7,567	6.31	0	
	WakeMed Cary	1	205	0.17	0	
	Duke Raleigh Hospital	3	463	0.39	0	
	TOTAL	**17**		**13**		**0**

*2014 data was utilized as the 2016 License Renewal Applications for these facilities could not be obtained.

Grey colored cells indicate changes from current methodology

Cardiac Catheterization Equipment Service Areas	Facility	Total Planning Inventory	2013 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed	Need Determinations
Catawba	Catawba Valley Medical Center	1	1,108	0.92	(0.08)	0	
	Frye Regional Medical Center	4	3,026	2.52	(1.48)	0	
	TOTAL	**5**					**0**
Forsyth	N.C. Baptist Hospital	5	3,775	3.15	(1.85)	0	
	Novant Health Forsyth Medical Center	8	4,730	3.94	(4.06)	0	
	TOTAL						**0**
Guilford	The Cardiovascular Diagnostic Center*	1	661	0.55	(0.45)		
	Cone Health	7	4,987	4.16	(2.84)		
	Cone Health Total				***(3.29)***	***0***	
	High Point Regional Health System	4	3,124	2.60	(1.40)	0	
	TOTAL						**0**
Iredell	Davis Regional Medical Center	1	462	0.38	(0.62)	0	
	Iredell Memorial Hospital	1	982	0.82	(0.18)	0	
	Lake Norman Regional Medical Center*	1	63	0.05	(0.95)	0	
	TOTAL						**0**
Mecklenburg	Carolinas Medical Center/Mercy	8	6,846	5.71	(2.29)		
	CHS Pineville	3	2,642	2.20	(0.80)		
	Carolinas Medical Center-University	1	34	0.03	(0.97)		
	Carolinas HealthCare System Total				***(4.07)***	***0***	
	Novant Health Matthews Medical Center	1	1,156	0.96	(0.04)		
	Novant Health Presbyterian Medical Center	4	2,933	2.44	(1.56)		
	Novant Health Total				***(1.59)***	***0***	
	TOTAL			**11**			**0**
Wake	WakeMed	9	7,567	6.31	(2.69)		
	WakeMed Cary	1	205	0.17	(0.83)		
	WakeMed Total				***(3.52)***	***0***	
	Duke Raleigh Hospital	3	463	0.39	(2.61)	0	
	Rex Hospital	4	6,934	5.78	1.78	2	
	TOTAL						**2**

*2014 data was utilized as the 2016 License Renewal Applications for these facilities could not be obtained.