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August 14, 2015

VIA ELECTRONIC MAIL

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

Re: Comments Opposing Petition Filed by Rex Healthcare for an Adjusted Need Determination for One Unit of Fixed Cardiac Catheterization Equipment in Wake County in the 2016 State Medical Facilities Plan

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

WakeMed appreciates the opportunity to provide comments regarding the petition filed by Rex Healthcare requesting an adjusted need determination for one additional unit of cardiac catheterization equipment for Wake County in the 2016 State Medical Facilities Plan (SMFP). For the reasons outlined below, WakeMed believes this petition should be denied.

Rex provides a number of arguments regarding the merits of its petition, and provides examples of circumstances where the State Health Coordinating Council (SHCC) approved adjusted need determinations for cardiac catheterization and other major medical equipment regulated in the SMFP. However, none of these arguments are sufficient to warrant inclusion of a need determination in Wake County.

Existing Surplus of Fixed Cardiac Catheterization Equipment in Wake County

The Proposed 2016 SMFP currently shows a surplus of five fixed cardiac catheterization units in the Wake County service area. This is one of the largest surpluses of major medical equipment in Chapter 9 of the SMFP. Other large surpluses of cardiac catheterization equipment can be found in the Mecklenburg and Guilford service areas, both with five units, as well as in the Forsyth service area, which has a surplus of six units. Please see Attachment 1. No other service areas have surpluses this large. With this in mind, any rational application of the medical facilities planning process would suggest that Wake County is one of the last places in the state where an upward adjustment to the need determination should be made. One of the central tenets of the Certificate of Need process is to prevent the unnecessary duplication of health care services and equipment.

The Certificate of Need Statute, specifically N.C.G.S. §131E-176, contains the following Findings of Fact which address unnecessary duplication and excess capacity:

(4) That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of healthcare services.

(6) That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers.

Approving additional capacity, in this case cardiac catheterization equipment, for a service area where significant surplus capacity already exists does nothing to address the root problem of underutilization. Approval of the Rex petition would not improve access to cardiac catheterization services within Wake County, considering the surplus that already exists.

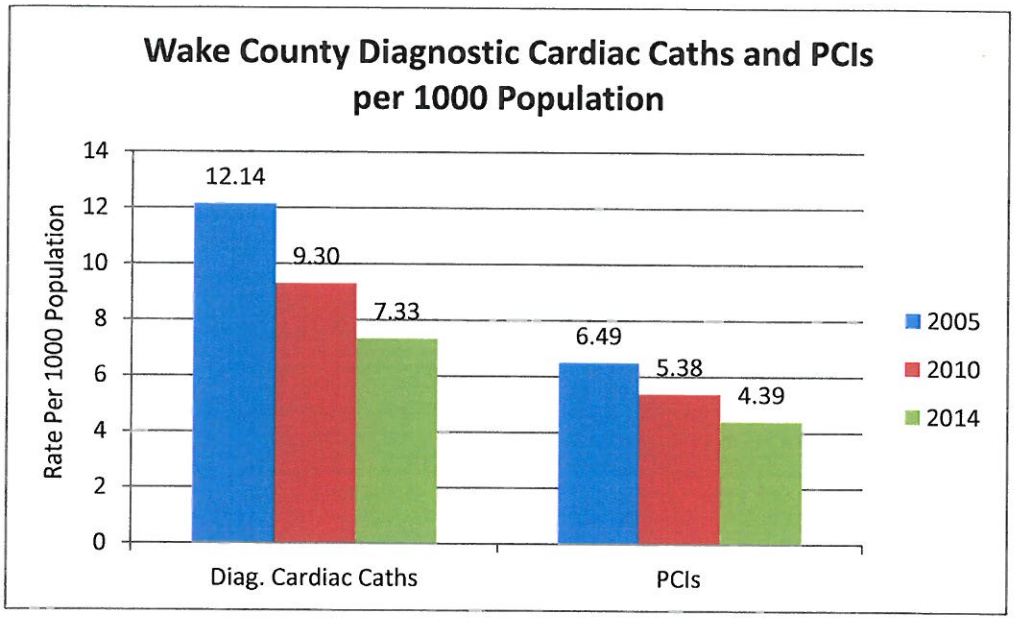
The annual State Medical Facilities Plan is developed under the governing principles of Safety and Quality, Access, and Value. The Rex petition offers no tangible improvements in these principles, particular Access. Wake County has five acute care hospitals, four of which offer cardiac catheterization services. Cardiac catheterization utilization has been declining at three of these facilities. Taking into account the excess capacity that exists for fixed cardiac catheterization equipment, one cannot justly claim that residents of Wake County need improved access for this service.

Declining Utilization of Cardiac Catheterization Equipment Statewide

The Proposed 2016 SMFP indicates that 48 hospitals statewide currently operate a total of 139 units of fixed cardiac catheterization equipment. Overall utilization of fixed cardiac catheterization equipment statewide has been steadily declining for a number of years. Statewide, the number of diagnostic cardiac catheterizations declined 33.1% between 2005 (the peak year) and 2014. During the same period, percutaneous cardiac intervention procedures (PCIs) decreased 12.4%. Conversely, the state's population *increased* by 14.6% from 2005-2014.

Declining Utilization of Cardiac Catheterization Equipment in Wake County

In Wake County, diagnostic cardiac catheterizations decreased 20.9% and PCIs decreased 11.3% between 2005 and 2014, a time period during which the total county population grew 31%, to nearly 1 million residents. This decrease can also be illustrated in terms of diagnostic cardiac cath and PCI use rates. Please see the following chart.



This is clearly a service with declining utilization and one in which equipment surpluses are likely to increase over time.

More recently, cardiac catheterization volumes at Wake County facilities have declined, even as the inventory of cardiac cath labs in service has increased. Please see the following table.

Table 1
Diagnostic-Equivalent Cardiac Catheterization Volumes at Wake County Hospitals
2010-2014

Facility	2010	2011	2012	2013	2014	Percent Change 2010-14	CAGR 2010-14
Duke Raleigh Hospital	967	701	366	447	393	-59.4%	-20.2%
Rex Hospital	3,002	3,132	3,875	5,029	6,006	100.1%	18.9%
WakeMed Cary Hospital	382	325	282	222	223	-41.6%	-12.6%
WakeMed Raleigh Campus	12,618	12,130	10,535	8,570	8,172	-35.2%	-10.3%
Total Cases All Facilities	**16,969**	**16,288**	**15,058**	**14,268**	**14,794**	**-12.8%**	**-3.4%**
Change from Previous Year	--	-4.0%	-7.6%	-5.2%	3.7%		
Fixed Cardiac Cath Units in Service	15	15	16	17	17		
Diag.-Equiv. Cases Per Unit	1,131.3	1,085.9	941.1	839.3	870.2		
Cath Labs Needed	14.1	13.6	12.5	11.9	12.3		
Surplus/(Deficit)	1	1	4	5	5		
Total Cases Excluding Rex	**13,967**	**13,156**	**11,183**	**9,239**	**8,788**	**-37.1%**	**-10.9%**
Change from Previous Year	--	-5.8%	-15.0%	-17.4%	-4.9%		
Fixed Cardiac Cath Units in Service	12	12	12	13	13		
Diag.-Equiv. Cases Per Unit	1,163.9	1,096.3	931.9	710.7	676.0		
Cath Labs Needed	11.6	11.0	9.3	7.7	7.3		
Surplus/(Deficit)	0	1	3	5	6		

Source: Hospital License Renewal Applications on file at DHSR

Over the last five years, the fixed cardiac catheterization equipment inventory in Wake County increased from 15 to 17, while the diagnostic-equivalent cases per unit declined from 1,131.8 to 870.2. Even with the slight uptick in volume from 2013-2014, overall case volume has declined 12.8% since 2010, or approximately 3.4% per year. When Rex's volume is excluded, the decline in volume becomes more pronounced, having decreased by 37.1% during 2010-2014, or by 10.9% per year. Considering that *overall* cardiac cath equipment utilization in Wake County has been declining in recent years, it is apparent Rex's increase in volume has been at the expense of the other providers in the county.

Reasons for Rex's Increased Utilization

One might reason that Rex Healthcare would generate a need of one fixed cardiac catheterization lab if it was the only provider in the service area, but it is not. The primary reason for the planning process to exist is to prevent the unnecessary duplication of services, which the Rex petition requests.

The Rex petition explains that the primary reason for the increase in cardiac catheterization procedures at Rex is the migration of the Wake Heart & Vascular physician group, renamed North Carolina Heart & Vascular (NCHV) following its acquisition by UNC Health Care System, from WakeMed facilities to Rex. This migration occurred between 2011 and December 2014, when all of the physicians in this group voluntarily relinquished their credentials to practice at WakeMed facilities.

Obviously, both Rex and NCHV knew all along that Rex had four cardiac catheterization labs, and knew, or should have known, that Wake County has a surplus of five units of fixed cardiac catheterization equipment. Rex now claims there is a problem because NCHV practices exclusively at Rex and that there are scheduling difficulties and inconveniences for patients and staff.

To the extent that Rex has a problem with cardiac catheterization capacity is entirely self-inflicted. No one other than Rex and NCHV determined that the group would no longer work at WakeMed facilities as they had previously done. The effect of this change in practice patterns has resulted in a corresponding shift in cardiac catheterization volume trends for WakeMed and Rex.

The SHCC denied a petition filed in 2013 by Iredell Health System for an adjusted need determination for fixed cardiac catheterization equipment in Iredell County in part because two other providers of cardiac catheterization located in Iredell County were in close proximity to Iredell Memorial Hospital (including one with 5 miles), and that local cardiologists could utilize these facilities to perform their cases. The circumstances in Wake County are similar to that of Iredell County, in that four of the five acute care hospitals in the county offer cardiac catheterization services, and many cardiologists based in Wake County practice at multiple sites. Given the distribution of cardiology practices and acute care hospitals within Wake County – Rex Hospital is located within 10 road miles and less than 15 minutes' driving time

from Duke Raleigh Hospital, WakeMed Cary Hospital, and WakeMed Raleigh Campus -- the notion that patients in need of cardiac catheterization cannot receive care in a timely manner is unfounded.

The SHCC has never made an adjusted need determination for fixed cardiac catheterization equipment in a multi-provider service area where a surplus existed, much less one where there is a surplus of *five* units.

Cardiac Catheterization Equipment Not Analogous to Linear Accelerator Equipment

On pages 7-9 of its petition, Rex discusses the circumstances that led to approval of one additional unit of linear accelerator equipment for the Wake County service area in the 2014 SMFP. Rex describes the similarities between its cardiac catheterization utilization and the radiation therapy utilization at Duke Raleigh Hospital, which successfully petitioned the SHCC in 2013 for an adjusted need determination for one additional linear accelerator in Service Area 20. Rex quoted former SHCC member Dr. Dennis Clements, who, in recommending approval of Duke Raleigh's petition, said:

> *"Most of these are cancer patients, and you get standardized on one machine you have to stay on that machine. You have maybe ten, twenty maybe more procedures on that machine. The machine tends to be associated with a hospital, often with oncologists in that hospital."*[1]

On page 9, Rex applies the logic of the Duke Raleigh linear accelerator petition to cardiac catheterization equipment:

> *"As with linear accelerator capacity in the Duke Raleigh Case, there is cardiac catheterization capacity available at other Wake County facilities, yet Rex's volume continues to grow. Rex believes the cardiac catheterization services and their physicians are similarly associated with one hospital and that capacity is not interchangeable as the SHCC determined in the case of Duke Raleigh."*

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

[1] Excerpted from discussion at the October 2, 2013 meeting of the State Health Coordinating Council. Referenced on page 8 of the Rex petition.

is not true, particularly when acknowledging differences in the type of care, and because cardiologists may treat patients at two or more hospitals.

In addition, Duke Raleigh's petition was submitted at a time that there was no need shown by the methodology because it included a linear accelerator that had been approved and a CON issued one and a half years, but had not been put into service. At the time the Duke petition was submitted there was not only no surplus of linear accelerators in Wake County, but there was an actual *deficit* because one of the linear accelerators existed only on paper and no timetable had been submitted suggesting when it would be brought into service.

Alternatives to the Petition Not Fully Vetted

The Rex petition, while lengthy overall, is remarkably brief in addressing the "Alternatives Considered". The only alternative truly considered appears to be tactics to get around the methodology of the SMFP so that it can obtain additional fixed cardiac catheterization equipment. Even if successful, this process would take a year or more. If the 2016 SMFP did include a need determination for another surplus cardiac catheterization lab in Wake County, an application for a CON would need to be prepared and submitted and approved, possible legal challenges overcome and a certificate issued before a new cardiac cath unit could be brought into operation.

An obvious alternative, not addressed in the Rex petition, which would help alleviate the problem more quickly and with considerably less cost, would be for some of the NCHV physicians to have their credentials reinstated at one or more of Wake County's other hospitals with existing cardiac catheterization labs, all of which have available capacity.

It may be that the underlying issue is not patient scheduling or staff inconvenience, but Rex's desire to collect the revenue produced by performing additional cardiac catheterization procedures and to reduce the share going to the county's principal safety net hospital. According to NCHA 2014 Community Benefit Reports, WakeMed provided $79.6 million of charity care, Rex Hospital $29.0 million, and Duke Raleigh $18.3 million. Continuing to reduce a significant source of revenue to WakeMed would reduce its capacity to provide the care upon which uninsured and underinsured patients

Petition Does Not Enhance Safety and Quality, Access or Value

Table 9W in the Proposed 2016 SMFP shows Wake County with a surplus of 5 units of fixed cardiac catheterization equipment. Rex's petition seeks to add to this surplus, which would only serve to duplicate existing resources. Approval of the petition would not result in any tangible improvements in safety and quality, access or value.

Safety and Quality

Rex discusses the need to ensure safety and quality for cardiac catheterization services yet the emergency patients described on page 15, who may require interventional treatment within 90 minutes of arrival at the hospital, can be accommodated into a daily schedule. High-volume cardiac catheterization programs make scheduling allowances to handle emergency cases that may present, much as their counterparts in the operating room suite must sometimes make adjustments for emergencies.

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

Access

Despite Rex's assertions, the petition contained no data or anecdotal evidence to demonstrate that access to cardiac catheterization equipment would be enhanced if it were approved. On page 20, Rex discusses the need to improve access for its main cardiology group:

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

Given the surplus of fixed cardiac catheterization equipment that currently exists in Wake County, the Rex petition is more about the desire to continue to shift procedures between hospitals than about improving access for patients.

Value

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

Summary

Approval of the Rex Healthcare petition would only serve to exacerbate the growing surplus of fixed cardiac catheterization equipment in Wake County. An additional cardiac cath lab in Wake County would do nothing to contain costs, improve access, or enhance safety and quality. For these reasons, the Rex petition should be denied.

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

Sincerely,

Donald R. Gintzig
President & CEO

Table 9W: Fixed Cardiac Catheterization Equipment, Capacity and Volume - Proposed 2016 SMFP

Cardiac Catheterization Equipment Service Areas	Facility	Current Inventory	CON Issued/ Pending Development	Pending Review or Appeal	Total Planning Inventory	footnote	2013 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed
Alamance	Alamance Regional Medical Center	1			1	b	987	0.82	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**1**		**0**
Buncombe/ Graham/ Madison/Yancey	Mission Hospital	5			5	a	5,421	4.52	0	
	Pending Review/ Appeal				0					
	TOTAL				**5**			**5**		**0**
Burke	Carolinas HealthCare System Blue Ridge [DLP Healthcare]	1			1	c	380	0.32	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**
Cabarrus	Carolinas Medical Center - NorthEast	2			2	b	2,455	2.05	0	
	Pending Review/ Appeal				0					
	TOTAL				**2**			**2**		**0**
Caldwell	Caldwell Memorial Hospital [DLP Healthcare]	1			1	c	237	0.20	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**
Carteret	Carteret General Hospital		1		1		0	0.00	0	
	Pending Review/ Appeal									
	TOTAL				**1**			**0**		**0**
Catawba	Catawba Valley Medical Center	1			1	b	841	0.70	0	
	Frye Regional Medical Center	4			4	b	4,323	3.60	0	
	Pending Review/ Appeal				0					
	TOTAL				**5**			**4**		**0**
Cleveland	Carolinas HealthCare System Cleveland [DLP Healthcare]	1			1	c	375	0.31	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**
Craven/Jones/ Pamlico	CarolinaEast Medical Center	2	1		3	b	2,570	2.14	0	
	Pending Review/ Appeal									
	TOTAL				**3**			**2**		**0**
Cumberland	Cape Fear Valley Medical Center	3			3	b	4,961	4.13	1	
	Pending Review/ Appeal				0					
	TOTAL				**3**			**4**		**1**

ATTACHMENT 1

Table 9W: Fixed Cardiac Catheterization Equipment, Capacity and Volume - Proposed 2016 SMFP

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Durham/ Caswell	Duke University Hospital	7			7	a	5,360	4.47	0	
	Duke Regional Hospital	2			2	b	912	0.76	0	
	Pending Review/ Appeal				0					
	TOTAL				**9**			**5**		**0**
Forsyth	Novant Health Forsyth Medical Center	8			8	b	4,489	3.74	0	
	N. C. Baptist Hospital	5			5	a	3,590	2.99	0	
	Pending Review/ Appeal				0					
	TOTAL				**13**			**7**		**0**
Gaston	CaroMont Regional Medical Center	4			4	b	2,955	2.46	0	
	Pending Review/ Appeal				0					
	TOTAL				**4**			**2**		**0**
Guilford	High Point Regional Health	4			4	b	3,069	2.56	0	
	Cone Health	7			7	b	4,893	4.08	0	
	The Cardiovascular Diagnostic Center	1			1	c	661	0.55	0	
	Pending Review/ Appeal				0					
	TOTAL				**12**			**7**		**0**
Halifax/ Northampton	Halifax Regional Medical Center	1			1	c	0	0.00	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**
Haywood	Haywood Regional Hospital	1			1	c	178	0.15	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**
Henderson	Margaret R. Pardee Memorial Hospital [DLP Healthcare]	1			1	c	82	0.07	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**
Iredell	Iredell Memorial Hospital	1			1	c	1,135	0.95	0	
	Davis Regional Medical Center	1			1	c	524	0.44	0	
	Lake Norman Regional Medical Center	1			1	c	63	0.05	0	
	Pending Review/ Appeal				0					
	TOTAL				**3**			**1**		**0**

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Johnston	Johnston Health	1			1	c	579	0.48	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**
Lee	Central Carolina Hospital	1			1		209	0		
	Pending Review/ Appeal				0					
	TOTAL				**1**			**1**		**0**
Lenoir	Lenoir Memorial Hospital	1			1	c	476	0.40	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**
Mecklenburg	Carolinas Medical Center	7			7	a	7,051	5.88	0	
	Carolinas Medical Center - Pineville	4			4	b	3,121	2.60	0	
	Novant Health Presbyterian Medical Center	4			4	b	3,021	2.52	0	
	Carolinas Medical Center-University	1			1	c	27	0.02	0	
	Novant Health Matthews Medical Center[DLP Healthcare]	1			1	c	852	0.71	0	
	Pending Review/ Appeal				0					
	TOTAL				**17**			**12**		**0**
Moore	FirstHealth Moore Regional Hospital	5			5	b	5,235	4.36	0	
	Pending Review/ Appeal				0					
	TOTAL				**5**			**4**		**0**
Nash	Nash General Hospital	2			2	c	1,216	1.01	0	
	Pending Review/ Appeal				0					
	TOTAL				**2**			**1**		**0**
New Hanover	New Hanover Regional Medical Center	5			5	b	5,494	4.58	0	
	Pending Review/ Appeal				0					
	TOTAL				**5**			**5**		**0**
Onslow	Onslow Memorial Hospital	1			1	c	0	0.00	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**

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Cardiac Catheterization Equipment Service Areas	Facility	Current Inventory	CON Issued/ Pending Development	Pending Review or Appeal	Total Planning Inventory	footnote	2013 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed
Orange	UNC Hospitals	4			4	a	3,679	3.07	0	
	Pending Review/ Appeal				0					
	TOTAL				4			3		0
Pasquotank/ Camden/ Currituck/ Perquimans	Sentara Albemarle Medical Center	1			1	c	817	0.68	0	
	Pending Review/ Appeal				0					
	TOTAL				1			1		0
Pitt/Greene/ Hyde/Tyrell	Vidant Medical Center	7			7	a	4,166	3.47	0	
	Pending Review/ Appeal				0					
	TOTAL				7			3		0
Randolph	Randolph Hospital	1			1	c	0	0.00	0	
	Pending Review/ Appeal				0					
	TOTAL				1			0		0
Robeson	Southeastern Regional Medical Center	2			2	b	1,477	1.23	0	
	Pending Review/ Appeal				0					
	TOTAL				2			1		0
Rowan	Novant Health Rowan Medical Center	1			1	c	673	0.56	0	
	Pending Review/ Appeal				0					
	TOTAL				1			1		0
Rutherford	Rutherford Regional Medical Center	1			1	c	63	0.05	0	
	Pending Review/ Appeal				0					
	TOTAL				1			0		0
Scotland	Scotland Memorial Hospital	1			1		345	0.29	0	
	Pending Review/ Appeal				0					
	TOTAL				1			0		0
Stanly	Stanly Regional Medical Center	1			1	c	0	0.00	0	
	Pending Review/ Appeal				0					
	TOTAL				1			0		0
Union	Carolinas Medical Center-Union	1			1	c	480	0.40	0	
	Pending Review/ Appeal				0					
	TOTAL				1			0		0

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Wake	Rex Hospital	4			4	b	6,006	5.00	1	
	WakeMed	9			9	b	8,172	6.81	0	
	WakeMed Cary Hospital	1			1	c	223	0.19	0	
	Duke Raleigh Hospital [DLP Healthcare]	3			3	c	393	0.33	0	
	Pending Review/ Appeal				0					
	TOTAL				**17**			**12**		**0**
Watauga	Watauga Medical Center	1			1	c	735	0.61	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**1**		**0**
Wayne	Wayne Memorial Hospital	1			1	c	588	0.49	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**
Wilkes	Wilkes Regional Medical Center	1			1	c	0	0.00	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**0**		**0**
Wilson	Wilson Medical Center	1			1	c	633	0.53	0	
	Pending Review/ Appeal				0					
	TOTAL				**1**			**1**		**0**
NORTH CAROLINA TOTALS		139	2	0	141		106,185	87		**1**

a Adult procedures plus angioplasty x 1.75 plus pediatric procedures x 2
b Adult procedures plus angioplasty x 1.75
c Adult procedures