Duke University Health System

Catharine W. Cummer
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Via Email

Greg Yakaboski
Assistant Chief, Healthcare Planning
North Carolina Division of Health Service Regulation
Medical Facilities Planning Branch
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Comments Regarding Wake County Cardiac Catheterization Need Determination Petition

Dear Mr. Yakaboski:

Duke University Health System, Inc. d/b/a Duke Raleigh Hospital submits the enclosed comments in response to the petition filed by Rex Healthcare for an adjusted need determination for cardiac catheterization equipment in Wake County. Please let me know if you have any questions. Thank you for your consideration of these comments.

Sincerely,

Catharine W. Cummer

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NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

COMMENTS REGARDING PETITION TO ADJUST NEED DETERMINATION FOR FIXED CARDIAC CATHETERIZATION EQUIPMENT IN WAKE COUNTY

Duke University Health System, Inc. d/b/a Duke Raleigh Hospital hereby submits these comments regarding the petition submitted by Rex Healthcare to adjust the need determination for cardiac catheterization equipment in Wake County in the 2016 State Medical Facilities Plan.

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Rex's proposal to adjust the need for cardiac catheterization equipment in Wake County would unnecessarily duplicate existing services that are already available to physicians and patients in the service area.

Decreasing utilization

Cardiac catheterization utilization has been decreasing over the last several years:

	Weighted Fixed Procedures	
Year	Statewide	Wake County
2014 (from 2016 Draft SMFP)	106,185	14,794
2013 (from 2015 SMFP)	109,885	14,268
2012 (from 2014 SMFP)	112,060	15,058
2011 (from 2013 SMFP)	114,567	16,288
2010 (from 2012 SMFP)	115,017	16,969
2009 (from 2011 SMFP)	115,865	16,692
2008 (from 2010 SMFP)	119,910	17,440

Although Wake County totals rose slightly last year, they still remain 15% lower than in 2008, with capacity remaining the same.

Rex's own utilization has been variable, and did not exceed 65% of capacity (defined as 1500 weighted procedures/machine) until 2013:

Year	Weighted Procedures	% of Capacity
2014 (from Draft 2016 SMFP)	6006	100%
2013 (from 2015 SMFP)	5029	84%
2012 (from 2014 SMFP)	3875	65%
2011 (from 2013 SMFP)	3132	52 %
2010 (from 2012 SMFP)	3002	50%
2009 (from 2011 SMFP)	3489	58%
2008 (from 2010 SMFP)	3581	60%

Only in this year's plan has Rex's utilization now barely reached 100% of "capacity."[1]

As Rex acknowledges, its growth in the past three years has resulted from the concerted recruitment of physicians within Wake County, primarily one major cardiology practice that previously practiced primarily at WakeMed, not from the addition of providers to the market or any long-term utilization increase in the service area. See news articles at http://www.newsobserver.com/2011/12/12/1705580/losing-hearts-brings-worries-to.html; http://m.bizjournals.com/triangle/news/2013/08/19/rexs-new-cardio-practice-goes.html?r=full.) Accordingly, WakeMed's cardiac catheterization volumes decreased from 5702 in 2010 to 3687 procedures in 2014.

In addition, Johnston Health has received regulatory approval to offer interventional cardiac catheterization (PCI) procedures at its hospital for the first time; therefore, it would be reasonable to expect that Johnston County patients who would have in the past received interventional procedures at Rex and other Wake County hospitals will instead be treated in Johnston County. Harnett Health has also petitioned for a need determination for a cardiac cath lab in Harnett County, in which it points out that "adding cardiac catheterization capability in Harnett County to meet the need of Harnett County residents will result in available capacity in Durham, Johnston and Wake Counties . . . ." Given the overall decrease in utilization in Wake County over the past several years and the likelihood of continued decline as other providers in neighboring counties expand their services, Rex's assumption that its volumes will continue to grow at the same rate is not reasonable. In fact, after its initial burst with the onboarding of the physicians recruited from WakeMed, Rex's rate of growth has slowed in each subsequent year.

Moreover, there is ample capacity in the service area to meet patient needs. All of the hospitals in Wake County with cath lab capacity have open medical staffs, and physicians who find any scheduling difficulties at Rex Hospital are free to seek privileges and schedule procedures at other facilities. Duke Medicine physicians practice and perform procedures at WakeMed and Rex in various specialties including cardiology as needed to respond to patient needs. Rex's apparent choice to prevent certain physicians from practicing elsewhere does not

[1] In previous CON litigation, Rex has taken the position that the capacity of a cath lab is 1712 procedures per year, leading to a 2014 utilization for Rex of 87% of capacity. See comments filed by WakeMed in response to Rex's 2014 cath lab petitions at http://www2.ncdhhs.gov/dhsr/mfp/pets/2014/tec/0818_cc_wm.pdf.

create the kind of special circumstance that supports a special adjustment to the service area need for this technology. Rather than allowing its physicians (and their patients) more flexibility in where to schedule procedures, Rex has chosen to increase its capacity by contracting with a mobile provider. As a result, there is no crisis of access, and creating a need for an additional cath lab in the county would simply duplicate existing health services.

Procedure times

Rex argues that it needs additional capacity to reflect increasing procedure times and claims that the presumed procedure length of 60-90 minutes is unreasonable. However, Duke's own average procedure times support this assumption. Even at Duke University Hospital, an academic medical center teaching hospital that treats high acuity patients and includes teaching involvement in 100% of procedures, with over 30 research studies conducted over the time period that Rex notes, the average procedure time is 82 minutes. Duke would also note that 70% of its acute care emergent cases occur between 7pm and 7am and/or weekend hours.

2013 linac adjusted need determination

Rex points to the approval of a petition filed by Duke Raleigh Hospital in 2013 for a local adjustment to the need for linear accelerators in Service Area 20 as support for its proposal. The linear accelerator petition raised issues unique to the provision of radiation oncology services in that service area which are not present in the Wake County cardiac cath market. Those factors included:

1) Linear accelerators are generally an integral part of a long-term and comprehensive treatment for cancer, where patients will receive as many as 20 or more linear accelerator treatments, often in addition to ongoing medical and surgical oncology treatment. For example, Duke Raleigh's linear accelerator patients had an average of 27.7 procedures last year; even assuming that some patient encounters included multiple procedures, patients routinely have separate treatments numbering in double digits on a linear accelerator over several weeks or months. Moreover, their treatment plans are equipment-specific. As identified in the SHCC's discussion of this petition, linear accelerators are a unique technology, where patients optimally receive their entire course of procedures on a single machine and have a multi-encounter treatment plan in place, so that it is not usually feasible for patients to seek out another linear accelerator at another provider during times of high demand or equipment downtime once they have begun treatment.

   In contrast, the vast majority of cardiac catheterization patients undergo a single catheterization procedure. For example, within the past 3 years at Duke University Hospital, 77% of cardiac catheterization patients received a single procedure and 15% received two over that multi-year period. Because the great majority of patients undergo only one procedure, because cath labs to do not need to be calibrated for individual treatments, and because there is no clinical benefit to having multiple procedures performed on the same machine, physicians are therefore free to schedule procedures for patients at any facility with capacity without compromising an

ongoing course of treatment and without subjecting patients to multiple treatment plans. The majority of cath procedures are outpatient, so in most cases there is similarly no need to coordinate care in an inpatient hospital setting.

2) Service Area 20 faced the unique situation of a linear accelerator provider holding a certificate of need on which no significant progress had been made in 2½ years, leaving a need determination first included in the SMFP in 2007 unmet 6 years later.

3) Service Area 20 showed steadily increasing linear accelerator utilization. By contrast, with the exception of last year, Wake County cardiac catheterization volumes have steadily decreased, by 15% over the past 7 years despite significant population growth.

4) At the time of its petition, Duke Raleigh had only one linear accelerator that had operated at approximately 140% of the regulatory threshold of 6750 ESTVs per year for the most recent 2 years, and had exceeded the regulatory threshold for at least 6 straight years. In the event of any equipment maintenance needs on that single piece of equipment, the hospital simply had no other equipment to accommodate patients in the middle of a treatment protocol. Rex is not in similar straits: Only in 2014 did its utilization reach 100% of defined capacity. For most of the previous 5 years, its utilization was never more than 65% of capacity. In addition, with multiple pieces of equipment, even at current utilization, it has more flexibility on its existing equipment to accommodate emergencies or equipment maintenance requirements than a provider with only one piece of equipment would have.

Conclusion

For all the foregoing reasons, an adjustment to the need determination in Wake County is not warranted at this time.