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Duke University Health System

Catharine W. Cummer
Regulatory Counsel, Strategic Planning

August 14, 2014

Via Email

Nadine Pfeiffer
North Carolina Division of Health Service Regulation
Medical Facilities Planning Branch
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Duke University Health System Comments Regarding Cardiac Catheterization Need Determination Petition

Dear Ms. Pfeiffer:

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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Enclosure

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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 2015 State Medical Facilities Plan.

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Rex proposes that despite declining utilization in the service area, the need for cardiac catheterization equipment in Wake County be adjusted to add a need for an additional machine. This would unnecessarily duplicate existing services that are already available to physicians and patients in the service area.

Decreasing utilization

Cardiac catheterization utilization has been steadily decreasing across the state and in Wake County over the last five years:

	Weighted Fixed Procedures	
Year	Statewide	Wake County
2013 (from 2015 Draft 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

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 Rex petition)	5883	97%
2013 (from 2015 Draft 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%

As Rex acknowledges, its growth in the past two 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 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 3822 procedures in 2013. In addition, Johnston Health has just 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. This may accelerate the decrease in Wake County catheterization volumes. Given the overall decrease in utilization in Wake County over the past 5 years and the likelihood of continued decline, Rex's assumption that its volumes will continue to grow at the same rate is simply not reasonable; if anything, its utilization may decline in a reflection of local and statewide utilization trends.

Even if the overall declining utilization of catheterization labs in Wake County were to reverse, however, there is sufficient 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. Many physicians already are privileged at multiple hospitals. Therefore, there is no crisis of access, and creating a need for an additional cath lab in the county would simply duplicate already underutilized existing health services.

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. Their treatment plans are

equipment-specific. Because patients optimally receive their entire course of procedures on a single machine and have a multi-encounter treatment plan in place, 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.

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, Wake County cardiac catheterization volumes have steadily decreased, by almost 20% over the past 5 years. Total utilization decreased by 5% alone from 2012 to 2013.

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 that 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: Rex's own utilization of its four machines in 2013 was 1257 weighted procedures per machine, or 84% of the defined capacity of 1500 weighted procedures per year, and only in 2014 did its utilization approach 100% of defined capacity. For the previous 5 years, its utilization was never more than 65% of capacity. 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 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.