NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

COMMENTS REGARDING PETITION TO ADJUST NEED METHODOLOGY FOR FIXED CARDIAC CATHETERIZATION EQUIPMENT

Duke University Health System, Inc. hereby submits these comments regarding the petition submitted by Rex Healthcare to change the need methodology for cardiac catheterization equipment in the 2015 State Medical Facilities Plan.

Contact: Catharine W. Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd.
Suite 1300
Durham, NC 27707
(919) 668-0857
catharine.cummer@duke.edu

Rex proposes that the need methodology for cardiac catheterization be driven by individual providers' utilization rather than the utilization in the service area as a whole. This is a deviation from the standard approach in the SMFP for equipment and technology, and is not warranted for this particular technology.

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 Rex Petition)		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 is the only provider identified in its petition who exceeded 80% of the state-defined capacity of 1500 weighted procedures per machine last year. Rex's own utilization has been variable, and has not exceeded 65% of capacity (defined as 1500 weighted procedures/machine) until this past year:

Year	Weighted Procedures	% of Capacity
2013 (from Rex Petition)	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%

Accordingly, there is no statewide need for additional cardiac catheterization capacity that would merit a change in methodology that would expand capacity.

Surpluses caused by statewide facility-specific equipment methodologies

Rex refers to the facility-specific methodology for fixed PET scanners as support for its proposal. However, that facility-specific methodology has resulted in a surplus of fixed PET scanners that the SHCC is now considering how to remedy, including considering proposals to allow conversions of fixed capacity to mobile capacity.

Single-provider needs

Rex claims that its proposal will address the situation of single provider-counties where providers with a single piece of equipment are forced to perform 1,800 procedures per year, or 120% of defined capacity, before a need is triggered for additional equipment. Creating a facility-specific methodology as Rex proposes would not affect those single-provider counties, however. Moreover, such situations have historically occurred only rarely, and the SHCC has successfully addressed any need by special adjustment, such as Southeastern Regional Medical Center's petition for the 2013 SMFP.

Recent linac petition

Rex points to a particular petition filed by Duke Raleigh Hospital last year 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, and does not support a more wholesale change to the regulation of other technology and equipment statewide. 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 2½ years at Duke University Hospital, 81% of cardiac catheterization patients received a single procedure and 13% received two over that period. Because patients generally 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 free to schedule procedures for patients at any facility with capacity without compromising an ongoing course of treatment or subjecting patients to multiple treatment plans or sites. The facilities with cardiac catheterization equipment in Wake County have open medical staffs and Rex acknowledges that many physicians have privileges at many hospitals.

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 had steadily increasing linear accelerator utilization. By contrast, Wake County cardiac catheterization volumes have decreased by almost 20% over the past 5 years.

4) At the time of its petition, Duke Raleigh had only <u>one</u> linear accelerator operating at approximately <u>140%</u> of the regulatory threshold of 6750 ESTVs per year for the most recent 2 years, and had exceeded 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 does not identify any cardiac catheterization providers in similar straits: Rex's own utilization of its <u>four</u> machines in 2013 was 1257 weighted procedures per machine, or <u>84%</u> of the defined capacity of 1500 weighted procedures per year. For the previous 5 years, its utilization was never more than 65% of capacity. Therefore, even at current utilization, it has capacity on its existing equipment to accommodate emergencies or equipment maintenance requirements.

5) Duke Raleigh sought an adjustment to an individual determination, not a statewide methodology change, to address these unique circumstances.

<u>Conclusion</u>

For all the foregoing reasons, the changes in fixed cardiac catheterization methodology as proposed by Rex are not warranted.