Healthcare Planning
and Certificate of Need

Technology & Equipment Committee Minutes - Draft

March 30, 2016
10:00 am
Brown Bldg Room 104

Members Present: Dr. Christopher Ullrich, Trey Adams, Kelly Hollis, Valarie Jarvis, Brian Lucas, Dr. Jeffrey Moore, Dr. Prashant Patel
Members Absent: Senator Ralph Hise
Staff Present: Paige Bennett, Elizabeth Brown, Amy Craddock, Tom Dickson, Kelli Fisk, Shelley Carraway, Martha Frisone, Fatima Wilson, Mike McKillip
DHSR Staff Present: Mark Payne
AG's Office: Jill Bryan

Agenda Items	Discussion/Action	Motions	Recommendations/ Actions
Welcome & Introductions	Dr. Ullrich welcomed members, staff, and the public to the first Technology and Equipment Committee meeting of 2016. Dr. Ullrich asked that Committee members and staff in attendance to introduce themselves. Dr. Ullrich explained that the meeting was open to the public; however, discussions, deliberations and recommendations would be limited to members of the Technology and Equipment Committee and staff. Dr. Ullrich stated that the purpose of this meeting was to review the policies, methodologies for the Proposed 2017 State Medical Facilities Plan (SMFP), review and vote on three petitions.		
Review of Executive Order No. 46: Reauthorizing the State Health Coordinating Council	Dr. Ullrich gave an overview of the procedures to observe before taking action at the meeting. Dr. Ullrich inquired if anyone had a conflict or needed to declare that they would derive a benefit from any matter on the agenda or intended to recuse themselves from voting on the matter. Dr. Ullrich asked members to review the agenda and declare any conflicts on today's agenda.		

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<tr><td></td><td>Dr. Ullrich stated that if a conflict of interest, not on the agenda, came up during the meeting that the member with the conflict of interest would make a declaration of the conflict.

There were no recusals.</td><td></td><td></td></tr>
<tr><td>Approval of September 16, 2015 Minutes</td><td>A motion made and seconded to approve the minutes.</td><td>Dr. Moore
Mr. Adams</td><td>Minutes approved</td></tr>
<tr><td>Cardiac Catheterization Equipment – Chapter 9</td><td>Ms. Bennett provided a review of the General Need Methodology.

Review of need methodology
The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The cardiac catheterization equipment's service 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 received inpatient acute care services. These service areas are reviewed every three years. This year they will reviewed again and preliminary data analysis indicates there will be minor changes.
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: Methodology Part 1
For fixed cardiac catheterization equipment, procedures are weighted based upon complexity as described on page 179.
The SHCC defines capacity as 1,500 diagnostic-equivalent procedures per year.</td><td></td><td></td></tr>
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	The number of fixed cardiac catheterization equipment required is determined by dividing the number of weighted o or diagnostic-equivalent procedures performed at each facility by 1200 procedures (80% 0f 1500 capacity). o The calculated number of required units of equipment is compared with the current inventory to determine if there is a need. • Steps: Methodology Part 2 o 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 this service area exceeds 240 (80% of 300 capacity) per year for each 8 hours per week in operation at that site. Ms. Bennett noted one petition was received: **Petitioner:** Rex Hospital **Comments:** Received two comments; both opposed. **Request Petition 1:** 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 steps 5 and 6 of the Cardiac Catheterization Methodology 1 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 into 2014, the data year of the 2016 SMFP.		

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	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 (the most recent dataset 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. In addition, the petitioner mentioned in the current written request and at the March 2, 2016 SHCC public hearing, that a meeting between WakeMed and Rex Hospital would take place in the coming weeks, "to discuss collaboration on these issues" and "determine a positive solution." The agency is interested to see if a mutually agreeable resolution maybe 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 catheterization methodology should include questions brought forth in this petition. Given available information and comments submitted by the March 18, 2016 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends denial of the petition. After the agency presentation, committee members had a discussion regarding the topics brought forth in the petition. The committee discussed the issue as a local rather than statewide issue and stated it may be more suitable for review during the adjusted needs petition process. Members		

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	asked if an update from the scheduled meeting between Rex and WakeMed could be provided. No one at the meeting had received an update, but members voiced support for a mutually agreeable solution. Broader discourse around the issues included changes in the landscape of medicine; decreases nationwide in cases; and consideration of a facility based model in any future reviews of the methodology. **Committee Recommendation** A motion made and vote taken to deny the petition. **Committee Recommendation** A motion made and seconded to accept the Cardiac Catheterization assumptions and methodologies, data, draft need projections and advance references to years by one as appropriate.	Mr. Adams Mr. Lucas	**6-0** **Petition denied.** **Motion approved**
Magnetic Resonance Imaging (MRI) – Chapter 9	Ms. Bennett provided a review of the General Need Methodology **<u>Magnetic Resonance Imaging (MRI) Scanners Section of Chapter 9</u>** There is one Policy TE-2: Intraoperative MRI scanners qualified applicants can apply for an intraoperative MRI scanner to be used in an operating suite. Page 25 **Review of MRI Need Methodology (page 153 in 2016 SMFP)** Just like cardiac catheterization services, the Acute Care Bed Service Area as defined in Chapter 5 of the 2015 SMFP continues to be the service area for the fixed MRI scanners. • The methodology for MRI scanners is a bit more intricate as there are tiers of need thresholds based on the number of scanners and, weighting of procedures based on complexity. • Steps:		

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	◦ The current inventory of l fixed and mobile MRI scanners in each MRI service area by site are converted to fixed equivalent magnets. ▪ A value of one fixed equivalent magnet will be assigned for each existing and approved fixed MRI scanner. ▪ The number of MRI scans performed at each mobile site are divided by the threshold for the service area to determine the mobile site fixed equivalent ◦ Using the weighting value chart on page 156, we multiply the number of MRI scans by type (i.e. inpatient, outpatient, with or without contrast or sedation) according to their weighting adjustment value in order to determine adjusted total MRI procedures for all sites in each MRI service area and then calculate the average of those procedures. ◦ Utilization thresholds are listed on page 157 and are used to compare the average procedures per fixed equivalent magnet, with the threshold, to determine if there is a need • There is an exception in the methodology that there will be no more than one MRI scanner need determination in any one service area per year unless there is an approved adjusted need determination Ms. Bennett noted one petition received for the MRI section. **Petitioner:** Cape Fear Valley Health System **Comments:** Fifteen comments received 12 comments in support, two against, and one neutral comment. **Request:** Cape Fear Valley Health System] (CFVHS) requests the State Health Coordinating Council (SHCC) continue its discussion regarding fixed MRI in community hospitals and requests that a new policy, Policy TE-3: Fixed MRI Scanners in Community Hospitals be included in the *2017 State*		

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	Medical Facilities Plan. The proposed wording can be found in the agency report or the petition. The agency analysis shows twelve counties would potentially be eligible to apply for a fixed MRI machine through the proposed Policy TE-3. The counties are Allegheny, Anson, Avery, Bladen, Chatham, Duplin, Hoke, Martin, Montgomery, Pender and Polk. Davie County was not included in the petition, but appears to meet the criteria. Table 1 in the agency report, shows that the number of procedures performed in those counties varies widely, ranging from a low of 45 weighted procedures to a high of 1,038. Using the current methodology a need is triggered in a service area without a fixed scanner at 1,716 weighted scans. In addition, just under half of the counties demonstrate negative growth and several counties show fluctuations in the number of procedures from year to year. According to the wording of the proposed policy, applicants would be able to apply without a need determination in the service area, but would still be required to meet the performance standards of 1,716 weighted scans after three years of service. Based on the data, it appears only Duplin; Hoke and Polk counties have the potential to demonstrate the growth to reach this performance standard since they are all above 1,000 weighted procedures. Another important consideration is that Duplin and Polk only have one hospital, but Hoke has two hospitals in the service area. They are Cape Fear Valley Hoke Hospital, a newly licensed facility, and FirstHealth Moore Regional Hospital – Hoke Campus. The intent of the policy appears to provide community hospitals with the ability to apply for a CON for a fixed MRI scanner regardless of their resources. However, applications from Hoke County may still be competitive if they are filed during the same review cycle. Overall, it appears only a select few hospitals would benefit from the policy change in the near term. It is possible, with the fluctuations in the number of procedures, that the policy will only benefit one or two facilities in the		

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	coming years. Given available information submitted by the March 18, 2016 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the Agency recommends that the petition for a policy for fixed MRI scanners in community hospitals be denied. The proposed changes affect a limited number of health service areas. After the agency presentation, committee members had a discussion regarding MRI for hospitals in counties without a fixed machine. There was consensus that the methodology provided a barrier to obtaining MRI scanners. Members suggested the threshold may be too high. Other issues discussed during the conversation included the use of MRI for emergency care and concerns regarding the cost of the equipment. **Committee Recommendation** A vote taken to deny the petition, with the understanding the issue is not dead. Dr. Ullrich asked that staff develop a proposal to bring to the next meeting for consideration by the committee. **Committee Recommendation** A motion made and second to accept the assumptions and methodologies, data, draft need projections and advance references to years by one as appropriate.	Dr. Moore Mr. Lucas	6-0 Petition denied Motion approved
Lithotripsy Section Chapter 9	Ms. Bennett provided a review of the General Need Methodology **<u>Lithotripsy Section of Chapter 9</u>** **Review of Need Methodology** • The lithotripter planning area is the entire state so this is a statewide determination.		

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	• Steps:
	  ○ First, using the July 1, 2017 estimated population from the North Carolina Office of State Budget and Management and the incidence of urinary stone disease of 16 cases per 10,000 population, the estimate of urinary disease cases is calculated.
	  ○ Based on the assumption that 90% of patients could be treated with lithotripsy, we use the estimate number of cases to calculate the number of patients in the state who have the potential to be treated by lithotripsy.
	  ○ The low range of annual treatment capacity is 1000. This is used to determine the number of lithotripters needed based upon the projected number of patients.
	  ○ The need will be identified when comparing the number of lithotripters in inventory to the number needed based upon projected incidence of urinary stone disease.
	
	Ms. Bennett noted there was one petition.
	
	Comments: Received three comments; all opposed.
	
	Petitioner: Hampton Roads Lithotripsy
	
	Request: Hampton Roads Lithotripsy, LLC requests that the *North Carolina 2017 State Medical Facilities Plan (SMFP)* include a new policy regarding lithotripsy. The proposed wording can be found in the agency report or the petition.
	
	A primary rationale for the proposed policy expresses the concern that the current complement of lithotripsy equipment in North Carolina may not meet the needs of patients in rural areas. To solve this problem, the		

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	petitioner recommends a new policy that limits a mobile lithotripsy unit to rural areas. Because these mobile units would serve patients in sparsely populated areas, the petitioner proposed that they should be exempt from the applicable performance standards (10A NCAC 14C .3203 - 1000 per year in third year). To determine whether the procedures were performed in a rural area, the agency's analysis used the definition and website proposed by the petitioner – the U.S. Department of Agriculture's (USDA) Business and Industry Guaranteed Loan program. The analysis of access (i.e. urban or rural) to lithotripsy services used the street address of the hospital where the mobile lithotripsy unit operated during 2013-2014. Table 1 in the agency report summarizes the number of procedures and identifies the areas as either rural or urban. An analysis of lithotripsy procedures in the 2016 SMFP shows that of the 10,164 procedures performed on mobile equipment 8,833 were performed in North Carolina. In addition, it shows that 39.4% of the procedures were performed in rural areas and 60.6% were performed in urban areas. Attachment A in the agency report shows the number of procedures for each facility, by provider. The petitioner claims that rural areas are not well served by lithotripters. Since the lithotripter service area is the entire state, procedures performed in rural versus urban areas should be proportional to the population in rural and urban areas of the state. The data from the 2010 census, which uses a slightly different definition of urban and rural than the USDA, shows that 66.1 percent of North Carolina's population resides in urban areas and 33.9 percent resides in rural areas as summarized in the agency report in Table 2. On a statewide basis, there does not appear to be a substantial disproportion in procedures performed in rural versus urban areas. Therefore, an access issue suggested by the petitioner does not appear to exist. Moreover, the 2016 SMFP reports a statewide need determination for one lithotripter, bringing the projected inventory to 15 machines. Finally, the petitioner may apply for the 2016 statewide need determination.		

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A vote taken to deny the petition.

Committee Recommendation
A motion made and seconded to recommend acceptance of the Lithotripsy assumptions and methodology for the Proposed 2017 SMFP, and to advance references to years by one as appropriate.</td><td>Dr. Moore
Mr. Adams</td><td>6-0
Petition denied

Motion approved</td></tr>
<tr><td>Positron Emission Tomography (PET) – Chapter 9</td><td>Ms. Bennett provided the review for Chapter 9 – PET:

<u>Positron Emission Tomography (PET) Scanner Methodology- Chapter 9 (page 137)</u>
There is one Policy TE1: Conversion of Fixed PET Scanners to Mobile. This policy allows an applicant to convert a fixed PET under specific conditions. (Page 24) 1 applicant has received CON to convert:

Review of Need Methodology
The Service areas for PET scanners are defined in the SMFP as follows:
There are six multi-county groupings called Health Service Area (HSA). A fixed PET scanner's service area is the HSA in which the scanner is located.
The two mobile PET scanner planning regions have been defined as the west region (HSAs II, III, and I) and the east region (HSAs IV, V, and VI).
Steps: Methodology Part 1
For PET scanners, we determine current inventory and multiply the number of fixed PET scanners at each facility by 3,000 procedures to determine capacity at each facility.
A need is determined for an additional fixed PET scanner if the utilization percentage is 80 percent or greater at a facility.</td><td></td><td></td></tr>
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	• Steps: Methodology Part 2 o This part of the methodology provides a condition to determine a need for one additional fixed PET scanner if a hospital based major cancer treatment facility program or provider does not own or operate a fixed dedicated PET scanner. • The exception to this is that for both parts of the methodology combined, the maximum need determination for a single HSA in any one year will be no more than two additional fixed PET scanners regardless of the numbers generated individually by each part of the methodology. • No distinct methodology has been developed specifically for mobile PET scanners. Mobile capacity has been described in the SMFP as 2,600 procedures.		
Linear Accelerator – Chapter 9	Ms. Bennett provided the review for Chapter 9 – Linear Accelerator **Linear Accelerators Section of Chapter 9 (page 132)** **Review of Need Methodology** • Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I (page 137). • The methodology to determine a need for an additional linear accelerator in a service area must look at three criterion: efficiency, geographic accessibility and patient origin. • For the Accessibility Criterion 1 o The area population (based on the 2016 population estimate from the North Carolina Office of Budget and Management)		

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	is divided by the inventory to determine the population per linear accelerator. If the result is greater than or equal to 120,000 per linear accelerator, Criterion 1 is satisfied.
	
	• For Patient Origin Criteria 2
	    o The number of patients served from outside the service area, based on reported patient origin data, is divided by the total number of patients served. If more than 45% of total patients served reside outside the service area, Criterion 2 is satisfied.
	
	• For Efficiency Criterion 3
	    o The average number of Equivalent Simple Treatment Visits (ESTV) per linear accelerator are calculated in each service area and divided by 6,750 ESTVs to determine how many are needed. If the difference between the number needed and the current inventory is greater than or equal to a positive 0.25, Criterion 3 is satisfied.
	• If any two of the three criterion are satisfied in a linear accelerator service area, a need is determined for one additional linear accelerator in that service area.
	• To complete the methodology, Criterion 4 provides an exception for counties who reach a population of 120,000 or more and do not have a linear accelerator in inventory for that county.		

Gamma Knife - Chapter 9	Ms. Bennett provided the review for Chapter 9 – Gamma Knife **Review of Need Methodology** 1. There are two gamma knife-planning regions, the west region (HSAs II, III, and I) and the east region (HSAs IV, V, and VI). The gamma knife located at Wake Forest University Baptist Medical Center in HSA II serves the western portion of the state. The gamma knife located at Vidant Medical Center in HSA VI serves the eastern		

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	portion of the state. There are no tables for data, but data is updated in the verbiage in the plan. 2. Unlike the other sections of Chapter 9, I do have the data for gamma knife for the proposed 2017 SMFP. During 2014-2015 as reported on the 2016 Hospital License Renewal applications 439 gamma knife procedures were reported by NC Baptist Hospital and 123 procedures were reported by Vidant Medical Center. • The two gamma knives assure that the western and eastern portions of the state have equal access to gamma knife services. There is adequate capacity and geographical accessibility for gamma knife services in the state. **Committee Recommendation** A vote taken to adopt the PET, Linear Accelerator, and Gamma Knife assumptions and methodologies.	Dr. Patel Mr. Adams	6-0 Approved
Other Business	A motion made and seconded for staff to make necessary updates and corrections to all narratives, tables and need determinations for the Proposed 2017 SMFP as new and updated data is received. There was no other business brought before the Committee.	Dr. Moore Mr. Adams	Motion approved
Adjournment	The next meeting of the Committee is Wednesday, April 27, 2016 at 10:00 am. A motion made and seconded to adjourn the meeting. There being no further business, the meeting adjourned.		Motion approved