Healthcare Planning and Certificate of Need Section

Technology & Equipment Committee - Draft
Minutes
May 10, 2017
10:00 am – 12 Noon
Brown Building, Room 104, Raleigh, N.C.

Members Present: Dr. Christopher Ullrich, Trey Adams, Stephen DeBiasi, Valerie Jarvis, Dr. Lyndon Jordan III, Brian Lucas, Dr. Prashant Patel
Members Absent: Senator Ralph Hise
Healthcare Planning Staff: Amy Craddock, Andrea Emanuel, Paige Bennett, Tom Dickson, Elizabeth Brown
DHSR Staff Present: Fatimah Wilson, Lisa Pittman, Celia Inman, Tonya Rupp, Greg Yakaboski
Attorney General's Office: Bethany Burgon

Agenda Items	Discussion/Action	Motions	Recommendations/ Actions
Welcome & Introductions	Dr. Ullrich welcomed members, staff and guests to the first Technology and Equipment Committee meeting scheduled for this year. He noted the meeting was open to the public, but that the meeting did not include a public hearing. Therefore, discussion would be limited to members of the committee and staff. He stated following the meeting, the Committee's recommendations would be forwarded to the State Health Coordinating Council for consideration at the June 7, 2017 meeting.		
Review of Executive Order No. 46 Reauthorizing the State Health Coordinating Council and Executive Order No. 122 Extending the State Health Coordinating Council	Dr. Ullrich reviewed Executive Order No. 46: Reauthorizing the State Health Coordinating Council and Executive Order 122: Extending the State Health Coordinating Council. He 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 declare conflicts as agenda items came up. Dr. Jordan disclosed that his organization owns and operates a fixed PET scanner facility. Mr. DeBiasi recused from multi-positional MRI votes. Dr. Ullrich disclosed his group interprets for Carolina Neurosurgery and Spine Associates, but does not have a financial		

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	interest in the MRI equipment. He also noted that he has not discussed the multi-positional issue with the demonstration project operators.		
Approval of minutes from May 10, 2017	A motion was made to approve the minutes.	Mr. Adams Mr. Jarvis	Minutes approved. Unanimously.
Positron Emission Tomography (PET)	Ms. Bennett provided the review of the methodology, the policy, data tables, and agency recommendations for regarding the PET section of Chapter 9. There were no petitions or comments on PET scanners. 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. **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 I, II, and III) 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. Steps: Methodology Part 2 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. **Data Review** Data for all the Sections of Chapter 9 are collected on the 2017 Hospital License Renewal Forms and Registration and Inventory Forms. The data shows the number of PET scans on fixed scanners rose from 35,158 to 37,847 for an increase of 2,689 procedures. (Show Table 9L) The number of scans on mobile provides increased as well. (Show Table 9M1 and 2). Last year the total number of scans was 6,505. This year the reported total is 7,159 on two scanners. The mobile scanners are operating at 135% and 140%. This percentage of capacity is calculated using a 2,600 threshold. There is a third mobile scanner in development through Policy TE-1 that came into operation in the last month or so. Next year once we receive data on the converted scanner, the committee will need to consider how to handle the scanner because it will need to accurately represented in both Tables 9L and 9M2. There are no needs for fixed PET Scanners. Based on the old business of the committee, there was discussion of continued review of the distribution of mobile PET machines and procedures. Based on this review and analysis, the staff is recommending a need for a mobile PET scanner. The new data shows that fixed PET scans have increased 16.9% (Table 1) in the last three years. Table 2: Mobile PET scans have seen a 22% increase over the same time frame. Table 3 is the same as Table 9M1. Table 4 includes the total number of procedures on the two machines reporting data for FY 2015-2016. It calculates the number of machines needed at 2600 (100% capacity) and at 2080 (80% capacity). 80% was chosen because this is aligned with the fixed PET methodology.		

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	It shows that there is a deficit in the number of scanners by almost a half of a scanner and since the number of procedures has been slowly, but steadily increasing the staff recommend adding a statewide need determination for 1 scanner as shown in Table 9O. After the analysis staff elected to recommend adding a statewide need in o Committee discussion included changes in reimbursement, clinical applications for the use of PET scans, and the recent increases in scans. Other questions arose about the urgency of scans, community access, and the appropriate capacity statewide for mobile scanners. Other questions including the service area of the mobile scanners and logistics of scheduling and moving the scanner across the state. Facilities are not able to add additional time based on the current use. The Agency reports are routinely treated as motions for committee discussions. Dr. Ullrich made a motion to accept the PET reports as presented.		Motion adopted. Unanimously; Dr. Jordan recused.
Magnetic Resonance Imaging	Ms. Bennett provided the review of the methodology, the policies, multi-positional MRI scanners, data tables, and agency recommendations for regarding the MRI section of Chapter 9. There were no petitions or comments for MRIs. There are two Policies for this section. The first is TE-2: Intraoperative MRI scanners qualified applicants can apply for an intraoperative MRI scanner to be used in an operating suite Pg 23. The second was added to the Plan last year, Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Scanners. This policy allows licensed facilities with 24 hour/7 day a week emergency care without a fixed MRI scanner to apply for one if they can demonstrate the machine will perform 850 weighted procedures.		

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	Review of Need Methodology The Acute Care Bed Service Area as defined in Chapter 5 of the 2017 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: The current inventory of 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 148, 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 147 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.		

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	Data Review As part of a continued review of the demonstration projects in the SMFP we were reviewing the data for the MRI machines in Table 9Q(6) – Fixed Multi-positional MRI scanners. Ms. Bennett discussed the analysis performed by staff for the adding the multi-positional scanners back into the tables for both the 2016 and 2017 SMFPs. You can see that in both service areas, because they are well utilized machines, they did not make a significant difference to the county calculations and no need determinations were changed as a result. The committee is probably interested in the proposed 2018. (Scroll down to the second page for Proposed data). Again this has made no difference in the need determinations. We were able to update the table and again it will be posted online. Discussion: The Committee discussed the service areas for these scanners and whether adding them back into the table would change it. Other topics included the increase in scans and the growth of population. Members also discussed the replacement of this equipment with regular MRI equipment. Dr. Ullrich explained that the vote would normalize the scanners rather than keep them out of the inventory. These highly utilized machines should not be segregated from the methodology. The Committee voted on placing the machines back into the main MRI table. Ms. Bennett provided a review of Table 9P and the need determinations. Ms. Bennett stated the number of MRI procedures as currently calculated in the Proposed 2018 SMFP decreased by 5,348, but there is still data cleaning and outstanding forms. So far there are 3 needs projected, 1 MRI in each: Mecklenburg County, Pasquotank/Camden/Currituck/Perquimans Health Service area, and Union County. There is one hospital in Mecklenburg County that has data, which doubled from last year to this year [Novant Health Matthews, 7666]. They have been asked to verify this information. The need determination may go away if the data is corrected.		Motion adopted. Unanimously; Dr. Jordan and Mr. DeBiasi recused.

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	Pasquotank HSA has only one facility with one fixed machine. They triggered the need by 1 procedure. It may be difficult for successful application to project procedure growth needed to meet the performance standards. The third need is in Union County and they are well above the threshold. A motion to adopt the MRI portion of 2018 Proposed SMFP.	Mr. DeBiasi Mr. Adams	Motion adopted. Unanimously.
Cardiac Catheterization	Ms. Bennett provided the review of the methodology, data tables, and agency recommendations for regarding the cardiac catheterization section of Chapter 9. There were no petitions and no comments for cardiac catheterization. **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. 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.		

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	The number of fixed cardiac catheterization equipment required is determined by dividing the number of weighted or diagnostic-equivalent procedures performed at each facility by 1200 procedures (80% 0f 1500 capacity). 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 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. **Data Review** The number of diagnostic cardiac catheterization procedures increased from 58,872 last year to 62,474, but the number of interventional procedures decreased from 27,168 to 25,486. Table 9W shows one need for fixed cardiac catheterization equipment in Buncombe County. A motion to adopt the cardiac catheterization portion of 2018 Proposed SMFP.	Ms. Jarvis Dr. Jordan	Motion adopted. Unanimously.
Lithotripsy	Ms. Bennett provided the review of the methodology, data tables, and agency recommendations for regarding the lithotripsy section of Chapter 9. There were no petitions or comments for lithotripsy. **Review of Need Methodology** The lithotripter planning area is the entire state so this is a statewide determination. Steps:		

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	First, using the July 1, 2018 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. **Data Review** The number of lithotripsy procedures decreased from this year to last year. Last year the total number of procedures was 10,019 and this year the total number is 9,529. As a result, the average number per machine decreased as well from 716 to 681. This calculation is using 14 as the denominator. There are 15 machines statewide including the need determination from the 2016 SMFP; however, the machine reported no data during the reporting year. The CON for the 2016 SMFP was awarded to Piedmont Stone Center. There were no need determinations for lithotripsy. Discussion: The Committee discussed the mobile lithotripsy capacity and the decrease in procedures. A motion to adopt the lithotripsy portion of 2018 Proposed SMFP.	Mr. Adams Dr. Patel	Motion adopted. Unanimously.

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Linear Accelerator	Ms. Bennett provided the review of the methodology, data tables, and agency recommendations for regarding the linear accelerator section of Chapter 9. There were no petitions or comments for linear accelerators. **<u>Review of Need Methodology</u>** Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I (pg 132). The methodology to determine a need for an additional linear accelerator in a service area must look at 3 criterion: efficiency, geographic accessibility and patient origin. For the Accessibility Criterion 1 The area population (based on the 2017 population estimate from the North Carolina Office of Budget and Management) 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 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 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.		

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	If any 2 of the 3 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. **Data Review** The average number of ESTVs per machine increased slightly from last year to this year from 4,520 procedures per machine to 4,602 procedures per machine. There were no need determination calculations for linear accelerators. A motion to adopt the linear accelerator portion of 2018 Proposed SMFP.		Motion adopted. Unanimously.
Gamma Knife	Ms. Bennett provided the review of the methodology, and data tables, for regarding the gamma knife section of Chapter 9. No petitions or comments were received regarding the Gamma Knife section. **Review of Need Methodology** There are two gamma knife planning regions, the west region (HSAs I, II, and III) 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 portion of the state. There are no tables for data, but data is updated in the verbiage in the plan. **Data Review** Unlike the other sections of Chapter 9, I do have the data for gamma knife for the proposed 2018 SMFP. During 2015-2016 as reported on the 2017 Hospital License Renewal applications 460 gamma knife procedures were reported by NC Baptist Hospital, and 230 procedures were reported by Vidant Medical Center. These were both increases over the past year. The two gamma knives assure that		

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	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. A motion to adopt the gamma knife portion of 2018 Proposed SMFP.	 Ms. Jarvis Mr. DeBiasi	 Motion adopted. Unanimously.
Other Business	The chair made a motion to adopt Chapter 9 as discussed and forward to the full Council on the June 7th meeting. A motion was made and seconded to allow staff to continue to make necessary updates to narratives, tables and need determinations in the Proposed 2018 SMFP as new and corrected data is received. The Committee discussed the sections of Chapter 9 that might require focus in the future. Mr. Adams initiated discussion about removing the need methodologies for gamma knife and lithotripsy. Dr. Ullrich indicated rather than eliminating the need methodology, the Committee may consider creating policies. Dr. Patel discussed the capacity and appropriate use of all technologies to ensure utilization is clinically appropriate. Mr. Adams had concerns about the amount of staff time used on the gamma knife and lithotripsy methodologies. Regarding Mr. Adams's question of review of the methodologies, Dr. Ullrich said staff would review the methodology as time allows, but changes also would require stakeholder input. Dr. Ullrich reminded all members about all of the upcoming public hearings in July and the next SHCC meeting on June 7, 2017.	Mr. Adams Ms. DeBiasi Dr. Jordan Ms. Jarvis	Motion adopted. Unanimously. Motion adopted. Unanimously.
Adjournment	Dr. Ullrich requested a motion to adjourn. The Committee voted to adjourn.	Dr. Patel Dr. Jordan	Motion adopted. Unanimously.