Healthcare Planning and Certificate of Need Section

Technology & Equipment Committee - Draft
Minutes
September 14, 2016
10:00 am – 12 Noon
Brown Building, Room 104, Raleigh, N.C.

Members Present: Dr. Christopher Ullrich, Trey Adams, Dr. Prashant Patel, Dr. Jeffrey Moore, Brian Lucas, Dr. Lyndon Jordan III, Kelly Hollis
Members Absent: Valarie Jarvis, Senator Ralph Hise
Healthcare Planning Staff: Patrick Curry, Amy Craddock, Andrea Emanuel, Paige Bennett, Tom Dickson, Elizabeth Brown
DHSR Staff Present: Mark Payne, Martha Frisone, Fatimah Wilson, Lisa Pittman, Gloria Hale, Mike McKillip
Attorney General's Office: Jill Bryan

Agenda Items	Discussion/Action	Motions	Recommendations/ Actions
Welcome & Introductions	Dr. Ullrich welcomed members, staff and guests to the third and final Technology and Equipment Committee meeting scheduled for this year. Dr. Ullrich stated the purpose of this meeting was to review petitions and comments received in response to the *Proposed 2017 State Medical Facilities Plan*. He stated the Committee would also review updated tables, reflecting changes since the *Proposed Plan* was published, in order to make the Committee's recommendation to the State Health Coordinating Council for the *Proposed 2017 State Medical Facilities Plan*. Dr. Ullrich noted this meeting was open to the public. However, discussions, deliberations and recommendations are limited to the members of the Technology and Equipment Committee. He noted following the meeting, the Committee's recommendations would be forwarded to the State Health Coordinating Council for consideration at the October 5, 2016 meeting.		

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Review of Executive Order No. 46: Reauthorizing the State Health Coordinating Council	Dr. Ullrich reviewed Executive Order No. 46: Reauthorizing the State Health Coordinating Council. 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. Mr. Adams recused himself from voting on the Wake County petition, Dr. Jordan also recused himself from voting on the Wake County petition. Dr. Ullrich recused himself from voting on the Lincoln County petition. No other members recused themselves from voting on any matter coming before the committee at the meeting. Dr. Ullrich asked members to declare conflicts as agenda items came up.		
Approval of minutes from May 13, 2015	A motion was made to approve the minutes.	Mr. Adams Mr. Lucas	Minutes approved
Cardiac Catheterization	Mr. Curry stated that the agency received two petitions regarding the Cardiac Catheterization section of Chapter 9. ***Request:*** UNC REX Healthcare (Rex) petitions the SHCC to create an adjusted need determination for two additional units of fixed cardiac catheterization equipment in Wake County in the 2017 SMFP. Rex is requesting the adjusted need determination based on "the unique utilization trends faced by Rex". Mr. Curry stated that two letters from the petitioner, one public hearing comment and two letters in opposition were received for this petition. ***Agency Report Summary:*** Mr. Curry summarized the Agency Report. Wake County has a total of 17 cardiac catheterization machines. Of those, Rex has a total current inventory of four machines. Using the standard methodology of 80% utilization, the number of machines for Wake County and Rex is 12.64 and 5.78, respectively. Thus, Rex has a 1.78 machine deficit and Wake County has a 4.36 machine surplus. Wake County's surplus has remained relatively consistent in the last four years while Rex's deficit has increased each year. In the face of steady increases and aging of the population in North Carolina, the number of cardiac catheterizations has remained fairly stable over the last decade.		

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	In Wake County, the last 10 years of data shows an average annual CAGR of -0.81% (a decline) while the NC CAGR over the same time period had an average annual decline of -1.08%. This data indicates an overall decline in the number of procedures for both the County and the State, with Wake County experiencing a slower decline than the State overall. Rex is the only provider in Wake County that has shown a consistent increase in the number of procedures over the last five years. More notably, in the most recent three years, Rex has demonstrated utilization greater than 80% – the utilization threshold for determining a need in the health service area. Application of the methodology does generate deficits for this facility. However, the standard methodology considers procedure volume and number of machines in the entire service area. Thus, Rex's deficit is offset by a surplus of machines in Wake County as a whole. Finally, Rex's utilization has increased from 84% two years ago to 116% in the most current year of data, which exceeds the need for one additional machine. ***Agency Recommendation:*** The Agency supports the standard methodology for fixed cardiac catheterization equipment. The current methodology calculates a 1.78 machine deficit for Rex. As discussed above, the deficits at Rex in the last three years have been offset by the surpluses at other facilities in Wake County. Wake County, and in particular Rex, are experiencing increases in the utilization of cardiac catheterization laboratories. Given available information and comments submitted by the August 12, 2016 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends approval of the Petition. Dr. Ullrich allotted three minutes for Dr. Ravish Sachar of Rex to respond to the Agency Report. Dr. Ullrich then allotted three minutes for Donald Gintzig, Chairman and CEO of WakeMed, to respond to the Agency Report. The Agency reports are routinely treated as motions for committee discussions.		

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	Committee Recommendation: The Committee also discussed how part of why the surplus at Rex is uniquely high is because of the heart and vascular physicians group who moved from WakeMed to UNC Rex in the last few years. The Committee also expressed uncertainty as to whether the upward trend would continue in coming years. Dr. Ullrich noted that the Committee has three options regarding the petition. First, it may deny the agency's recommendation. Second, it may approve the agency's recommendation. Finally, it may modify the agency's recommendation. Dr. Patel made a motion to amend the Agency recommendation to adjust the need determination to one additional unit instead of two units. The committee voted to approve this amendment to the petition. Dr. Ullrich then called a vote to approve the amended petition for one additional unit of cardiac catheterization equipment in Wake County. The committee approved.	Dr. Patel Dr. Moore	Motion approved to amend (Unanimous, 4-0.) (Mr. Adams, and Dr. Jordan recused themselves from voting.) Motion approved (Unanimous, 4-0.) (Mr. Adams, and Dr. Jordan recused themselves from voting.)

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	Request: Cape Fear Valley Health System (CFVHS) requests an adjusted need determination to remove the need determination for one additional unit of fixed cardiac catheterization equipment in Cumberland County in the 2017 SMFP. One public hearing comment from the petitioner was received. ***Agency Report Summary:*** The Agency Report was summarized by Mr. Curry. As noted in the petition, the 2016 SMFP identified a need for a new shared fixed cardiac catheterization unit in Harnett County and a fixed cardiac catheterization unit in Cumberland County. The Harnett County need determination resulted from an approved adjusted need petition. The Cumberland County need was generated by the standard methodology. Harnett Health submitted a Certificate of Need (CON) application for the unit in Harnett County for the May 1, 2016 CON application review cycle and was approved. CFVHS is also an applicant for an additional unit of cardiac catheterization equipment in Cumberland County. The standard methodology generated an additional need in the Proposed 2017 SMFP for one fixed cardiac catheterization equipment in Cumberland County. In Cumberland County, the last 5 years of data shows an average annual CAGR of 4.64% while the NC CAGR over the same time period shows an average annual decline of -2.02%. This analysis indicates that Cumberland County is having an increase in procedures even as the State is experiencing an overall decline. However, a key issue in this Petition is not just Cumberland County's growth and subsequent need determination. It is also the pending cardiac catheterization services in neighboring Harnett County and what that could mean for the demand for services in Cumberland County. Patient origin numbers for cardiac catheterization procedures are not collected by the Agency in the License Renewal Applications. But as previously mentioned, Harnett Health petitioned for an additional fixed cardiac catheterization unit in summer of 2015; and, that Petition included Truven data on use rates with patient origin.		

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	According to Step 4 of Methodology 1, a need is triggered by 1,200 annual procedures. Truven's data indicates that 24% of Harnett residents are going to Cumberland County and that Harnett had 1,482 projected diagnostic catheterizations procedures in 2015. Multiplying the 24% by 1,482 gives an estimated 359 procedures performed on Harnett County residents at CFVHS in Cumberland County. This 359 is subtracted from the 5,494 Cumberland County 2015 procedures (weighted totals) in the Proposed 2017 SMFP for an adjusted total of 5,135. Dividing this figure by the 1,200 procedure threshold per the methodology leaves a quotient of 4.28, and by subtracting the current planning inventory of 4 machines (per the methodology) this leaves 0.28, which is rounded to zero. ***Agency Recommendation:*** The Agency supports the standard methodology for fixed cardiac catheterization equipment. The unique situation of increased need determinations and cardiac catheterization equipment along with patient migration between Cumberland County and Harnett County demonstrates that a need determination in the 2017 SMFP would not be necessary. Given available information and comments submitted by the August 12, 2016 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the Agency recommends approval of the Petition to adjust the need determination the 2017 SMFP to zero. The Agency recommended approving the petition. The Agency reports are routinely treated as motions for committee discussions. **Committee Recommendation:** The Committee concurred with the Agency Report and had no questions to ask. Dr. Ullrich made a motion to approve the petition. The committee voted to approve the petition. **Data Updates to Table 9W** Mr. Curry noted there were updates to data in Harnett County, which can be seen in Table 9W.		Motion approved (Unanimous, 6-0.)

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	Dr. Ullrich recommended that the Committee adopt Chapter 9 as a whole at the end of the meeting rather than in individual sections.		
Magnetic Resonance Imaging	Mr. Curry stated that the agency received one petition regarding the Magnetic Resonance Imaging section of Chapter 9. ***Request:*** Carolinas HealthCare System (CHS) requests the need for an additional fixed MRI scanner in Lincoln County be removed from the North Carolina 2017 SMFP. Similar to the past two years, the application of the methodology in the Proposed 2017 SMFP generated a need determination for one additional fixed MRI scanner in Lincoln County. One letter of opposition to this petition was received. ***Agency Report Summary:*** The Agency Report was summarized by Mr. Curry. The need determination in Lincoln County is driven by CHS Lincoln's MRI utilization of 4,952 MRI weighted procedures reported for the Proposed 2017 SMFP. The threshold for a service area with one fixed machine is an average of 3,775 scans per machine. Therefore, the service area surpassed the threshold for a need determination by 1,177 weighted scans. In the last six years, Lincoln County has demonstrated a relatively quick growth rate in MRI procedures as compared to the growth statewide. The county had a 10.38% compound annual growth rate (CAGR). If the 10.38% CAGR were used to project the number of procedures one would expect in Lincoln County after five years, the total number of projected procedures would be 8,114. Hypothetically, a Certificate of Need (CON) application would be prepared and approved during 2017. If development of the approved project is completed by the end of 2018 (Year 2 of the process) then 2019 would be the first year of operation of the new scanner. Under this scenario, the anticipated procedures in the third year of operation nearly reach the 7,550 threshold (Year 5 of the process). If development requires another year, then the third year of operation would be Year 6 of the process.		

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	Unless the CAGR drops significantly next year, the anticipated growth shows this threshold being crossed during an applicant's third operating year of a proposed scanner. ***Agency Recommendation:*** The agency supports the standard methodology for fixed MRI equipment in the Proposed 2017 SMFP. In consideration of the above, the agency recognizes procedure volumes in Lincoln County could reasonably cross the threshold during an applicant's third operating year of a proposed scanner. Given available information submitted by the August 12, 2016 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends denial of the Petition to adjust the projected need determination for an additional unit of fixed MRI equipment to zero (0) in Lincoln County in the 2017 SMFP. The Agency determined that procedure volumes in Lincoln County could reasonably cross the threshold during an applicant's third operating year of a proposed scanner, thus the need determination should remain. The Agency recommended denying the petition. The Agency reports are routinely treated as motions for committee discussions. **Committee Recommendation:** The Committee discussed how the trend in total procedure volumes and migration of patients supported the Agency Report. Dr. Ullrich called for a vote to deny the petition. The motion was approved. Mr. Curry noted two general comments were received regarding Policy TE-3. The North Carolina Hospital Association submitted a comment in support of Policy TE-3, but requesting that the policy may be used in a county where a fixed MRI has already been approved. Alliance Healthcare submitted a comment in opposition to Policy TE-3 expressing concerns regarding limiting the type of qualified applicant, the potential for underutilized MRI scanners in community hospitals, and the level of the proposed threshold.		Motion approved (Unanimous, 6-0.) (Dr. Ullrich recused himself from voting.)

	Request: Cape Fear Valley Health System (CFVHS) requests the following two changes be made to the Proposed Policy TE-3 in the 2017 SMFP. 1. The policy should be amended to allow an individual community hospital with a 24- hour emergency department to apply for a CON for a fixed MRI. 2. The threshold in the policy should be changed to 500 weighted MRI procedures. One public hearing comment from the petitioner, one letter of opposition, and one general letter were received. Mr. Curry noted that the Agency would be responding to this request as a comment rather than a petition. ***Agency Report Summary:*** The Agency Report was summarized by Mr. Curry. The Agency recommended removing "is located in a county that" from Policy TE-3 policy language but retaining the 850 weighted procedure threshold. Mr. Curry read the proposed wording of Policy TE-3 into the record. The Agency reports are routinely treated as motions for committee discussions. **Committee Recommendation:** The Committee disagreed as to whether the threshold was too high or too low, but agreed on access to MRI being important. Dr. Ullrich called for a vote to amend the 850 threshold to 500. The Committee voted 3-3 to deny this amendment. The Committee agreed that moving to a hospital-based model was preferable to a county-based model as it may benefit rural communities. Dr. Ullrich called for a vote to adopt the language as recommended by the Agency. The Committee voted to adopt the Agency's recommendation. **Data Updates to Table 9P** Mr. Curry noted there were updates to data in Brunswick and New Hanover counties, which can be seen in Table 9P.		Motion is lost. (3-3 tie. Majority needed for motion to carry.) (Dr. Ullrich did not vote.) Motion approved (Unanimous, 5-1.) (Dr. Ullrich did not vote.)

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Lithotripsy	***Request:*** Triangle Lithotripsy requests an adjusted need for one additional mobile lithotripter statewide. One letter of support, one comment from the petitioner, and three documents opposed to the petition were received. ***Agency Report Summary:*** The Agency Report was summarized by Dr. Craddock. Although the state population has increased by 29% since 1998 (the implementation of the Lithotripsy methodology), the 2016 SMFP represents the first time that the methodology has calculated a need for a lithotripter. Certificate of Need applications are currently under review for the need for one lithotripter in the 2016 SMFP. The petitioner proposes a threefold rationale for the adjusted need determination. 1. Out of State Lithotripsy Sites cause NC to have less than full use of its available lithotripters According to the Proposed 2017 SMFP, 17.5% of sites are located and 14.0% of procedures are performed in either South Carolina or Virginia. Just as with other health services, it is likely that some proportion of ESWL patients served in NC are residents of other states. Likewise, some NC residents probably receive ESWL in other states. However, no patient origin data is available to test the accuracy of either this proposition or the petitioner's assertion. 2. Distribution of Lithotripsy Services is uneven The petition correctly notes that several lithotripters have low use rates. It asserts that these low use rates are related to uneven access, primarily because 55 counties don't provide lithotripsy services. Although this number is accurate, it is also accurate that all but three counties have a lithotripsy site either in the county or in		

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	a contiguous county. Figure 1 (at the end of the agency report) illustrates this point. The methodology assumes an annual incidence of 16 cases of urinary stone disease per 10,000 population, with 85-90% of cases appropriate for lithotripsy. Therefore the methodology uses a standard use rate of 14.4 per 10,000 as full utilization (90% of 16 per 10,000 population). The petitioner points out that the average calculated use rate is only 8.77 cases per 10,000 population and contends that the low use rate as well as the uneven use rates statewide are related to access limitations. However, other factors may influence both use rates and access. Possible factors may include, e.g., actual need for ESWL, physician practice patterns, business decisions of lithotripter owners and/or sites, reimbursement models, and patient preference. Moreover, to assure an adequate inventory statewide, the standard methodology would be expected to reflect a use rate that is higher than the average. That being said, the Agency acknowledges that because the methodology is statewide, we would expect variation in use rates across counties and would expect that the use rate in some areas may exceed the use rate assumed in the methodology. 3. Finally, petitioner claims that the Need Determination Methodology underestimates need. The need determination methodology is based on the annual incidence of kidney stones (i.e., newly diagnosed cases) rather than on the proportion of the population that reports ever having a kidney stone (i.e., lifetime prevalence). Data suggests that the incidence has decreased over time, but that prevalence has increased. This observation is common in epidemiological data. As the population ages, a larger proportion will have had a kidney stone at least once in their lives. Along with the increase in the prevalence of kidney stones, North Carolina has increased lithotripter services. The number of lithotripter sites in NC has increased from 76 in 2008 (when most recent lithotripter came online) to 80 in 2015. Also,		

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	19.5% of procedures were at South Carolina or Virginia sites in 2008 compared to 13.1% in 2015. Our data also shows that the statewide ESWL use rate has declined 11% in the past 10 years, even though the population has increased about 16%. There is some evidence in the literature that the decrease in utilization is a larger trend. ***Agency Recommendation:*** The Agency supports the standard methodology for lithotripsy services. In addition, the SHCC cannot require a lithotripter owner to limit its services to North Carolina sites, as requested in the petition. Given available information and comments submitted by the August 12, 2016 deadline for comments on petitions and comments, and in consideration of factors discussed in the agency report, the Agency recommends denial of the petition. The Agency determined that petitioner did not demonstrate that the methodology suppresses the need nor that access to lithotripsy services is limited, as claimed in the petition. Further, the *2016 SMFP* contained a need determination for one lithotripter, which will increase inventory. The Agency recommended denying the petition. Dr. Ullrich allotted three minutes for David Driggs of Triangle Lithotripsy to respond to the Agency Report. The Agency reports are routinely treated as motions for committee discussions. **Committee Recommendation:** The Committee concurred with the Agency Report. The Committee expressed that need was being met by the inventory, particularly with another coming. Dr. Ullrich made a motion to accept the Agency recommendation to deny the petition. The committee voted to deny the petition.		Motion approved (Unanimous, 6-0.)
Linear Accelerator	Mr. Curry stated no petitions or comments were received regarding the Linear Accelerator section. **The Prostate Health Center Demonstration Project**		

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	Mr. Curry provided an update on the demonstration project. In the 2009 SMFP, there was a statewide need determination for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer particularly in African American (AA) men. The CON was awarded to The Prostate Health Center in Wake County. The CON was issued 2/23/11 and the project was complete 5/1/13. The applicant, as one of the conditions on the CON, is to provide annual reports for the first three years that includes data on the number of patients treated, the number of African Americans treated; the number of other minorities treated; and the number of insured, underinsured and uninsured patients served by payment category. 2013: 227 Total; 83 AA; 8 other minority; 206 insured; 46 underinsured; 3 uninsured. 2014: 339 Total; 95 AA; 19 other minority; 306 insured; 18 underinsured; 15 uninsured; 2015: 269 Total; 81 AA; 6 other minority; 256 insured; 7 underinsured; 6 uninsured. The three-year trend indicates that total numbers treated in 2013 and 2015 were comparable, but 2014 featured an approximately 30% increase versus the other years. The number of AA has remained somewhat stable and the number of underinsured has dropped each year, but other minority and insurance figures also increased considerably in 2014 versus 2013 and 2015 figures. This is the third and final year of data reporting. A condition of the Certificate of Need states the applicant shall make arrangements with a third party researcher (preferably a historically black university) to evaluate the efficacy of the model during the fourth operating year of the Center and develop recommendations whether or not the model should be replicated in other parts of the State. The report and recommendations of the researcher shall be provided to the Healthcare Planning and Certificate of Need Section in the first quarter of the fifth operating		

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	year of the project. This information will be shared with the SHCC and the T&E Committee.		
Positron Emission Tomography (PET) Scanner	Mr. Curry stated no petitions and two comments were received regarding the Positron Emission Tomography (PET) section.		
Gamma Knife	Mr. Curry stated no petitions or comments were received regarding the Gamma Knife section.		
Other Business	**Committee Recommendation:** A motion was made and seconded to allow staff to continue to make necessary updates to narratives, tables and need determinations in the 2017 SMFP as new and corrected data is received. A motion was made to forward Committee recommendations to the October 5th meeting of the SHCC regarding Chapter 9 data and need determinations. Dr. Ullrich asked if there was any old business, concerns or comments. He reminded those present of the Operating Room Workgroup which will begin meeting in October. The dates are posted on the website. Any Committee members who are interested should contact Paige Bennett by email. Those interested must commit to the five meetings. Individuals can also nominate another individual. The list of all members of this Workgroup is due by September 30th. Regarding Mr. Adams's question of review of the methodology, Dr. Ullrich said staff will review the methodology as staff time allows. Mark Payne and the staff will give priority to the methodologies with the most urgency. Dr. Ullrich reminded all members of the October 5, 2016, SHCC meeting.	Dr. Patel Dr. Moore Dr. Patel Dr. Jordan	Motion approved (Unanimous, 6-0.) Motion approved (Unanimous, 6-0.)
Adjournment	Dr. Ullrich requested a motion to adjourn. The Committee voted to adjourn.	Mr. Adams Mr. Lucas	Motion approved (Unanimous, 6-0.)