

**Comment on
WakeMed's Petition for Cardiac Catheterization Methodology Change**

COMMENTER

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In response to WakeMed Health and Hospitals' (WakeMed's) petition to change the methodology for cardiac catheterization in the *2016 State Medical Facilities Plan*, Johnston Health would like to provide reasons that it believes the petition should be denied.

1. The current methodology assumes an appropriate average capacity for statewide use.

Johnston Health disagrees with WakeMed that the average case time assumption is too long, for several reasons. First, WakeMed is incorrect in asserting that the methodology assumes a particular case time; in fact, the methodology does not indicate an assumption regarding a particular case time, but establishes 1,500 weighted (diagnostic-equivalent) procedures as the capacity.

Moreover, the actual time required to complete a single procedure is not the sole consideration in determining capacity. In addition to the time required by the procedure, the room must be cleaned and prepared for another patient, which often requires as much time as the time required to conduct the procedure, as noted in some of the information cited by the petitioner. Additionally, the procedure counts reported by providers and included in the *SMFP* methodology actually understate the total number of procedures performed. Specifically, the Hospital License Renewal Application forms require hospitals to provide only one ICD-9 coded procedure per case/patient; thus, patients undergoing multiple procedures are counted only once. It is not uncommon for patients to require multiple procedures or require more time than what might be "average." Just this week, Johnston Health treated a complex cardiac catheterization patient that required more than two hours of time in the cath lab—not including the time needed to turn the room over following the case. Physicians also vary in the amount of time they need to perform cases, as some prefer to work slower or more quickly than their colleagues, which can cause variation in the time required for the procedure. Given these facts, Johnston Health believes the assumptions in the current methodology are reasonable for assessing statewide need.

2. Many providers do not operate more than 2000 hours per year.

Although WakeMed does not define the number of providers it believes has longer hours of operation, it is certainly possible that providers with 24/7 coverage for STEMI's operate more hours than those that do not perform emergency PCI's. In order for the *SMFP* methodology to be effective, however, the capacity definition must also account for providers with only one unit of equipment and those that do not provide full-time coverage, both of which appear to be the case for most of the providers in the state. Unlike facilities such as WakeMed with multiple pieces of equipment, Johnston Health must contend with the challenges of only one cardiac cath unit. It is likely that similar operational limitations exist at many of the facilities with only one unit of equipment or for those that do not provide 24/7 care for emergency cardiac catheterizations. Changing the capacity definition to apply to only a limited number of providers would unfairly disadvantage lower volume, single unit providers like Johnston Health.

3. WakeMed asserts that decline in volume and the problems with the methodology have resulted in overcapacity.

While it is accurate to state that the overall number of cardiac catheterization procedures has declined statewide in recent years, some providers have experienced an increase in volume, particularly those that have initiated elective PCI, such as Johnston Health. The analysis provided by WakeMed, including the statewide surplus of cardiac catheterization units, is also irrelevant, given that capacity in one part of the state does not enable a patient needing an interventional cardiac cath in another part of state to have access to that procedure in a timely manner, close to home. Moreover, some of the "surplus" is at providers in areas that may never fully utilize a single unit of equipment; however, the access provided by that equipment to life-saving diagnosis and possibly intervention is nonetheless essential. As with multiple other methodologies, and, in fact, as addressed in the Findings of Fact in the CON statute as well as the Basic Principles in the *SMFP*, capacity of existing providers is not the sole consideration when determining need. Adequate access, including geographic and temporal access, must be considered as well. WakeMed's petition would fail to consider the access provided by smaller, single-unit providers like Johnston Health.

4. Increasing the capacity definition in the methodology would not solve any issues alleged by WakeMed, but could harm some existing providers.

Although Johnston Health does not agree with WakeMed's assertion that a statewide issue exists, the changes it proposes would actually increase, not decrease the surplus that WakeMed states it is trying to address. Increasing the capacity definition and/or decreasing the weighting for interventional

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procedures would significantly increase the surplus of cardiac catheterization units in the state—something the WakeMed petition purports to address.

Further, Johnston Health does not believe that the issue even exists. WakeMed cites the request by New Hanover Regional Medical Center to remove a need determination as evidence, but other providers have made similar requests in the past for services including acute care beds and MRIs—without requesting that the entire methodology be changed. In addition, since only hospitals can be approved for fixed cardiac catheterization units, and since the majority of service areas include only one hospital, that sole provider can more easily determine whether a need exists in the service area and petition the SHCC accordingly. Given the lack of such petitions, it seems that the situation in New Hanover County is rather unique.

Instead of truly being a statewide issue, Johnston Health believes that WakeMed is attempting to address an issue specific to its situation that should not be addressed by a change that impacts the entire state. As shown on Table 9W of the 2015 SMFP, WakeMed and WakeMed Cary have a total planning inventory of 10 units of equipment, but require only 7.33 machines, based on the current methodology. Thus, even without enacting the change proposed by WakeMed, it already has a surplus of nearly three machines. If, as WakeMed has indicated, it has even greater capacity than what is defined by the methodology, then it may have an even greater surplus. While amending in the methodology will not change that fact, no provider, particularly those with multiple units that are not well utilized, is prevented from decreasing its inventory of cardiac cath units, which would decrease the surplus.

Finally, Johnston Health believes changing the methodology as suggested has the potential to harm some providers. The methodology already makes it nearly impossible for facilities in counties with only one unit of equipment to generate the need for a second unit, as has been addressed in past SHCC petitions¹. For such providers, including those with growing volumes like Johnston Health, increasing the capacity definition would make it even more difficult to generate need for a second unit. But the changes would also have the potential to be harmful to larger providers as well. As a provider of PCI without on-site open heart capabilities, Johnston Health conforms to strict guidelines regarding the patients it treats as well as the protocols it has in place for emergencies. Included among these standards are select lesion criteria for determining which patients can be treated at Johnston Health versus those that need to be treated at a facility with open heart backup. As is the case with most providers in a similar situation, Johnston Health has established protocols and agreements with a single tertiary provider, in this case Rex Healthcare, to accept patients that would like to be treated at Johnston Health but do not meet the selection criteria. Rex

¹ See, e.g. 2012 petition from Southeastern Regional Medical Center at page 7, “Capacity Constraints.” http://ncdhhs.gov/dhsr/mfp/pets/2012/tec/0802_roberson_cce.pdf

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also serves as the site for transfers in case of emergencies. As such, patients at Johnston Health benefit from the enhanced safety of the back-up capacity provided at Rex Healthcare. A change in the methodology as proposed could make it more difficult for Johnston Health's tertiary partner to have capacity available when needed.

In summary, Johnston Health believes that the changes proposed by WakeMed are not needed, will not accomplish the goals of the petition, and would negatively impact other providers, particularly those in smaller, more rural areas. For these reasons, it should be denied.

Thank you for your consideration.