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Petition to the North Carolina State Health Coordinating Council

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Purpose: Request that the methodology for determining need for cardiac catheterization equipment in North Carolina be revised for the 2016 State Medical Facilities Plan.

Rationale for the Petition:

Problems with the Methodology Acknowledged in 2013

The first indication of the problem with the methodology surfaced in 2013. New Hanover Regional Medical Center petitioned the SHCC to *remove* a need determination of one unit of fixed cardiac catheterization equipment for New Hanover County shown in the Proposed 2014 SMFP. The petition explained that the hospital's cardiac catheterization labs were open ten hours a day, five days a week, year-round. The five units of equipment that the hospital operates are therefore available approximately 13,000 hours per year [calculation: 10 hours per day x 5 days per week x 52 weeks per year x 5 units = 13,000]. The petition further stated that the average case time for both diagnostic and therapeutic catheterizations at its facility was approximately one hour each and, as a result, NHRMC considered its catheterization labs were only utilized at 55 percent, even though the methodology used in the SMFP indicated that they were over 95 percent of capacity.

The SHCC approved the petition with both the Agency Report and the Technology and Equipment Committee recommending the action. The petition questioned the need methodology for cardiac catheterization equipment and argued successfully that the capacity thresholds in the plan were too low.

The Average Time Required to Perform Cardiac Catheterization Procedures Used in the SMFP Methodology is Too Long

The current need methodology for fixed cardiac catheterization equipment was adopted in 2000 and first used in the 2001 SMFP. It was approved using mostly data from the 1990s, during a time when utilization was rising and the SHCC was concerned about staying ahead of the curve and meeting demand. The defined capacity of 1,500 procedures per year, with a weight of 1.00 for diagnostic and 1.75 for therapeutic procedures (in a facility that operates its labs eight hours a day, five days a week, 50 weeks a year or 2,000 hours per year) computes to

1 hour 20 minutes for a diagnostic procedure¹ and 2 hours 20 minutes for a therapeutic procedure².

Many sources suggest that cardiac catheterization procedures take much less time than the current methodology assumes. The following internet sites all provide estimated times well below that used by the SMFP methodology:

- <http://my.clevelandclinic.org/services/heart/diagnostics-testing/invasive-testing/cardiac-catheterization> – The cardiac catheterization procedure itself generally takes 30 minutes, but the preparation and recovery time add several hours to your appointment time.
- <http://www.webmd.com/heart-disease/guide/cardiac-catheterization1?page=2> – A cardiac catheterization procedure usually takes about 30 minutes (and longer if you undergo an intervention), but the preparation and recovery time add several hours.
- <http://www.cathlabdigest.com/articles/How-long-should-it-take-do-a-cardiac-catheterization> – Once vascular access has been obtained, the procedure should take less than 20 minutes, barring complicating features of vascular disease, aortic tortuosity or hemodynamic instability. Start to finish, a routine left heart catheterization should take no more than 30 minutes. Add 15 to 20 minutes for a right heart catheterization. The time for cath lab turnover should be no longer than the case time.
- <http://www.nlm.nih.gov/medlineplus/ency/article/003419.htm> - A service of the U.S. National Library of Medicine National Institutes of Health - The test may last 30 - 60 minutes. If you also need special procedures, the test may take longer.
- <http://www.upmc.com/patients-visitors/education/cardiology/pages/cardiac-catheterization.aspx> – A complete cardiac cath usually lasts about 1 hour. It may be uncomfortable for you to lie still on the x-ray table for this period of time.
- http://www.medicinenet.com/cardiac_catheterization/page3.htm – Cardiac catheterization usually takes about 30 minutes, but the preparation and recovery time add several hours.

¹ Calculation: 2000 hours per year ÷ 1500 procedures per year = 1.33 hours, or 1 hour 20 minutes (80 minutes) per procedure. ¹ Assuming a diagnostic catheterization takes 1 hour 20 minutes, or 1.33 hours, a therapeutic procedure would take 2 hours 20 minutes [Calculation: 1.33 hours per case x 1.75 weighted = 2.33 hours, or 2 hours 20 minutes (160 minutes) per procedure].

² Assuming a diagnostic catheterization takes 1 hour 20 minutes, or 1.33 hours, a therapeutic procedure would take 2 hours 20 minutes [Calculation: 1.33 hours per case x 1.75 weighted = 2.33 hours, or 2 hours 20 minutes (160 minutes) per procedure].

- <http://www.HeartPoint.com/cathtell.html> - The actual catheterization procedure takes about 15-30 minutes. This is the time it takes the physician to perform the procedure. It takes time before this to get to the room, have the skin prepared and draped, etc.
- http://www.heart.org/HEARTORG/Conditions/HeartAttack/SymptomsDiagnosisofHeartAttack/Cardiac-Catheterization_UCM_451486_Article.jsp - American Heart Association – The procedure lasts about an hour.

All of the sources cited above suggest that the current SMFP methodology with its diagnostic-equivalent average case time of one hour twenty minutes is clearly out of step with widely accepted actual times. If there is some reason that North Carolina physicians and hospitals require longer times for the procedure it is not explained in the methodology. The average estimated time needed for an interventional procedure of two hours twenty minutes is even more outside the realm of national standards. A procedure taking that long must be a very rare occurrence in any hospital.

Considering that a need for additional capacity is triggered when average utilization reaches 80 percent, or 1,200 weighted procedure per unit per year on equipment available 2,000 hours per year, suggests that defined capacity should be re-evaluated. This threshold could be reached by performing only 600 diagnostic and 343 interventional procedures, or only 943 procedures in 2,000 hours.

Many Hospitals Have Cardiac Catheterization Labs Available More than 2000 Hours per Year

It is unlikely that cardiac catheterization equipment at most hospitals, with the exception of very low-volume programs, is idle for a full two weeks each year. Likewise, busy interventional cardiology programs are capable of operating more than eight hours per day, to accommodate emergencies and “add-on” cases. In its 2013 petition, New Hanover Regional stated that its cardiac catheterization labs are open 10 hours per day, 5 days a week, 52 weeks (or 260 days) a year, for a total of 2,600 hours per unit per year. Most hospitals with Code STEMI response teams operate cardiac catheterization labs 24/7/365 to treat patients who present to the emergency department with an acute myocardial infarction. Procedures done outside normal operating hours should really not count in defining capacity during the 2,000 hours the equipment is assumed to be available.

The Declining Volume of Cardiac Catheterizations Coupled With a Methodology That Overstates the Need Has Resulted in a Large Overcapacity

The number of cardiac catheterization procedures performed has been declining in recent years. The number of diagnostic cardiac catheterizations peaked statewide in 2005 at 84,662. It has declined every year since, and in 2013 only 60,127 procedures were performed. That is a decrease of 29 percent over the past eight years.

The declining number of cardiac catheterizations has resulted in a substantial surplus of cardiac catheterization machines. On a statewide basis, North Carolina has 141 fixed cardiac catheterization machines. According to the existing methodology only 90 machines are needed to handle existing volumes, and that is based on a methodology with the overly-long assumed procedure times. Every service area in the state with more than two labs, with the exception of Cumberland and New Hanover, has a surplus of at least one machine. Service areas with more than five machines all have surpluses of two or more. North Carolina does not suffer from a lack of access to cardiac catheterization labs anywhere.

Possible Solutions:

Because of limited staffing the State Health Coordinating Council has been reluctant to create work groups for wide-scale study of policies and methodologies as have sometimes been done in the past, although that remains an option.

A second approach would be for the Technology and Equipment Committee to review and revise the methodology for publication in the Proposed 2016 State Medical Facilities Plan and then receive comments on it at the summer public hearings. Changing the thresholds for need determinations by increasing the number of weighted procedures needed to trigger a need and changing the weighting of those procedures could modify the methodology rather easily. For example, if the capacity were determined to be 2,000 procedures or one per hour, 80% of capacity would be 1,600 diagnostic-equivalent procedures. In addition, if the weighting for interventional procedures were changed from 1.75 to 1.5, more realistic timeframes for performing cardiac catheterizations would be created – diagnostic procedures would be assumed to require one hour on average and interventional procedures would be assumed to require one and one-half hours on average. These assumptions would remain longer than the lengths of time suggested by the estimates of the various websites cited earlier in the petition, but would bring them closer to contemporary standards.

A third approach would be to plan a study between this spring and next spring and defer making any new need projections for 2016.

Obviously, the Technology and Equipment Committee may decide on a variety of other options. The important point is that the current methodology be reviewed in light of current conditions.

At the State Health Coordination Council's final meeting of Calendar Year 2014, each member was given an opportunity to make suggestions for priorities of the Council going forward. Among those offered was one from Technology and Equipment Committee member Trey Adams, who cautioned that the SHCC needed to take care to keep the policies and methodologies appropriate for changing conditions and guard against allowing them to become stale or out of date. The methodology for cardiac catheterization is demonstrably in need of such updating.

Petition Will Not Result in Unnecessary Duplication:

The petition seeks to modify the need methodology for fixed cardiac catheterization equipment by increasing the volume threshold required to generate additional units of equipment. If the need methodology is changed, the desired effect will be to *reduce* unnecessary duplication of fixed cardiac catheterization equipment statewide.

Consistency with SMFP Basic Principles:

This petition is consistent with the three Basic Principles governing the development of the State Medical Facilities Plan, as follows:

Safety and Quality

By increasing the volume threshold required to generate need for new cardiac catheterization equipment, the petition is, at the very least neutral regarding the principle of Safety and Quality, and at most seeks to reduce the risk of unnecessary duplication, which is detrimental to both safety and quality.

Access

North Carolina is adequately served by cardiac catheterization equipment. According to the 2015 SMFP, only 90 machines are needed to serve the existing volume in a state where 141 fixed units exist. No service area showed a need for additional equipment in 2015. Given that cardiac catheterization volumes are declining statewide, it is evident that there are no issues regarding access to cardiac catheterization equipment.

Value

In an era where population health management, cost containment and accountable care are being actively touted, continued reliance on a methodology that may generate excess capacity for a service does little to add value and potentially only increases the costs to the health care system as a whole.