



**Comment on Petition filed by Johnston Memorial Hospital Regarding
Temporary Rule for Cardiac Catheterization Equipment**

Proposed 2013 State Medical Facilities Plan

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Thank you for the opportunity to comment on the special need petition filed by Johnston Memorial Hospital requesting addition of the following wording to the *2013 State Medical Facilities Plan*.

“It is further determined that fixed cardiac catheterization equipment shall not be limited to diagnostic procedures only.”

Johnston Memorial indicates its intent is to provide a basis for DHSR staff to file a Temporary Rule that would eliminate Special Rule 10 NCAC 14C .1604(a). That rule requires presence of open heart surgery, if a cardiac catheterization laboratory operator wishes to offer Interventional (PCI) procedures. Halifax Regional Medical Center has a catheterization laboratory that operates under that restriction. We do not, nor do we expect to offer open heart surgery. Our service area is medically underserved with high prevalence of Medicaid and uninsured patients. Rates of heart disease are high, as are the risk factors, hypertension, diabetes and obesity.

With one exception, Halifax Regional Medical Center agrees with the Johnston petition. The equity argument speaks to our concern.

We began offering cardiac catheterization in 2009 in a shared angiography/cardiac catheterization laboratory. Our service volume is steadily increasing. Last year, we did 102 diagnostic procedures and transferred 16 PCI patients. Last year, there were 868 cath patients in our service area and 268 received interventional therapy. Most went to WakeMed. We have an arrangement with WakeMed's group, Raleigh Cardiology, to provide invasive cardiac catheterization 1 to 2 days a week and we have back up from WakeMed for the referral care. WakeMed is an hour and a half away by car and closer by helicopter. These trips are expensive.

Though our volumes are low, our outcomes have been good because we have excellent staff. The group has ten cardiologists who are board certified in both interventional and invasive cardiology and they maintain their skills by working at WakeMed Raleigh. They also work at WakeMed Cary. When they are here, our patients would benefit if they could perform PCI as well. In a small program, they would not schedule high risk patients. However, responding to STEMI patients within the 30-minute window would improve outcomes in our rural area. Technically, we could perform emergency procedures now, but we are reluctant to do so, given the specific limitations on our Certificate of Need.

We believe that residents of North Carolina should have access to PCI within 30 minutes, as recommended by the American Heart Association. We support the petition. We would ask that during the implementation you not further limit us by requiring that we provide 24/7 elective PCI. That would be an unnecessary expense. In a rural area we need to keep our programs cost effective.

We would modify the Johnston proposal to agree with the DHSR CON Section position that the state should follow the most current ACCF/AHA/SAIC Guidelines. The 2013 Guidelines focus on quality over volume and provide very clear guidelines about the quality programs that should be in place for any program offering therapeutic cardiac catheterization services.

Excerpt from Johnston County 2012 Petition on AHA/ASA policy guidance:

States should require all PCI programs without surgical back-up to participate in programs like the Action Registry-Get with the Guidelines (AR-G), National Cardiovascular Data Registry (NCDR), or the Atlantic Cardiovascular Patient Outcomes Research Team (CPORT) to monitor their quality and outcomes, allowing program leaders to show their commitment to quality by subjecting their program performance to independent peer review.

- The programs should adhere to strict patient-selection criteria (e.g. exclusion of patients with EF <30%, unprotected Left Main intervention, intervention on last conduit to the heart).
- Have an annual institutional volume of at least 200 to 400 cases.
- Should include only AHA/ACC-qualified operators who meet standards for training and competency.
- Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program development to include routine care process and case selection review.
- Agree to develop and maintain a quality and error management program.
- Perform primary PCI 24/7.
- Develop and maintain necessary agreements with a tertiary facility (which must agree to accept emergent and non-emergent transfers for additional medical care, cardiac surgery or intervention).
- Develop and sustain agreements with an ambulance service capable of advanced life support and IABP transfer that guarantees a 30-minute-or-less response time.