PETITION

Petition for Cardiac Catheterization

PETITIONER

Johnston Health
509 North Bright Leaf Boulevard
Smithfield, NC 27577

April S. Culver, JD
Vice President, Planning and External Affairs
919.938.7198
aculver@johnstonhealth.org

STATEMENT OF REQUESTED ADJUSTMENT

Johnston Health respectfully petitions the State Health Coordinating Council to create language in the *2015 State Medical Facilities Plan* that would clarify that fixed cardiac catheterization equipment at hospitals should be able to perform both diagnostic and interventional procedures. Specifically, Johnston Health requests that the following language be added to Chapter 9, in the Cardiac Catheterization Equipment section in the *2015 State Medical Facilities Plan*:

"*It is further determined that hospitals with fixed cardiac catheterization equipment shall be permitted to perform both diagnostic and therapeutic (interventional) procedures.*"

BACKGROUND

Johnston Health, the health system in Johnston County, includes a 199-bed acute care hospital in Smithfield. Since 1994, Johnston Health has provided cardiac catheterization (cath) services, beginning first with mobile service, and then with fixed service subsequent to a 2001 Certificate of Need. Since the hospital acquired its cardiac cath lab after 1993, it is subject to the Certificate of Need regulations (rules) for cardiac cath, which then and now state in 10A N.C.A.C 14C .1604(a): "*If the applicant proposes to perform therapeutic cardiac catheterization procedures, the applicant shall demonstrate that open heart surgery services are provided within the same facility*." As a result, Johnston Health is not permitted to use its cardiac cath service for interventional procedures, but for diagnostic only. As described in greater detail below, this same restriction does not apply to more than a dozen hospitals across the state that are able to do interventional procedures without on-site open heart surgery. This petition, if approved, would be one step in alleviating the unequal treatment that currently exists, based solely on the timing of a hospital's acquisition of fixed cardiac cath equipment. The proposed language would be an affirmation on the part of the SHCC that all providers in the state, irrespective of when they obtained their cardiac cath equipment, should be able to develop a quality, life-saving interventional cardiac cath program.

In August 2012, over 18 months ago, Johnston Health submitted a petition to the SHCC with a similar request. While the petition was denied, the summary of the discussion from the Technology and Equipment Committee's deliberations on that petition includes the "*desire to present a unanimous voice of concern to the full SHCC about the issue brought forth in the petition of the need to change the rule to more appropriately reflect new guidance and standards of care in dealing with Percutaneous Coronary Intervention (PCI) without surgical back-up*[1]." In addition, the discussion included concern over the length of time it takes to change a rule under the permanent rule-making process. As the SHCC is no doubt aware, part of the time required for a permanent rule change is the actual process of filing a petition for the change, receiving public comments on the change, making final updates to the rule and then eventually promulgating the rule; however, even though more than 18 months have passed, a petition for a change in the rules has yet to be submitted. Johnston Health continues to be concerned about the passage of time without a change in the rules, particularly as Johnston County patients continue to be denied local access to life-saving PCI. In the meantime, more than 1,400 PCI's were performed at hospitals in 11 North Carolina hospitals that do not have open heart surgery on site.

While the proposed change would not initiate the permanent rule change process, we do believe it is an appropriate step in the process to eventually level the playing field for all hospitals that provide fixed cardiac catheterization services. We understand that immediately following the SHCC's recommendations in 2012, the CON Section and the North Carolina Hospital Association discussed updating the rules to reflect the current standard of care for PCI without on-site surgical back-up, and we certainly appreciate those efforts. However, it is also our understanding that there has been little activity on this issue in the past year, and given the amount of time that has passed since our initial request and the SHCC's agreement (through approval of the Committee's actions) that a change needed to be made, Johnston Health believes that it is entirely appropriate for the SHCC to include the requested clarifying language in the *2015 SMFP*. It is important to understand that such a change would not, in any way, preclude the CON Section or any other party from proposing permanent changes to the CON rules for cardiac catheterization, nor would the SHCC be dictating what changes, if any, should be made. The addition of the proposed language would simply recognize in the *SMFP* what is already taking place at multiple hospitals across the state, and what is appropriate per the current standard of care for PCI.

While the focus of our previous petition was a change in the *SMFP* language in order to permit a temporary rule-making process (which is reportedly easier for staff as compared to the more cumbersome permanent rule-making process), this petition requests that the SHCC affirm the need for equitable and reasonable access to PCI through a change in the language of the *SMFP*, notwithstanding any impact that may or may not have on certificate of need rules. We recognize that whenever a methodology or need threshold is changed in the *SMFP*, whether for acute care beds, MRI scanners or nursing care beds, CON rules are also changed through the temporary rulemaking

---

1 http://www.ncdhhs.gov/dhsr/mfp/pdf/2012/shcc/0926_techreport.pdf

process to bring the rules in line with the *SMFP* changes. In deference to DHSR and the staff recommendation in 2012, the SHCC decided to deny Johnston Health's previous petition and allow the much lengthier, permanent rule-making process to commence. Johnston Health realizes that the process can be cumbersome, and, indeed, that was the impetus for our initial request for a change in the *SMFP*; however, we believe that after more than 18 months, the SHCC should agree that equitable access to PCI is needed, and should do so by adding the appropriate language to the *2015 SMFP*. We believe that such a statement would also support the permanent rulemaking process, if that is used to eventually amend the applicable CON rules.

Johnston Health recognizes that this petition is unusual in its request; however, it believes that does not minimize its merit. It is appropriate for the SHCC, as an advisory body to the Governor, to include language in the *2015 State Medical Facilities Plan* to ensure patients have adequate access to treatment and that all providers are treated equitably. In addition, we believe it is proper for the SHCC to clarify in the *SMFP* that the methodology for cardiac catheterization has never and does not limit the ability of providers to perform interventional cardiac cath procedures, irrespective of the availability of open heart surgery on site. The detailed reasons for this petition and the need for the SHCC's involvement in this matter are discussed in the next section.

REASON FOR THE REQUESTED ADJUSTMENT

The primary purpose of this petition is to include language in the *2015 SMFP* that would affirm that all providers in the state should be able to develop a quality, life-saving interventional cardiac cath program. Johnston Health believes such a change would also permit the CON Section to change the rule at 10A N.C.A.C. 14C .1604(a), which would resolve the current inequalities for providers of cardiac cath services without open heart surgery on site. However, whether such a change in the rules is an outcome of this process, Johnston Health believes that it is nonetheless appropriate for the SHCC to add the clarifying language in Chapter 9 of the *2015 SMFP*. Given the circumstances of the current provision of cardiac cath services in the state, particularly the inequities faced by providers who acquired their equipment after 1993, Johnston Health believes this is a reasonable request that should be approved by the SHCC.

As described above, the only barrier to a provider's ability to provide interventional cardiac catheterization services are the Certificate of Need regulatory criteria (rules) that the provider is subject to, if at all, based on the timing of its acquisition of the equipment. As the SHCC is aware, while the cardiac cath need methodology does distinguish between diagnostic and interventional cath services for calculating "diagnostic-equivalent procedures," it does not allocate cardiac cath equipment in such a way as to direct whether it should be used to provide diagnostic only or interventional service. Since the establishment in 1993 of cardiac cath services as "per se" reviewable in the CON statute, the CON rules have required that only providers with open heart surgery services on site could provide interventional cardiac cath. As a result, any provider without open heart surgery that acquired its cardiac cath unit after 1993 is not allowed to provide interventional cardiac cath, per the conditions of its certificate of

need. Providers with equipment that existed prior to 1993, including mobile providers, are not subject to those rules. As a result of this situation, there currently exist four types of providers of cardiac cath services in the state:

1. Providers with open heart surgery services: no limit on the ability to provide interventional cardiac cath;
2. Providers without open heart surgery services, but cardiac cath equipment that was acquired prior to 1993: no limit on the ability to provide interventional cardiac cath;
3. Providers without open heart surgery services, but cardiac cath equipment that was acquired after the CON law change in 1993: unable to provide interventional cardiac cath.
4. Providers utilizing mobile cardiac cath units (most, if not all of which were acquired prior to 1993): no regulatory limit on the ability to provide interventional cardiac cath (includes hospital and non-hospital[2] sites).

No relevant distinctions exist among providers without open heart surgery, except the timing of the acquisition of cardiac cath equipment. Thus, across North Carolina, the availability of life-saving treatment is not equitable, no longer for clinical reasons as discussed below but solely on the basis of when a provider's equipment was acquired. Moreover, providers utilizing "grandfathered" equipment, either fixed or mobile, have no restrictions on the types of cath procedures they can perform. According to the *2014 SMFP*, there are currently 36 providers with interventional cardiac cath volume in 2012; of these 14, or 39 percent, do not have open heart surgery on site.

Hospital Providing Interventional Cardiac Catheterization	Diagnostic Cases (2012)	PCI Cases (2012)	Open Heart Surgery on site?
Cape Fear Valley	1,838	1,238	Yes
CarolinaEast	1,092	826	Yes
Carolinas Medical Center	3,388	1,267	Yes
CaroMont Regional	1,897	616	Yes
CMC Mercy-Pineville	1,419	557	Yes
CMC-Northeast	1,010	664	Yes
Duke Regional	440	296	Yes
Duke University	3,782	1,784	Yes
FirstHealth Moore	3,171	1,181	Yes
Novant Health Forsyth	2,444	1,181	Yes
Frye Regional	2,630	1,161	Yes
High Point Regional	1,783	1,479	Yes
Mission Hospital	3,103	1,365	Yes
Cone Health	3,344	1,347	Yes

[2] Thus, hypothetically, a grandfathered mobile unit operating at a physician office without any hospital emergency facilities on-site can perform interventional cardiac cath, while many licensed hospitals with emergency capabilities cannot.

NC Baptist	1,552	928	Yes
New Hanover Regional	3,131	2,309	Yes
Novant Health Presbyterian	1,533	1,278	Yes
Rex Hospital	2,067	1,033	Yes
Southeastern Regional	818	408	Yes
UNC Hospitals	2,088	928	Yes
Vidant Medical Center	2,447	1,319	Yes
WakeMed	4,718	3,324	Yes
Alamance Regional	741	210	No
Catawba Valley	347	119	No
CMC-Blue Ridge	433	76	No
CMC-Union	364	27	No
Davis Regional	321	49	No
Duke Raleigh	292	42	No
Halifax Regional	71	8	No
Iredell Memorial	756	300	No
MedWest Haywood*	290	5	No
Nash General	1,302	110	No
Novant Health Matthews	438	199	No
Novant Health Rowan	371	199	No
WakeMed Cary	271	6	No
Wilson Medical Center	433	142	No

Note: Although the *2014 SMFP* indicates that Johnston Health performed interventional cath procedures in FY 2011, this is based on the classification of procedure codes reported on the Hospital License Renewal Application; Johnston does not perform interventional cath procedures. In addition, some hospitals historically provided interventional cath procedures, but may not currently be doing so.
*Table 9V lists MedWest Harris, which appears to be a typo, as MedWest Harris does not provide cardiac catheterization services, but MedWest Haywood does.

As shown, nearly 40 percent of the providers of interventional cath services in the state do not have open heart surgery services on site. Johnston Health understands that most, if not all, of these providers have arrangements with tertiary medical centers with open heart services to provide any necessary backup and emergency surgery services, should the need arise. For example, Alamance Regional Medical Center in Burlington has an arrangement with Duke University Hospital and Nash General Hospital in Rocky Mount has a clinical affiliation with Vidant Health for its cardiac cath services. Thus, both the provider and its tertiary partner believe that the provision of interventional cath services at hospitals without open heart surgery is warranted. Collectively, these hospitals providing interventional cath without open heart on site are part of several healthcare systems (e.g. Duke, Duke/LifePoint, CHS, Novant, HMA, and Vidant) that represent at least 66 hospitals in the state, or more than one-half of the 125 hospitals statewide. Clearly, the question of whether interventional cath should only be provided

with open heart surgery back-up on site has been answered overwhelmingly by the state's providers, both community and tertiary, and the response is no.

Based on the outcome of the petition filed over 18 months ago, Johnston Health believes that the SHCC recognizes that there is a need to permit interventional cath at hospitals without "grandfathered" (i.e. acquired prior to 1993) cardiac cath units. The previous petition included documentation of research from the American College of Cardiology, the American Heart Association, among others, that clearly made the case that on-site open heart backup should no longer be required for interventional cardiac cath. Johnston Health believes that most of this research is well-known to the SHCC members and DHSR staff and will not include it again in this petition, but it is available in the petition filed in August 2012, and we will be happy to provide the information to any SHCC member if requested. We understand that some of the discussion that has taken place over the past 18 months has focused on issues such as the particular volume requirements for any site that wishes to commence interventional cath service. Given the potential for regular updates in the standards, we do not believe that the *SMFP* necessarily needs to reflect those specific requirements, and therefore, we have not petitioned for the inclusion of such language. We do, however, believe that such standards are helpful, particularly those recommended by the ACCF/AHA/SCAI Guidelines; however, it should be noted that even those guidelines are generally subject to interpretation. The amount of available documentation is quite extensive, but rather than reprint it all in this petition, Johnston Health refers to the 2011 guidelines published at http://content.onlinejacc.org/data/Journals/JAC/23293/08007.pdf. We do believe that guidelines to ensure quality can be incorporated into any changes that may be made to the CON rules, and that the CON rules are the appropriate venue for such requirements. We recognize that some may wish to have more specific language included in the *SMFP* itself; however, given that no such guidelines exist in the *SMFP* for other services, including higher risk services such as open heart surgery, the CON rules are a more effective location for specific quality criteria for a particular service.

We further wish to suggest that much of the published research around minimum case volume for PCI indicates that the volume requirements apply more to the physician than to the facility. Given the existence of large cardiology practices, such as North Carolina Heart & Vascular Associates, which provides services at Johnston Health and multiple other hospitals in the area, it should be recognized that physicians may perform cardiac cath procedures, including PCI, at multiple hospitals, not just one. Thus, the physician's and cath team's volume is much more relevant to having the experience necessary to perform quality PCI, as compared to the facility itself. Based on the table above, the range of diagnostic cases performed at sites also doing PCI without on-site cardiac surgery is from a low of 271 cases to a high of 1,302 cases. Some sites report fewer than 10 PCI cases, and may not be regularly performing elective PCI, but most sites report within a range of 27 and 300 PCI cases.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

The primary adverse effect is the continued lack of action to enable equitable treatment of all providers of fixed cardiac cath services.

ALTERNATIVES CONSIDERED

Continue to Wait for a Rule Change

Johnston Health considered several alternatives. The first was to continue waiting to see if a permanent rule change petition would be filed. However, given the length of time that has passed since the original petition was filed, and since there appears to be little progress being made at this time, Johnston Health decided to file the petition.

File a Permanent Rule Change Petition

Johnston Health also considered petitioning for a permanent rule change. While we could have initiated this process already, we had hoped that DHSR might file a petition following the SHCC's discussion 18 months ago. Johnston Health is hopeful that the approval of this petition might make a rule change more probable; however, if the rules are not changed, it may file a petition itself to change the rules in the future.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

If approved, the petition would not result in unnecessary duplication because it does not result in the allocation of any additional equipment, nor does it add any new providers of cardiac cath services. Even if providers without on-site open heart surgery are all able to perform PCI at some point in the future, no unnecessary duplication would result. Specifically, the cardiac cath equipment utilized to perform diagnostic procedures can also be used to perform interventional procedures, with little or no modifications required. While some hospitals may need to acquire additional software, camera upgrades or intra-aortic balloon pumps, these items are not governed by the *SMFP*, nor is the cost of them such that they would likely be subject to the CON law.

EVIDENCE OF CONSISTENCY WITH THE THREE BASIC PRINCIPLES

This petition clearly supports the principle of access. The first word in the *SMFP* language for this principle is "equitable." As outlined above, equitable access clearly does not currently exist, because of the CON rule that is the subject of this petition. Moreover, the primary reason for providing PCI at more hospitals is to expand geographic, and thereby, temporal access to life-saving services. While other healthcare services in the *SMFP* are needed by a wide-range of patients and providers, few have such a direct and immediate impact on patients' lives than cardiac catheterization.

The petition is also consistent with the Quality and Safety principle. As discussed above, not only have non-open heart sites with interventional cath been as safe and effective as those with open heart, but, as documented in research literature, the need for emergency surgery is actually lower at hospitals *without* open heart surgery on site. While every provider should provide care in as safe and high quality an environment as possible, the provision of interventional cath can no longer be limited because of the question of quality and safety.

The petition also advocates healthcare value. According to a study by Dr. Melissa Walton-Shirley, quoted in Johnston Health's petition from August 2012, "'The staggering economic implication of the NCDR [National Cardiovascular Data Registry] data should attract the attention of any government leader with implications for savings in transfer costs, length of stay, readmit costs, and the decrease in congestive-heart-failure care that can occur with timely revascularization,' she continued. 'It's time for the culture of American intervention to change permanently in the best interest of our patients, who are helpless to help themselves at a time when they are most vulnerable. Dooming them to an early death or a life of CHF care is no longer an acceptable option. We should use these data to help us treat our AMI patients as we would want to be treated if we found ourselves in a similar situation.'" As noted by Dr. Walton-Shirley, who led a pilot study at her hospital in Kentucky to provide PCI without open heart back-up on site, the economic value from expanding the provision of PCI is consistent with federal healthcare reform efforts, including decreasing lengths of stay, unnecessary readmissions and overall healthcare costs.

CONCLUSION

In conclusion, Johnston Health believes that the SHCC should approve the petition to affirm the need for equitable access among providers of cardiac cath services. The provision of PCI services without cardiac surgery on site is already a reality for over one-third of the PCI providers in the state; the proposed petition would ensure that the SMFP reflects the need to expand the life-saving service to quality providers of cardiac cath service across the state.

Thank you for your consideration.