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PETITION

Petition for Cardiac Catheterization

PETITIONER

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STATEMENT OF REQUESTED ADJUSTMENT

Johnston Health respectfully petitions the State Health Coordinating Council to create language in the *2013 State Medical Facilities Plan* to enable a change in the Certificate of Need rules that would allow for the provision of interventional cardiac catheterization services in Johnston County. Specifically Johnston Health requests that the following language be added in the *2013 State Medical Facilities Plan*:

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

BACKGROUND

Johnston Health is a 199-bed acute care hospital in Smithfield, Johnston County. Since 1994, Johnston Health has provided cardiac catheterization services, beginning first with mobile service, and then subsequent to a 2001 Certificate of Need approval, fixed service. 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.*"

In the summer of 2011, the Technology and Equipment Committee considered a petition for a special need adjustment for shared cardiac cath equipment. Although that petition was denied, the petition raised several issues which Committee members discussed, including the fact that hospitals without open heart surgery on site that acquire cath equipment today may not use that equipment for interventional procedures because of the CON rule, yet they can use any "grandfathered" equipment for those procedures because grandfathered equipment was not subject to the CON rule. The inconsistency of a situation that would allow a hospital with two identical, side-by-side cardiac cath labs to have to determine which patients could be treated in which lab based on when the equipment was first acquired prompted the Committee to suggest that a

methodology change be considered in the spring of 2012. Unfortunately, no petitions were filed and the SHCC did not form a work group to study the cardiac cath methodology. Even if a methodology change were enacted, depending on the type of changes made, it is possible that the CON rules would remain as they are. The most effective way to correct this inequitable situation is to delete the outdated rule; the most expeditious way to accomplish that is by including language in the *2013 SMFP* to enable the CON Section to do just that.

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 *2013 State Medical Facilities Plan* to ensure patients have adequate access to treatment and that all providers are treated equitably. Johnston Health also realizes that the timing of the petition may be questioned, as it is not requesting an adjusted need determination. However, the petition does not ask for a change in the methodology or in any *SMFP* Policies with statewide impact. In fact, approval of the petition would not allocate any additional equipment anywhere in the state, nor would it require hospitals to provide services they do not wish to provide. Rather, the petition asks the SHCC to clarify 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 sole purpose of this petition is to include language in the *2013 SMFP* to enable the Certificate of Need Section to use the temporary rule-making process to eliminate 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. As the SHCC is no doubt aware, changes in the *SMFP* that require a corresponding change in the CON rules allow the CON Section to make changes using the temporary rule-making process. This process is much simpler than the permanent rule-making process; further, Johnston Health understands that the temporary rule-making process is preferred by the CON Section, whenever possible. 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 is 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[1] 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 *Proposed 2013 SMFP*, there are currently 35 providers of interventional cardiac cath services; of these 13, or 37 percent, do not have open heart surgery on site.

Hospital Providing Interventional Cath	Open Heart Surgery on site?
Cape Fear Valley Medical Center	Yes
CarolinaEast Medical Center	Yes
Carolinas Medical Center	Yes
CMC Mercy-Pineville	Yes
CMC-Northeast Medical Center	Yes
Duke University Hospital	Yes
Durham Regional Hospital	Yes
First Health Moore Regional	Yes
Forsyth Medical Center	Yes
Frye Regional Medical Center	Yes
Gaston Memorial	Yes

[1] Thus, 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.

High Point Regional Hospital	Yes
Mission Hospital	Yes
Moses Cone	Yes
NC Baptist Hospital	Yes
New Hanover Regional Medical Center	Yes
Presbyterian Hospital	Yes
Rex Hospital	Yes
Southeastern Regional Medical Center	Yes
UNC Hospitals	Yes
Vidant Medical Center	Yes
WakeMed	Yes
Alamance Regional	No
Albemarle Health	No
Catawba Valley Medical Center	No
CMC-Union	No
Davis Regional	No
Duke Raleigh Hospital	No
Grace Hospital	No
Iredell Memorial Hospital	No
Nash General	No
Presbyterian Hospital - Matthews	No
Rowan Regional Medical Center	No
WakeMed Cary	No
Wilson Medical Center	No

Note: Although the *Proposed 2013 SMFP* indicates that Johnston Medical Center-Smithfield 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 (and may not) perform interventional cath procedures. In addition, some hospitals historically provided interventional cath procedures, but may not currently be doing so.

As shown, over one-third 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, Wilson Medical Center works with WakeMed and Nash General Hospital partners with Vidant Health. 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 services are part of several healthcare systems (e.g. Duke, CHS, Novant, HMA, WakeMed, Vidant) that represent at least 66 hospitals in the state, or 53 percent 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.

Johnston Health believes that this petition, or any workgroup, methodology change or other discussion that evolves from it should not question whether interventional cath procedures should be performed only at hospitals with open heart surgery on site. That question has already been answered, not only by the majority of hospitals and health systems in the state as described above, but also by DHSR itself. Specifically, although the outdated CON rules cannot prevent "grandfathered" hospitals or mobile sites from providing interventional cath, rules from the Licensure Section could have been written to do so; the absence of such rules certainly indicates that DHSR does not believe it is inappropriate for these "grandfathered" hospitals to provide interventional cath. However, given that some discussion around the appropriateness of interventional cath without open heart will likely ensue, the remainder of this section of the petition will address the reasons that on-site open heart backup should no longer be required for interventional cardiac cath.

According to a 2009 study published in the *Journal of the American College of Cardiology*, there are no differences in patient outcomes for PCI[2] between facilities with open heart surgery on site and those without. The research, some of which was conducted by the Wake Forest University School of Medicine, concluded that providers of PCI without on-site open heart surgery had no differences compared to providers with open heart in measures such as procedural success, morbidity and risk-adjusted mortality. In fact, the risk of emergency surgery was actually higher at facilities with open heart surgery on site. The study also found that similar results for both primary (emergency) PCI and elective PCI were possible. Please see Attachment 1 for the study and Attachment 2 for an article summarizing the study. Such results are also supported by a recent article in *The New England Journal of Medicine*[3] which noted "[t]he overall feasibility and safety of nonprimary PCI without on-site cardiac surgical backup have now been assessed in multiple observational studies, a recent randomized trial, and a large meta-analysis. These findings suggest that the results of nonprimary PCI are similar at centers with and at those without on-site cardiac surgical backup, although more definitive, longer-term, randomized comparisons are forthcoming."

This study, as well as others that have preceded it, have been part of the impetus for many states to change or discontinue their regulation of PCI based on whether the provider has open heart services. For example, since 2004, the Maryland Health Care Commission has permitted PCI at hospitals without cardiac surgery, through a waiver process. Pennsylvania also permits PCI at hospitals without cardiac surgery, subject to

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[2] Although the *SMFP* refers to interventional (therapeutic) procedures as percutaneous transluminal coronary angioplasty, or PTCA, the current terminology for these procedures is usually PCI, or percutaneous coronary intervention.

[3] Shahian DM, Meyer GS, Yeh RW, Fifer MA, Torchiana DF. Percutaneous Coronary Interventions without On-Site Cardiac Surgical Backup. N Engl J Med (May 10, 2012) 366:1814-23.

certain conditions. South Carolina allows primary (emergency) PCI at hospitals without cardiac surgery with Certificate of Need approval for the service. Many states do not regulate PCI without on-site open heart surgery at all, while others control the service through the licensure process, such as Florida. North Carolina is one of the few states that have not instituted any changes to expand the provision of PCI to hospitals without cardiac (open heart) surgery.

The most recent guidelines from the American College of Cardiology, published in 2011, indicate that PCI without open heart surgery on site is appropriate. The guidelines do suggest certain factors that should be present, including facility, personnel and physician requirements. These factors, along with the evidence of the efficacy of PCI at providers without open heart surgery capabilities, are discussed in policy guidelines published in March 2012 by the American Heart Association, found in Attachment 3. Johnston Health understands that most or all of the 13 hospitals in the state providing PCI without open heart surgery on site have established policies and procedures similar to those in Attachment 3. If DHSR wished to ensure these policies were implemented by all providers of interventional cardiac cath procedures, it could do so through Licensure rules; however, the CON rules would still need to be amended to enable all cardiac cath providers to perform interventional procedures, as would be accomplished through the approval of this petition.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

The primary adverse effect is the continuing disparity among providers with no cardiac surgery services on site. Those with "grandfathered" equipment will continue to operate outside the CON rules and be able to provide life-saving interventional cath services on site; those operating under the CON rules will continue having diagnostic service only. The adverse effects on patient care and access are obvious, particularly given that there are no guarantees that the providers with "grandfathered" equipment will offer the service with any higher degree of safety or quality than other providers would.

ALTERNATIVES CONSIDERED

<u>File a Petition in the Spring Cycle</u>

Johnston Health considered several alternatives. The first was to wait and file a petition in the spring of 2013. However, this petition does not request a change to the methodology or any other policies in the SMFP; therefore, it is not any more appropriate for filing during that timeframe. In addition, petitioning in 2013 would delay any change in the CON rule until 2014, which Johnston Health does not believe is necessary or appropriate. For these reasons, the hospital decided not to wait to file its petition.

Limit the Language Change to Johnston County

Johnston Health also considered requesting that it be a test site for the change in rule. In fact, if the SHCC were so inclined, it could include language in the SMFP to state the following:

"*It is further determined that cardiac catheterization equipment* ***in Johnston County*** *shall not be limited to diagnostic procedures only.*"

However, there are already 13 test sites in the state, many of which have been offering interventional cath without on-site open heart surgery for several years. Johnston Health does not believe that the establishment of an incremental test site will provide any additional information or assurances of the efficacy of the expansion of interventional cath services.

File a Permanent Rule Change Petition

As discussed above, Johnston Health also considered petitioning for a permanent rule change. However, it understands that the permanent rule-making process is a time-consuming and difficult one. For example, the location of the CON Section offices is a rule at 10A NCAC 14C .0102. The CON Section relocated its offices as of June 1, 2011; more than one year later, the rule listing the address of the CON Section has yet to be updated, because of the challenges of the permanent rule-making process. Rather than subject the proposed change in this petition to that process, Johnston Health believes that a more effective method is to include language in the *2013 SMFP* that will allow the CON Section to make the necessary changes through the temporary process.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

If approved, the petition would not result in unnecessary duplication because it would not require any additional equipment to be approved. 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 in Attachment 2, not only have non-open heart sites with interventional cath been as safe and effective as those with open heart, but 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 Dr. Melissa Walton-Shirley, as quoted in the article in Attachment 2, "'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 enable the CON Section to delete the rule that creates inequitable 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 access to this life-saving service is equitable across providers and not limited by an outdated CON rule.

Thank you for your consideration.