PETITION
Petition for Change to Cardiac Catheterization Need Determination Methodology

PETITIONER

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INTRODUCTION

Johnston Health respectfully petitions the State Health Coordinating Council (SHCC) to change the Cardiac Catheterization Need Determination Methodology in the *2023 State Medical Facilities Plan* (*2023 SMFP*). The proposed change is requested to address the disproportionate treatment of service areas based on cardiac catheterization inventory. As a result of the rounding rules used in the current methodology, providers located in service areas with only one unit of cardiac catheterization equipment must reach 1,800 procedures or 120 percent of defined capacity before a need is triggered for an additional unit of cardiac catheterization equipment. Notably, this percentage required is significantly higher than the percentage required to trigger a need in service areas with more than one unit of cardiac catheterization equipment. As such, the current Cardiac Catheterization Need Determination Methodology places providers in service areas with lower cardiac catheterization inventory – particularly, those in service areas with only one unit of cardiac catheterization equipment – at a disadvantage.

Johnston Health, the health system in Johnston County, includes a 149-bed acute care hospital in Smithfield and a 50-bed acute care hospital in Clayton. Since 1994, Johnston Health has provided cardiac catheterization services in Smithfield, beginning with mobile service, and then with fixed services following a 2001 certificate of need (CON). Johnston Health began performing percutaneous coronary intervention (PCI) procedures in 2015.

Johnston Health has experienced rapid growth in diagnostic-equivalent cardiac catheterization procedures from Federal Fiscal Year (FFY) 2018 through FFY 2021. Despite this rapid growth and despite showing the need for more than one unit for three consecutive years as demonstrated in the table below, Johnston Health has been unable to trigger an additional need for Johnston County in the *SMFP* based on the current methodology.

	FFY 2018	*FFY 2019*	*FFY 2020*	*FFY 2021*	*FFY 2018 – FY 2021 CAGR^*
Weighted Scans*	1,126	1,362	1,465	1,637	13.3%
Percent Capacity**	75%	91%	98%	109%	
Units Needed**	0.94	1.13	1.22	1.36	

**2020-2022 SMFPs* and Johnston Health internal data.
**Capacity based on 1,500 diagnostic-equivalent procedures. Units needed based on Step 4 of the *SMFP* need methodology.
^Compound Annual Growth Rate.

A review of the *2022 SMFP* reveals that there are currently 43 service areas with cardiac catheterization equipment. Of these, 25 service areas have a current inventory of one cardiac catheterization unit.[1] In the past 15 years, only one service area, Robeson County, has increased its inventory from one unit of cardiac catheterization equipment to two. The development of a second unit of cardiac catheterization equipment in Robeson County was the result of an approved Certificate of Need (CON) application filed by Southeastern Regional Medical Center (SRMC), which was only possible after the SHCC approved a petition filed by SRMC for an adjusted need determination in the *2013 SMFP* for one additional unit in Robeson County. The *2013 SMFP* shows that SRMC performed 1,363 weighted (diagnostic-equivalent) cardiac catheterization procedures in Federal Fiscal Year (FFY) 2011, which was insufficient to generate a need for an additional unit through the standard need methodology, necessitating a petition for a special need adjustment.

Under the current *SMFP* Cardiac Catheterization Need Determination Methodology, the utilization necessary for providers located in a service area with only one unit of cardiac catheterization equipment to generate a need for an additional unit of equipment is significantly greater than the utilization for providers located in a service area with more than one unit of cardiac catheterization equipment. In fact, **providers located in service areas with one unit of equipment must operate at 120 percent of maximum capacity to trigger a need for a second unit**. Such levels place significant burdens on the equipment and staff, and are also detrimental to patients in need of these services. As shown below, this is a significantly greater capacity requirement to add an additional unit of equipment than that applicable to providers located in a service area with more than one unit of cardiac catheterization equipment.

[1] Table 17A-3 of the *2022 SMFP* shows a total planning inventory of two for Henderson County (one in Current Inventory, which includes a stationary mobile cardiac catheterization unit owned by DLP Healthcare being operated via contract at Pardee UNC Health, and one as CON Issued/Pending Development, which was awarded to Pardee UNC Health pursuant to Project ID # B-11861-20 in response to the adjusted need determination in the *2020 SMFP*). However, upon development of the fixed cardiac catheterization unit awarded pursuant to Project ID # B-11861-20, Pardee UNC Health must cease operation of the DLP Healthcare-owned unit within 90 days. As a result, for purposes of this analysis, this service area is considered to have an inventory of one unit.

A	B	C	D	E
# of Counties	*Fixed Cardiac Cath Inventory*	*Total Number of Units Needed to Generate Need Determination*	*Weighted Procedures Required to Generate Need Determination*	*Percent of Maximum Capacity Required to Generate Need Determination*
25	1	1.5	1,800	120%
2	2	2.5	3,000	100%
4	3	3.5	4,200	93%
2	4	4.5	5,400	90%
2	5	5.5	6,600	88%
2	6	6.5	7,800	87%
1	7	7.5	9,000	86%
1	9	9.5	11,400	84%
1	11	11.5	13,800	84%
1	13	13.5	16,200	83%
1	16	16.5	19,800	83%
1	19	19.5	23,400	82%

Source (A and B): *2022 SMFP*.
C = B + 0.5
D = C x 1,200
E = D / (B x 1,500)

Johnston Health believes the current methodology that requires an applicant in a county with only one existing fixed cardiac catheterization may be based on a legacy from the past that is no longer needed and is, in fact, detrimental to ensuring appropriate, timely access to care. In particular, overall growth in cardiac catheterization procedures was historically higher than it has been in recent years; thus, there may have been a concern that too many additional units could be approved given the growth rate, or that too many could be approved in a single service area with multiple providers. For example, from 2000 to 2005, the total number of diagnostic and interventional catheterization procedures performed in the state grew from 96,437 to 113,391, a compound annual growth rate (CAGR) of 3.3 percent; by 2015 the total number declined to 86,040, a CAGR of -2.7 percent since 2005[2]. According to Table 17A-1 in the *2021 SMFP* (used to capture pre-pandemic data), the total number of procedures performed statewide in 2019 was 99,865. Thus, while cardiac catheterization utilization is once again growing statewide, even more remarkable is the change in the number of providers of PCI. In 2005, there were only 25 providers of interventional catheterizations in the state; by 2020 the number had nearly doubled to 48. The significant growth in the number of providers, particularly PCI providers, has resulted in a decanting of volume from a few providers in mostly urban areas to many providers in urban, suburban and even rural areas of the state providing interventional cardiac catheterization services. As such, it is vital that providers in areas with fewer units of equipment have sufficient capacity to meet the need of the patients they serve—patients that were once served in larger service areas with multiple units of equipment but are now provided better access closer to their homes.

[2] See Tables 9R and 9U in the *2007 SMFP* and Tables 9S and 9V in the *2017 SMFP*.

STATEMENT OF THE PROPOSED CHANGE

Johnston Health requests that the threshold for additional cardiac catheterization equipment in the Cardiac Catheterization Need Determination Methodology be adjusted. Johnston Health proposes the change described below to Chapter 17: Technology and Equipment, Methodology A (Fixed Cardiac Catheterization Equipment), Step 5. Please note that Johnston Health does not propose any change to Steps 1-4 or 6.

> Step 5: Sum the number of units of fixed cardiac catheterization equipment required for all facilities in the same service area as calculated in Step 4 (*Column I*). ~~Round to the nearest whole number (*Column J*).~~ ***Round up to the next whole number [e.g., 1.1 is rounded up to 2] (Column J).***

IMPACT OF THE PROPOSED CHANGE

As previously shown, the current standard need methodology creates inconsistent capacity requirements that result in inequitable treatment of service areas with varying cardiac catheterization inventory. Notwithstanding the fact that the need methodology assumptions outlined on page 310 of the *2022 SMFP* indicate that "*[t]he capacity of a unit of cardiac catheterization equipment is defined as 1,500 diagnostic-equivalent procedures per year, with the trigger of need at 80% of capacity*[,]" rounding to the **nearest** whole number (which may be lower or higher) in Step 5 of the current need methodology effectively creates capacity requirements that are above the 80 percent capacity threshold stated in the assumptions. [*emphasis added*] As shown above, the effective threshold in counties with a single unit is actually 120%, not 80%. This places providers in service areas with lower cardiac catheterization inventory – particularly, those in service areas with only one unit of cardiac catheterization equipment – at a disadvantage. The proposed change to round up to the **next** whole number will trigger a need for all service areas that exceed the 80 percent of capacity threshold as defined in the standard need methodology assumptions and as calculated in Step 4 of the methodology.

Based on Johnston Health's review of the *2022 SMFP*[3], the proposed change will result in need determinations for an additional unit of cardiac catheterization equipment in both Johnston and Wayne counties. Johnston and Wayne counties are the only service areas with a required number of units (Column I) that is greater than their total planning inventory of equipment (Column F). Both Wayne UNC Health Care and Johnston Health are operating well above 100 percent capacity and have far exceeded the 80 percent of capacity required to trigger a need based on the standard capacity of a unit of cardiac catheterization equipment.

REASONS FOR THE PROPOSED CHANGE

The need for the proposed change is to promote an equitable approach in the application of the standard need methodology to service areas with varying cardiac catheterization inventory. As noted previously, the need methodology assumptions outlined on page 310 of the *2022 SMFP* state in part that "*[t]he capacity of a unit of cardiac catheterization equipment is defined as 1,500 diagnostic-equivalent procedures per year, with the trigger of need at 80% of capacity*." Johnston Health believes that the cardiac catheterization methodology should determine need based on the 80 percent capacity threshold

[3] Data for all cardiac catheterization providers are not yet available for FY 2021 as of the filing of this petition; as such, data from the *2022 SMFP* are the most recent available.

as defined in the standard need methodology assumptions and as calculated in Step 4 of the methodology. Currently, rounding to the nearest whole number (which may be lower or higher) in Step 5 of the need methodology effectively creates capacity requirements that are above the 80 percent capacity threshold stated in the assumptions. This proposed change is consistent with the current MRI and PET need methodologies where a need is generated if the volume is greater than or equal to the service area threshold. As a practical matter, if a service area has reached 80 percent of its capacity, then a need determination for another unit is warranted, to allow time for the CON process and development of the project. As noted in the previous table, the current rounding methodology requires all service areas to perform above the 80 percent threshold before a need is generated; however, this is of minimal consequence in areas with 10 or more units of equipment. The smaller service areas—those with the fewest number of units to absorb the additional volume—are required to operate at disproportionately higher capacity thresholds.

As currently calculated, the need methodology requires providers in service areas with one unit of equipment to exceed 120 percent of capacity in order to generate a need determination. This capacity requirement places a burden on providers, as they have no other equipment with available capacity once their single unit of equipment reaches maximum capacity or if the equipment is down for service, and it limits options for patients to receive needed services. The change proposed in this petition will create an equitable standard for all service areas based on the 80 percent threshold, providing a clear and consistent path for all service areas to generate need determinations and appropriately allowing providers to meet patients' needs. This change may also help reduce the number of special need adjustment requests from providers in service areas with one unit of cardiac catheterization equipment.

In addition, the proposed change will assist healthcare systems that are working to improve their quality, improve their continuity of care, and expand their service offerings, particularly in smaller service areas with only one unit of cardiac catheterization equipment. As noted above, historically, PCI was rarely performed in small communities. Now, 19 of the 25 service areas with one unit of cardiac catheterization equipment perform interventional cardiology procedures despite only one of these providers offering open heart procedures. As new procedures are added, it is vital that capacity to perform the procedures is adequate.

Finally, the need for the proposed change is highlighted by Johnston Health's current situation. Johnston Health's diagnostic-equivalent cardiac catheterization procedures have been growing at a compound annual growth rate of 13.3 percent for the past three years. Its volume originally exceeded the 80 percent threshold in FFY 2019 and has continued to grow in FFY 2020 and FFY 2021. Despite operating at 109 percent of capacity in FFY 2021 and far exceeding the 80 percent threshold, Johnston Health has been unable to trigger a need for an additional unit of cardiac catheterization equipment for Johnston County based on the way Step 5 in the methodology is written. Based on recent growth rates, Johnston Health anticipates exceeding the 1,800 diagnostic-equivalent procedure requirement in FFY 2022. However, the FFY 2022 volume will not trigger a need until the *2024 SMFP*. As such, Johnston Health will have far exceeded the 80 percent threshold for a minimum of six years (FFY 2019 through FFY 2024) before the current need methodology is likely to identify a need for an additional unit of equipment.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

The cardiac catheterization need methodology remaining unchanged will have an adverse impact on providers in service areas with lower cardiac catheterization inventory, Johnston Health, and most importantly, patients.

As noted above, the current need determination methodology requires providers in service areas with one unit of equipment to exceed 120 percent capacity in order to generate a need. This percentage required is significantly higher than the percentage required to trigger a need in service areas with more than one unit of cardiac catheterization equipment. As previously discussed, only one service area has increased from one unit to two units in the past 15 years and that increase required a special need petition. Without a change such as proposed in this petition, these providers are unlikely to meet the capacity required to acquire an additional unit of equipment. This will limit competition in the state as well as available capacity for patients.

Johnston Health has experienced rapid growth in its cardiac catheterization volume, which it will be unable to maintain due to capacity constraints. Johnston Health is currently operating above capacity at a volume equivalent to 1.36 machines on only one unit. Continually exceeding capacity has negative ramifications. First, growth will ultimately be limited as there will be no capacity to perform additional procedures. Second, operating a unit beyond capacity increases wear and tear and could lead to downtime. The downtime needed to address maintenance issues can cause additional delays in treatment and further exacerbate the overutilization of the equipment. As the only provider of cardiac catheterization services in the service area, there are no alternatives in Johnston County for patients during equipment downtime. Third, as discussed below, this will have a significant impact on Johnston Health's patients.

If providers continue to operate above capacity, patients will be negatively impacted. As units are operated above capacity, patient wait times will increase, which may lead to delays in care. Given the importance of cardiac catheterization procedures, a delay in care can have a harmful impact on a patient's health. If patients are unable to make an appointment, patients may be forced to travel outside of the service area for timely care. Further, as the SHCC is aware, some cardiac catheterization services, specifically emergent PCI, are provided as emergency, life-saving procedures. As such, having sufficient available capacity for these emergent cases is essential, yet providers like Johnston Health with no excess capacity often struggle to balance scheduled elective cases (which are often needed to *prevent* emergency cases) with the emergency cases that present through the Emergency Department.

ALTERNATIVES CONSIDERED

Johnston Health considered alternatives to this proposal but determined they were inadequate as discussed below.

Maintain the Status Quo

Johnston Health could maintain the status quo and wait to trigger a need for an additional unit of cardiac catheterization equipment under the current need methodology. However, as discussed above, given Johnston Health's current growth rates, it expects to exceed 1,800 diagnostic-equivalent procedures in FFY 2022. Despite Johnston Health's rapid growth and projected volume, such volume will not trigger a need until at least the *2024 SMFP*. That would require Johnston Health to continue to operate above capacity for at least two additional years. With the proposed change, Johnston Health could trigger the need for an additional unit of equipment in 2023 and alleviate capacity issues one year earlier. As a result, while maintaining the status quo was considered, it was ultimately rejected as it is not in the best interest of Johnston Health or its patients.

Contract for Mobile Service

While Johnston Health is aware that there are currently nine mobile catheterization units approved in the state, given its current utilization and growth trends, it believes that a mobile unit would be less effective, particularly as a second laboratory. Given the location of its existing catheterization laboratory on the second level (first floor), the use of mobile unit would require clinicians to travel a considerable distance to access the mobile trailer; further, the mobile unit would not be in close proximity to the existing cardiac catheterization staff and would therefore likely require duplication of registration and clinical staff to accommodate those patients. Compared with another fixed unit, a mobile unit would also likely be more expensive to operate and would require the use of the staff of the mobile vendor, who would not be interchangeable with Johnston Health's own staff members. Finally, while a mobile unit can be effective for lower volume sites that cannot support a fixed unit, Johnston Health's current volume and growth trends demonstrate that a second fixed laboratory would be more effective, particularly to provide backup for patients needing an emergent PCI while the one laboratory is in use. For these reasons, Johnston Health determined that using a mobile service is not an effective alternative.

File a Petition for a Special Need Adjustment

Johnston Health could file a petition for a special need adjustment. Such an alternative represents a similar strategy that several providers in service areas with one unit of equipment have utilized in the past. While SRMC was successful with this strategy, others have not been. It is important to note that SRMC represented a unique circumstance as it was the only provider of open-heart surgery without multiple units of cardiac catheterization equipment. While a special need petition remains an option for Johnston Health, it believes the issue lies with the methodology itself, which is why it is filing this Spring petition.

Johnston Health believes that the current methodology is not equitable as it places a greater burden on providers in service areas with lower cardiac catheterization inventory to trigger a need. A petition in the summer for a special need adjustment would alleviate Johnston Health's capacity issue, but it would not address the structural flaw in the methodology, which results in the inequitable treatment of service areas with a single unit under the current methodology. Since a special need adjustment would not address the larger issue at hand, this alternative was rejected at this time.

UNNECESSARY DUPLICATION

Johnston Health does not believe the proposed change will result in unnecessary duplication of health resources. The current need methodology assumptions state that a need is triggered at 80 percent of capacity, yet the rounding rules actually prevent this from occurring until the provider reaches as much as 120 percent of capacity. The proposed change would create an equitable standard for all service areas (regardless of inventory) based on this 80 percent threshold. In addition, the proposed change is similar to the MRI and PET need methodologies where a need is generated if the volume is greater than or equal to the service area threshold.

BASIC PRINCIPLES

Johnston Health believes the petition is consistent with the three basic principles: safety and quality, access, and value.

Safety and Quality

The proposed change will allow providers to generate additional capacity as the 80 percent threshold is met. Without this change, a provider could operate significantly above capacity without generating additional need through the current need methodology. Performing beyond capacity limits the ability to see patients, leads to delays in care, and ultimately increases healthcare costs.

As noted previously, Johnston Health is currently operating well above capacity. Continually exceeding capacity has negative ramifications. If the demand for cardiac catheterization services at a facility exceeds its reasonable capacity, delays result in patients beginning their procedures late in the day, thus requiring a more expensive and inconvenient overnight stay, or waiting until a later scheduled time. Overutilized catheterization labs must operate in the evenings and on weekends. Scheduled procedures, while not emergency cases, are needed to improve the health of these patients and the delays that may result from overutilized equipment results in delays in their recovery and return to normal life. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues. The downtime needed to address maintenance issues can cause additional delays in treatment and further exacerbate the overutilization of the equipment. If patients and physicians are forced to access care at another facility with available capacity, they may encounter disruptions in continuity of care. Physicians and providers work every day to improve the systems of care which leverage information technology, multidisciplinary teams, and processes of care to deliver the right care at the right time to the right person. A facility under the control of another healthcare system cannot provide the same system of care to an unfamiliar physician and patient. As a result, safety and quality may be reduced without the proposed change in the methodology.

Access

The proposed change will enable the addition of cardiac catheterization equipment once the 80 percent threshold is met. This will allow for increases in the inventory of cardiac catheterization equipment when needed and will improve access throughout the state. In particular, providers in service areas with one unit of equipment will be able to expand before exceeding maximum capacity, improving access to their communities.

Johnston Health is the sole provider of cardiac catheterization services in Johnston County. The proposed change will trigger a need for an additional unit of cardiac catheterization equipment in Johnston County in the *2023 SMFP*, thus allowing Johnston Health to submit a CON application to develop an additional unit of cardiac catheterization equipment, thereby improving access and ensuring availability for its patients as its cardiac catheterization service continues to grow.

Value

Providers that are able to expand and add capacity as needed will be able to provide safer and higher quality services compared to those operating over capacity. Delays in needed treatment or unanticipated

overnight stays at the hospital add to healthcare expenditures. In addition, overutilized equipment requires more maintenance, which results in additional expenses.

The proposed methodology change will help ensure cardiac catheterization services are immediately available for patients as need is generated and – in the case of Johnston Health – before volumes become even more unmanageable on one unit of equipment. As a result, the proposed change will allow providers to offer greater healthcare value.

CONCLUSION

In conclusion, Johnston Health asks the SHCC to approve this petition to change the cardiac catheterization need methodology. By modifying Step 5 of the need methodology, service areas may add additional units of equipment as the need is generated and all service areas (regardless of equipment inventory) will receive equitable treatment.

Thank you for your consideration.