Technology and Equipment Committee
Agency Report
Adjusted Need Petition for
Cardiac Catheterization Equipment in the
2025 State Medical Facilities Plan

Petitioner:
Catawba Valley Medical Center
810 Fairgrove Church Road, SE
Hickory, NC 28602

Contact:
Greg Billings
gbillings@catawbavalleymc.org

Request:
Catawba Valley Medical Center requests an adjusted need determination for one additional unit of hospital-based fixed cardiac catheterization equipment in Catawba County in the *2025 State Medical Facilities Plan (SMFP or "Plan").*

Background Information:
Chapter Two of the *SMFP* notes that during the summer, the Agency accepts petitions that "involve requests for adjustments to need determinations in the *Proposed SMFP*. Petitioners may submit a written petition requesting an adjustment to the need determination in the *Proposed SMFP* if they believe that special attributes of a service area or institution give rise to resource requirements that differ from those provided by the standard methodologies and policies." Any person may submit a certificate of need (CON) application for a need determination in the *SMFP*. The CON review could be competitive and there is no guarantee that the Petitioner would be the approved applicant.

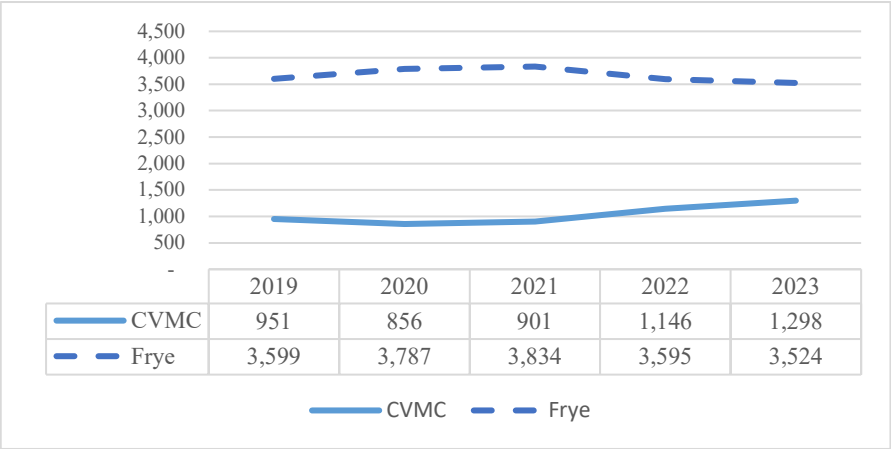
The standard methodology in the *SMFP* states that a unit of fixed cardiac catheterization (CC) equipment is considered fully utilized when it is at 80% of capacity. The capacity of a unit of CC equipment is defined as 1,500 diagnostic equivalent procedures per year. One interventional procedure is valued at 1.75 diagnostic-equivalent procedures. One procedure performed on a patient aged 14 or younger is valued at 2 diagnostic equivalent procedures. All other procedures are valued at 1 diagnostic-equivalent procedure. The *SMFP* provides an additional method for obtaining a shared fixed unit of CC equipment for service areas that have no CC equipment. This additional method is not applicable to the current petition.

Catawba County currently has five units of CC equipment; one is at Catawba Valley Medical Center (CVMC) and four are at Frye Regional Medical Center (Frye). CVMC performed 1,298 weighted procedures in the 2023 reporting year, which yielded a requirement for 1.08 units of equipment. Frye performed 3,524 procedures, which yielded a requirement for 2.94 units of equipment. To calculate a need determination, the methodology first rounds each facility's requirement to the next higher whole number. Thus, CVMC requires two units of equipment and

Frye requires three. The requirements are added to obtain the need determination for the service area. This calculation results in a requirement for five units in Catawba County, which is the number currently available. Therefore, the county has no need determination in the *Proposed 2025 SMFP*.

Analysis/Implications:
According to the 2024 License Renewal Applications (LRAs), Frye performed 211 open-heart surgeries and CVMC performed none. The Petitioner points out that cardiac care is evolving such that the need for open-heart surgery is decreasing and the need for less invasive procedures is increasing. This change may partially explain why CVMC has a deficit of CC equipment and Frye has a surplus. Figure 1 shows the change in the number of CC procedures over the last five reporting years. CVMC experienced a 36% increase in CC procedures during this period, while Frye has remained relatively stable.

Figure 1. Change in Cardiac Catheterization Procedures 2019-2023



	2019	2020	2021	2022	2023
CVMC	951	856	901	1,146	1,298
Frye	3,599	3,787	3,834	3,595	3,524

Source: 2021-Proposed 2025 State Medical Facilities Plans

Another partial explanation for the trend may be the difference in the types of CC services provided at CVMC and Frye. Before 2014, a single group of cardiologists served Catawba County and all the physicians had privileges at both hospitals. In 2014, the physicians split into two groups and each hospital now employs its own group. According to the Petitioner, this division led to each hospital developing different focuses in cardiac care, as described above. Also, CVMC now operates an accredited 24/7 ST-Elevation Myocardial Infarction (STEMI) program.

The American Heart Association and the Joint Commission offer three levels of STEMI certification:

- Level I: Comprehensive Hearth Attack Center (CHAC) – for hospitals performing cardiac surgical services and primary percutaneous coronary intervention (PCI) 24/7/365;
- Level II: Primary Heat Attack Center (PHAC) – ideal for hospitals performing primary PCI 24//7/365; and

- Level III: Acute Heart Attack Ready (AHAR) – for STEMI referring hospitals that may or may not perform primary PCIs[1].

The Petitioner did not specify the STEMI program level applicable to CVMC. It is most likely that the facility is Level II because they perform PCI procedures but do not report any cardiothoracic surgery on their LRA.

The primary rationale for the request is based on the need to perform STEMI procedures. Specifically, if CVMC's only CC unit is in use, a STEMI patient may have to wait for the necessary procedure, either at CVMC or Frye. CVMC notes that transportation of a patient to Frye in this type of emergency situation is not medically advisable. The Petitioner also points out that coordination of services between the two cardiology practices is not possible after the 2014 split. Although the Petitioner did not allude to any existing *SMFP* policies, this request could be understood as parallel to *SMFP* Policy AC-6 regarding heart-lung bypass machines:

> To protect cardiac surgery patients, who may require emergency procedures while scheduled procedures are underway, any hospital with an open-heart surgery program that has only one heart-lung bypass machine may submit a certificate of need application for a second machine. The additional machine is to be used to assure appropriate coverage for emergencies and in no instance shall this machine be scheduled for use at the same time as the machine used to support scheduled open-heart surgery procedures. A certificate of need application for a machine acquired in accordance with this provision shall be exempt from compliance with the performance standards set forth in 10A NCAC 14C .1703. (Proposed 2025 State Medical Facilities Plan, page 21)

As mentioned above, the *Proposed 2025 SMFP* has no need determination because the service area has excess CC capacity. Based on the methodology, the surpluses and deficits offset each other to yield no need determination. In this specific situation, Frye has excess CC capacity, while CVMC needs additional capacity. The Petitioner references several previous petitions in which the State Health Coordinating Council (SHCC) approved adjusted need determinations in similar situations in service areas where the surplus in a single facility would likely prevent another facility from expanding services in the foreseeable future. One such example is in Catawba County. Greystone Eye Associates (Greystone) submitted a petition in 2016 for an operating room (OR). In this case, Frye had far more ORs than its utilization is ever likely to require.[2] The SHCC denied this petition. The following year, Greystone submitted a petition with a similar rationale, but also noted that the facility had substantial increases in physician staff; as a result, the SHCC approved the petition.

CVMC also discussed a petition from UNC Rex Hospital (Rex) in Wake County. Wake County had experienced a rearrangement of cardiology providers somewhat similar to that in Catawba County. In 2013, Rex established a new cardiovascular practice that combined physicians from both Rex Heart and Wake Heart & Vascular Associates.[3] As a result, by 2015, WakeMed Hospital (WakeMed) had substantial excess CC capacity and Rex had a deficit. Rex submitted a petition in the summer of 2015 for one unit of CC equipment. The Agency recommended approval of the

[1] https://www.jointcommission.org/what-we-offer/certification/certifications-by-setting/hospital-certifications/cardiac-certification/

[2] Note that this petition came before the OR methodology was revised in 2017, to be effective in the 2018 *SMFP*; this situation would not occur under the current methodology.

[3] https://www.bizjournals.com/triangle/news/2013/08/19/rexs-new-cardio-practice-goes.html

petition, but the Technology and Equipment (T&E) Committee voted 2-2, with the Chairperson abstaining. As a result, the motion was not sustained, and the Committee did not recommend approval of the petition. The SHCC upheld the denial of the petition. One reason for the denial was that Rex presented no information indicating that they had attempted an agreement with WakeMed regarding sharing of resources. In 2016, Rex petitioned for two CC units. This time they showed that, despite attempts, sharing of resources between the two facilities was not possible. The SHCC approved Rex's petition, in part, for an adjusted need determination for one additional CC unit.

In considering its recommendation regarding any Petition, the Agency always examines whether approval would be likely to create excess capacity. Currently, of the 40 hospitals with CC labs, 24 (60%) had only one existing or approved unit of CC equipment during the 2023 reporting year. (This number includes CVMC.) Of the 24, it appears that 23 would not be likely to file a petition for a second CC unit (i.e., 8 performed no procedures and an additional 15 had less than 50% utilization).

~~The~~ SHCC also works to strike a balance between providing services where and to whom they are needed while avoiding the creation of excess capacity when considering a new policy. To apply this notion to the current situation, the issue raised by the Petitioner can occur only in service areas with more than one hospital. Otherwise, the need determination is based solely on the procedures at the only existing hospital. The *Proposed 2025 SMFP* (see Table 1) shows that no hospital in service areas with more than one hospital has a deficit of CC equipment, although a few are very close (e.g., Novant Health Huntersville Medical Center in Mecklenburg County, and Rex in Wake County). Based on this observation, it does not appear that a policy similar to AC-6 applied to hospitals with STEMI programs would lead to a proliferation of excess CC equipment.

Table 1. Excerpt from Table 15A-3, *Proposed 2025 SMFP*: Service Areas with More than One Hospital with Cardiac Catheterization Equipment

Cardiac Catheterization Equipment Service Areas	Facility	Total Planning Inventory*	2023 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization
Catawba	Catawba Valley Medical Center	1	1,298	1.08
	Frye Regional Medical Center	4	3,524	2.94
	TOTAL	**5**		**5**
Durham/ Caswell/Warren	Duke Regional Hospital	2	1,350	1.13
	Duke University Hospital	7	5,978	4.98
	TOTAL	**9**		**7**
Forsyth	Atrium Health Wake Forest Baptist	5	4,788	3.99
	Novant Health Forsyth Medical Center	8	5,510	4.59
	TOTAL	**13**		**9**
Guilford	Cone Health	7	5,055	4.21
	High Point Regional Medical Center	4	3,349	2.79
	TOTAL	**11**		**8**
Iredell	Davis Regional Medical Center	1	0	0.00
	Iredell Memorial Hospital	2	984	0.82
	Lake Norman Regional Medical Center	1	558	0.46
	TOTAL	**4**		**2**
Mecklenburg	Atrium Health Pineville	3	2,758	2.30
	Carolinas Medical Center	9	6,653	5.54
	Novant Health Huntersville Med. Center	1	1,040	0.87
	Novant Health Matthews Med. Center	2	1,842	1.53
	Novant Health Presbyterian Med. Center	2	2,818	2.35
	TOTAL	**17**		**13**
Wake	Duke Raleigh Hospital	3	834	0.69
	Rex Hospital	6	7,125	5.94
	WakeMed	9	5,302	4.42
	WakeMed Cary Hospital	1	756	0.63
	TOTAL	**19**		**12**

* Including adjustments for CONs under development and previous need

Agency Recommendation:

The arguments presented in this Petition are similar to those posed in several past petitions that the SHCC approved. The Agency supports the standard methodology for CC equipment. Given available information submitted by the August 7, 2024 deadline, and in consideration of factors discussed above, the Agency recommends approval of the Petition. Further, the Agency recommends that during the Spring petition process, the T&E Committee consider a policy that facilitates acquisition of CC equipment for hospitals with an accredited Level I or Level II STEMI program (or other appropriate cardiac program to be determined), but that have only one CC lab.