Technology and Equipment Committee Agency Recommendation Proposed Policy TE-5 2026 State Medical Facilities Plan (SMFP)

Background:

In the summer of 2024, Catawba Valley Medical Center (CVMC) submitted a petition to the Technology and Equipment Committee ("Committee" or "T&E Committee") of the State Health Coordinating Council (SHCC) requesting one additional unit of hospital-based fixed cardiac catheterization (CC) equipment to support their ST-Elevation Myocardial Infarction (STEMI) program. The Committee and SHCC approved the petition. Part of the approval included a further recommendation from the Agency "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." This Agency recommendation proposes a policy for consideration by the Committee and for public comment.

Several organizations accredit/certify a range of programs that concern cardiac care. For example, the American Heart Association (AHA) and The Joint Commission (TJC) offer an accreditation program with three levels:

- Level I: Comprehensive Heart Attack Center (CHAC) for hospitals performing cardiac surgical services and primary percutaneous coronary intervention (PCI) 24/7/365;
- Level II: Primary Heart 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 recommendation in the Agency Report on the CVMC Petition included a reference to "other appropriate cardiac" program. In addition to AHA and TJC, other national and international organizations accredit programs related to cardiac care, primarily the American College of Cardiology (ACC) and DNV (formerly Det Norske Veritas). Aside from the ACC, no organization appears to provide a comprehensive listing of accredited facilities that is available to the public.²

Rationale:

The rationale for a policy is the need to perform time-sensitive STEMI procedures. A hospital with a single CC unit has several options when their equipment is in use and a STEMI patient arrives: (1) transfer the STEMI patient to another facility; (2) remove the current patient from the CC lab

¹ <u>https://www.jointcommission.org/what-we-offer/certification/certifications-by-setting/hospital-certifications/cardiac-certification/</u>

https://www.cardiosmart.org/find-your-heart-a-home/searchResultsData?hospitalName=&hospitalLocation=NC&serviceId=11&isParticipating=false&page=1&searchHospital=false

and wait to complete the procedure until the STEMI patient is treated; or (3) have the STEMI patient wait until the lab completes the procedure on the current patient.

The Agency suggested limiting a policy to Level I and Level II STEMI programs because they are more likely than Level III programs to encounter a situation in which a scheduled CC procedure is ongoing when a STEMI patient arrives since hospitals with these programs routinely perform PCIs. Level III programs may or may not perform PCIs.

Discussion:

When considering a new policy, it is always important to assess how the proposal reflects the Basic Principles of the SMFP – Safety and Quality, Access and Value.

The proposed policy would comport with the Safety and Quality principle by providing hospitals with a "safety net" for treating patients with a relatively common life-threatening condition. These hospitals already have evidence of quality care, by virtue of their STEMI accreditation. The proposed policy could enhance the quality of care they are able to provide. The addition of a "back-up" cc lab would also enable access to the facility when needed, thus reflecting the Access principle.

The Value principle is often described in terms of assuring, to the extent feasible, that a policy will not lead to an unnecessary proliferation of resources. The Agency first projected the number of additional units of CC equipment that might be approved under the proposed policy to assess how it reflects this principle. To provide some context, the 2025 SMFP shows that 33 hospitals have only one unit of existing or CON-approved CC equipment (see Table below). Seven of these facilities performed no CC procedures during the most recent reporting year (2023).

The Agency has no data on the number of hospitals in North Carolina with certified STEMI programs. However, 20 of the hospitals listed in the table have ACC's Acute Myocardial Infarction Treatment accreditation and/or accreditation for catheterization-related procedures (diagnostic, PCI)³. This information is provided as an example of an "other" accreditation program, not as a specific recommendation for applicability of the ACC categories to the proposed policy.

home/searchResultsData?hospitalName=&hospitalLocation=NC&serviceId=11&isParticipating=false&page=1&searchHospital=false retrieved December 1, 2024

³ https://www.cardiosmart.org/find-your-heart-a-

Hospitals with One Unit of Cardiac Catheterization Equipment, 2023

County	Hospital	Diagnostic	PCI	Total	Number of Licensed Acute Care Beds
Alamance*	Alamance Regional Medical Center	717	220	937	170
Brunswick****	Novant Health Brunswick Medical Center	18	0	18	74
Burke	UNC Health Blue Ridge	457	153	610	289
Caldwell*	Caldwell UNC Health Care	619	298	917	110
Carteret*	Carteret General Hospital	435	127	562	132
Catawba*	Catawba Valley Medical Center	773	265	1038	180
Cleveland	Atrium Health Cleveland	0	0	0	280
Halifax*	ECU Health North Hospital	206	69	275	184
Harnett	Cape Fear Valley Betsy Johnson Hospital	212	155	367	126
Haywood*	Haywood Regional Medical Center	819	258	1077	120
Henderson*	Margaret R. Pardee Memorial Hospital	1,066	381	1,447	201
Iredell	Iredell Davis Regional Medical Center	0	0	0	102
Iredell*	Iredell Memorial Hospital	658	186	844	199
Iredell*	Lake Norman Regional Medical Center	283	157	440	115
Jackson	Harris Regional Hospital	0	0	0	82
Johnston* / ***	UNC Health Johnston	847	551	1398	176
Lee	Central Carolina Hospital	355	46	401	126
Lenoir	UNC Lenoir Health Care	284	0	284	182
Mecklenburg*	Novant Health Huntersville Medical Center	632	233	865	135
Mecklenburg* /	Novant Health Matthews Medical Center	1,005	478	1,483	146
Onslow	Onslow Memorial Hospital	0	0	0	144
Pasquotank	Sentara Albemarle Medical Center	672	0	672	182
Randolph	Randolph Hospital	0	0	0	145
Rowan*	Novant Health Rowan Medical Center	339	221	560	198
Rutherford	Rutherford Regional Medical Center	0	0	0	129
Scotland*	Scotland Memorial Hospital	310	54	364	92
Union *	Atrium Health Union	310	54	364	178
Vance*	Maria Parham Health	115	53	168	88
Wake*	WakeMed Cary Hospital	534	127	661	200
Watauga*	Watauga Medical Center	331	159	490	113
Wayne* / **	UNC Health Wayne	1,245	253	1,498	251
Wilkes	Wilkes Medical Center	0	0	0	120
Wilson*	Wilson Medical Center	86	11	97	267

Source: 2025 State Medical Facilities Plan

^{*} ACC Acute Myocardial Infarction and/or diagnostic/PCI catheterization accreditation

^{**} Applied for CON for second unit based on 2024 Need Determination

^{***} Has CON for second unit.

^{**** 2023} procedures are on third party mobile. Has CON for shared fixed unit.

Recommendation:

In considering the components of a policy for hospitals with STEMI programs, the Agency Report on the CVMC Petition pointed out that Policy AC-6 similarly exists for hospitals that operate an open-heart surgery program with only one heart-lung bypass machine.

Policy AC-6: Heart-Lung Bypass Machines for Emergency Coverage

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 .1703.⁴

The Agency proposes Policy TE-5- similar in construct to Policy AC-6 below, for hospitals with STEMI (or similar) programs:

Policy TE-5: Cardiac Catheterization Equipment for Emergency Coverage

To protect cardiac patients who may require emergency diagnostic or interventional cardiac catheterization while scheduled cardiac catheterization procedures are underway, any hospital with a Level I or Level II ST-Elevation Myocardial Infarction (STEMI) program⁵ that has been approved to develop or operates only one unit of fixed or shared fixed cardiac catheterization equipment may submit a certificate of need application for a second unit of equipment without regard to a need determination in the State Medical Facilities Plan. Hospitals with at least one cardiac-related program that includes treatment of myocardial infarction and is accredited by a national or international organization other than the American Heart Association or The Joint Commission may also submit a certificate of need application under this policy.

The additional unit of fixed or shared fixed cardiac catheterization equipment shall be used to assure appropriate coverage for emergencies and in no instance shall this equipment be scheduled for contemporaneous use as the existing equipment used for scheduled diagnostic or interventional cardiac catheterization procedures. A certificate of need application submitted for the approval of a unit of fixed or shared fixed cardiac catheterization equipment in accordance with this policy shall be exempt from compliance with the performance standards set forth in 10A NCAC 14C .1603.

⁴ 2025 State Medical Facilities Plan, Chapter 4.

⁵ Cardiac Certification | The Joint Commission