A. CARDIAC CATHETERIZATION EQUIPMENT

Amendment to Chapter 11, Effective June 26, 2024

The State Health Coordinating Council (SHCC), at its March 6th, 2024 meeting, voted to recommend an amendment to the North Carolina 2024 State Medical Facilities Plan to include a need determination for one unit of cardiac catheterization equipment in the Wayne County service area to the Governor. Corrected Table 15A-3 and an amended Table 15A-4 are included in this section.

Introduction

G.S. § 131E-176(2f) defines *cardiac catheterization equipment* as "equipment used to provide cardiac catheterization services." G.S. § 131E-176(2g) defines *cardiac catheterization services* as "those procedures, excluding pulmonary angiography procedures, in which a catheter is introduced into a vein or artery and threaded through the circulatory system into the heart specifically to diagnose abnormalities in the motion, contraction, and blood flow of the moving heart or to perform surgical therapeutic interventions to restore, repair, or reconstruct the coronary blood vessels of the heart." Tables 15A-1 and 15A-2 show the number of cardiac catheterization procedures performed during the reporting year.

Changes from the Previous Plan

This section contains no substantive changes from the previous State Medical Facilities Plan (SMFP).

Assumptions of the Methodology

- 1. Cardiac catheterization equipment service areas are the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.
- 2. The capacity of a unit of cardiac catheterization equipment is defined as 1,500 diagnosticequivalent procedures per year, with the trigger of need at 80% of capacity. One interventional cardiac catheterization procedure is valued at 1.75 diagnostic-equivalent procedures. One cardiac catheterization procedure performed on a patient ages 14 or younger is valued at two diagnosticequivalent procedures. All other procedures are valued at one diagnostic-equivalent procedure.
- 3. Cardiac catheterization equipment and services shall only be approved for development on hospital sites (i.e., in facilities that are on a hospital's license) or in a licensed ambulatory surgical facility (excluding endoscopy-only facilities).

Application of the Methodology

Fixed Equipment

Methodology 1 (Table 15A-3)

The need determination methodology in service areas with at least one unit of equipment in the current inventory is as follows:

- Step 1: For each facility with fixed cardiac catheterization equipment, sum the total units of equipment in operation *(Column C)*, CON-approved equipment under development *(Column D)*, and equipment available pursuant to need determinations pending review or appeal *(Column E)* to determine the planning inventory *(Column F)*.
- Step 2: Determine the number of adult and pediatric diagnostic and interventional procedures performed at each facility during the current reporting year *(Table 15A-1)*. If mobile procedures are provided in a county that is part of more than one service area, divide the procedures equally between the service areas.

- Step 3: Calculate the total weighted (diagnostic-equivalent) cardiac catheterization procedures for each facility by multiplying adult diagnostic procedures by 1.00, interventional procedures by 1.75, and pediatric procedures performed on patients ages 14 or younger by 2.00 (*Column H*).
- Step 4: For each facility, determine the number of units of fixed cardiac catheterization equipment required for the number of procedures performed by dividing the number of weighted (diagnostic-equivalent) cardiac catheterization procedures performed at each facility by 1,200 procedures (i.e., 80% of the 1,500-procedure capacity). Round the result to the nearest hundredth (*Column I*).
- 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. Round up to the nearest whole number *(Column I)*.
- Step 6: In each service area, subtract the total planning inventory (*Column F*) from the number of units of fixed cardiac catheterization equipment required (*Column I*). The difference is the number of additional units of fixed cardiac catheterization equipment needed (*Column J*).

Unless otherwise specified by the methodology, calculations do not use rounded values. However, fractional values are rounded automatically when displayed.

Methodology 2 (Table 15A-2)

For cardiac catheterization equipment in a service area that does not have a unit of fixed cardiac catheterization equipment, a need determination exists for one unit of shared fixed cardiac catheterization equipment (i.e., fixed equipment that is used to perform both cardiac catheterization procedures and angiography procedures) when:

- 1. The number of cardiac catheterization procedures as defined in 10A NCAC 14C .1601(5) performed at any mobile site in the service area exceeds 240 procedures (80% of 300 procedures) for each eight hours per week the mobile equipment is operated at that site during the current reporting year (*Table 15A-2*); and
- 2. No other fixed or mobile cardiac catheterization service is provided in the same service area.

Unless otherwise specified by the methodology, calculations do not use rounded values. However, fractional values are rounded automatically when displayed.

<u>Mobile Equipment</u>

The SMFP does not have a methodology to project need for additional mobile cardiac catheterization equipment. A summer petition is required to place a need in the upcoming SMFP. If the need determination is approved, any person may apply for a CON to acquire the mobile cardiac catheterization equipment.

			Diag	nostic			Interve	ntional		
County	Hospital	Ad	lult	Pedi	atric	Ad	ult	Pedi	atric	Total
		Fixed	Mobile	Fixed	Mobile	Fixed	Mobile	Fixed	Mobile	
Alamance	Alamance Regional Medical Center	734	-	-	-	179	-	-	-	913
Buncombe	Mission Hospital	3,614	-	-	-	1,192	-	-	-	4,806
Burke	UNC Health Blue Ridge	373	-	-	-	129	-	-	-	502
Cabarrus	Atrium Health Cabarrus	1,813	-	-	-	1,347	-	-	-	3,160
Caldwell	Caldwell UNC Health Care	-	-	-	-	979	-	-	-	979
Carteret	Carteret General Hospital	489	-	-	-	159	-	-	-	648
Catawba	Catawba Valley Medical Center	666	-	-	-	274	-	-	-	940
Catawba	Frye Regional Medical Center	1,862	-	-	-	990	-	-	-	2,852
Cleveland	Atrium Health Cleveland	3	-	-	-	-	-	-	-	3
Craven	CarolinaEast Medical Center	1,014	-	-	-	826	-	-	-	1,840
Cumberland	Cape Fear Valley Medical Center	806	-	-	-	1,666	-	-	-	2,472
Durham	Duke Regional Hospital	730	-	-	-	320	-	-	-	1,050
Durham	Duke University Hospital	4,087	-	274	-	1,490	-	230	-	6,081
Forsyth	Atrium Health Wake Forest Baptist	2,306	-	3	-	1,303	-	8	-	3,620
Forsyth	Novant Health Forsyth Medical Center	2,924	-	-	-	1,393	-	-	-	4,317
Gaston	CaroMont Regional Medical Center	1,946	-	-	-	601	-	-	-	2,547
Guilford	Cone Health	2,910	-	-	-	1,156	-	-	-	4,066
Guilford	High Point Regional Health	1,322	-	-	-	695	-	-	-	2,017
Halifax	Vidant North Hospital	69	-	-	-	9	-	-	-	78
Harnett	Cape Fear Valley Betsy Johnson Hospital	240	-	-	-	108	-	-	-	348
Haywood	Haywood Regional Medical Center	590	-	-	-	167	-	-	-	757
Henderson	Margaret R. Pardee Memorial Hospital	851	-	-	-	253	-	-	-	1,104
Iredell	Davis Regional Medical Center	111	-	-	-	48	-	-	-	159
Iredell	Iredell Memorial Hospital	797	-	-	-	244	-	-	-	1,041
Iredell	Lake Norman Regional Medical Center	248	-	-	-	138	-	-	-	386
Jackson	Harris Regional Hospital	87	-	-	-	2	-	-	-	89
Johnston	UNC Health Johnston	956	-	-	-	404	-	-	-	1,360

Table 15A-1: Fixed Cardiac Catheterization Procedures by Facility and Type, 2022

			Diag	nostic			Interve	ntional		
County	Hospital	Ad		Pediatric		Adult		Pedi	atric	Total
		Fixed	Mobile	Fixed	Mobile	Fixed	Mobile	Fixed	Mobile	
Lee	Central Carolina Hospital	190	-		-	34	-	-	-	224
Lenoir	UNC Lenoir Health Care	236	-	-	-	-	-	-	-	236
Mecklenburg	Atrium Health Pineville	1,129	-	-	-	809	-	-	-	1,938
Mecklenburg	Carolinas Medical Center	2,557	-	345	-	1,286	-	162	-	4,350
Mecklenburg	Novant Health Huntersville Medical Center	553	-	-	-	301	-	-	-	854
Mecklenburg	Novant Health Matthews Medical Center	1,022	-	-	-	552	-	-	-	1,574
Mecklenburg	Novant Health Presbyterian Medical Center	1,146	-	-	-	1,002	-	-	-	2,148
Moore	First Health Moore Regional Hospital	2,693	-	-	-	1,056	-	-	-	3,749
Nash	Nash General Hospital	892	-	-	-	559	-	-	-	1,451
New Hanover	New Hanover Regional Medical Center	3,372	-	-	-	2,198	-	-	-	5,570
Onslow	Onslow Memorial Hospital	-	-	-	-	-	-	-	-	-
Orange	University of North Carolina Hospitals	2,088	-	31	-	1,074	-	106	-	3,299
Pasquotank	Sentara Albemarle Medical Center	685	-	-	-	-	-	-	-	685
Pitt	Vidant Medical Center	2,904	-	3	-	964	-	15	-	3,886
Randolph	Randolph Hospital	-	-	-	-	-	-	-	-	-
Robeson	Southeastern Regional Medical Center	626	-	-	-	505	-	-	-	1,131
Rowan	Novant Health Rowan Medical Center	479	-	-	-	313	-	-	-	792
Rutherford	Rutherford Regional Medical Center	54	-	-	-	-	-	-	-	54
Scotland	Scotland Memorial Hospital	297	-	-	-	46	-	-	-	343
Stanly	Atrium Health Stanly	-	-	-	-	-	-	-	-	-
Union	Atrium Health Union	357	-	-	-	13	-	-	-	370
Vance	Maria Parham Health	154	-	-	-	62	-	-	-	216
Wake	Duke Raleigh Hospital	576	-	-	-	155	-	-	-	731
Wake	Rex Hospital	2,628	-	-	-	2,776	-	-	-	5,404
Wake	WakeMed	2,159	-	-	-	1,680	-	-	-	3,839
Wake	WakeMed Cary Hospital	407	-	-	-	124	-	-	-	531
Watauga	Watauga Medical Center	336	-	-	-	154	-	-	-	490

Table 15A-1: Fixed Cardiac Catheterization Procedures by Facility and Type, 2022

			Diagi	nostic						
County	Hospital	Adult		Pediatric		Adult		Pediatric		Total
		Fixed	Mobile	Fixed	Mobile	Fixed	Mobile	Fixed	Mobile	
Wayne	Wayne UNC Health Care	1,044	-	-	-	221	-	-	-	1,265
Wilkes	Wilkes Regional Medical Center	-	-	-	-	-	-	-	-	-
Wilson	Wilson Medical Center	101	-	-	-	16	-	-	-	117
Total		60,233	-	656	-	31,972	-	521	-	93,382

Table 15A-1: Fixed Cardiac Catheterization Procedures by Facility and Type, 2022

 Table 15A-2:
 Mobile Cardiac Catheterization Capacity and Volume

		Days/Week	Procedure	Procedures
County	Service Site	On Site	Capacity	Reported in 2022
Columbus	Columbus Regional Healthcare System	1.00	300	3
Davidson	Novant Health Thomasville Medical Center	1.00	300	97
Jackson	Harris Regional Hospital	1.00	300	177
Brunswick	Novant Health Brunswick Medical Center	1.00	300	25
Total		4.00	1,200	302

Table 15A-3: Fixed Cardiac Catheterization Equipment, Capacity and Volume

А	В	С	D	Е	F	G	Н	Ι	J	К
Cardiac Catheterization Equipment Service Areas	Facility	Current Inventory	CON Issued/ Pending Development	Pending Review or Appeal	Total Planning Inventory	F o o t n o t e	2022 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Number of Additional Machines Required by Facility	Number of Additional Machines Needed by Service Area
Alamance	Alamance Regional Medical Center	1			1	b	1,047	0.87	0	
Alamance	TOTAL				1			1		0
Brunswick	2023 Need Determination TOTAL			1	1					
Buncombe/Graham/ Madison/Yancey	Mission Hospital TOTAL	5			5	b	5,700	4.75 5	0	0
Burke	UNC Health Blue Ridge 2023 Need Determination TOTAL	1		1	1 1 2	b	599	0.50	0	0
Cabarrus	Atrium Health Cabarrus TOTAL	2	1		3	b	4,170	3.48 4	0	1
Caldwell	Caldwell Memorial Hospital TOTAL	1			1 1	d	1,713	1.43 2	0	1
Carteret	Carteret General Hospital TOTAL	1			1 1	b	767	0.64	0	0
Catawba	Catawba Valley Medical Center Frye Regional Medical Center TOTAL	1 4			1 4 5	b b	1,146 3,595	0.95 3.00 4	0	0
Cleveland	Atrium Health Cleveland TOTAL	1			1 1	с	3	0.00	0	0
Craven/Jones/ Pamlico	CarolinaEast Medical Center TOTAL	3			3 3	b	2,460	2.05 3	0	0
Cumberland	Cape Fear Valley Medical Center TOTAL	4			4 4	b	3,722	3.10 4	0	0
Durham/ Caswell/Warren	Duke Regional Hospital Duke University Hospital	2 7			2 7	b a	1,290 7,703	1.08 6.42	0	
	TOTAL Atrium Health Wake Forest Baptist	5			9 5	a	4,608	8 3.84	0	0
Forsyth	Novant Health Forsyth Medical Center TOTAL	8			8 13	b	5,362	4.47 9	0	0
Gaston	CaroMont Regional Medical Center TOTAL	3			3	b	2,998	2.50 3	0	0
Guilford	Cone Health High Point Regional Medical Center TOTAL	7 4			7 4 11	b b	4,933 2,538	4.11 2.12 7	0 0	0
Halifax/ Northampton	Vidant North Hospital TOTAL	1			1 1 1	b	85	0.07	0	0
Harnett	Cape Fear Valley Betsy Johnson Hospital	1			1	b	429	0.36	0	0
Haywood	TOTAL Haywood Regional Hospital TOTAL	1			1	b	882	1 0.74	0	0

Table 15A-3: Fixed Cardiac Catheterization Equipment, Capacity and Volume

А	В	С	D	Е	F	G	Н	Ι	J	К
Cardiac Catheterization Equipment Service Areas	Facility	Current Inventory	CON Issued/ Pending Development	Pending Review or Appeal	Total Planning Inventory	F o o t n o t e	2022 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Number of Additional Machines Required by Facility	Number of Additional Machines Needed by Service Area
Henderson	Margaret R. Pardee Memorial Hospital	1	1		2	b	1,294	1.08	0	
	TOTAL				2		1.0.2	2		0
	Davis Regional Medical Center	1			1	b	195	0.16	0	
Iredell	Iredell Memorial Hospital	1	1		2	b	1,224	1.02	0	
	Lake Norman Regional Medical Center	1			1	b	490	0.41	0	
	TOTAL	-			4			2		0
Jackson	Harris Regional Hospital	1			1	b	91	0.08	0	2
	TOTAL				1	- 1	1.((2	1		0
Labuston	UNC Health Johnston	I		1	1	b	1,663	1.39	0	
Johnston	2023 Need Determination TOTAL			1	1			2		0
		1			2	1	250	2	0	U
Lee	Central Carolina Hospital TOTAL	1			1	b	250	0.21	0	0
		1			-		22(1	0	0
Lenoir	UNC Lenoir Health Care TOTAL	1			1	с	236	0.20	0	0
	Atrium Health Pineville	3			3	b	2,545	1 2.12	0	0
	Carolinas Medical Center	3			3	a	2,545	4.85	0	
	Novant Health Huntersville Medical	9			9	a	3,822	4.83	0	
	Center	1			1	b	1,080	0.90	0	
Mecklenburg	Novant Health Matthews Medical	1			1	D	1,080	0.90	0	
Mecklehburg	Center	1	1		2	b	1,988	1.66	0	
	Novant Health Presbyterian Medical	1	1		2	U	1,900	1.00	0	
	Center	2			2	b	2,900	2.42	0	
	TOTAL	2			17	U	2,900	12	0	0
	FirstHealth Moore Regional Hospital	6			6	b	4,541	3.78	0	U
Moore	TOTAL	0			6	U	4,541	4	0	0
	Nash General Hospital	2			2	b	1,870	1.56	0	U
Nash	TOTAL	2			2	0	1,070	2	0	0
	New Hanover Regional Medical Center	5	1		6	b	7,219	6.02	0	U
New Hanover	2023 Need Determination	5	1	1	1	U	7,219	0.02	0	
The full of the fu	TOTAL			1	7			7		0
	Onslow Memorial Hospital	1			1		0	0.00	0	U
Onslow	TOTAL	1			1		, , , , , , , , , , , , , , , , , , ,	0.00	U U	0
	UNC Hospitals	4	1		5	а	4.242	3.53	0	U
Orange	TOTAL	T	1		5	a	.,212	4	0	0
	TOTAL							-		v
Pasquotank/ Camden/										
Currituck/ Perquimans		1			1	с	685	0.57	0	
-	TOTAL				1			1		0
Pitt/Greene/	Vidant Medical Center	7			7	a	4,627	3.86	0	
Hyde/Tyrell	TOTAL				7			4		0
Randolph	Randolph Hospital	1			1		0	0.00	0	
runuo.p.	TOTAL				1			0		0

Table 15A-3: Fixed Cardiac Catheterization Equipment, Capacity and Volume

А	В	С	D	Е	F	G	Н	Ι	J	К
Cardiac Catheterization Equipment Service Areas	Facility	Current Inventory	CON Issued/ Pending Development	Pending Review or Appeal	Total Planning Inventory	F o t n t e	2022 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Number of Additional Machines Required by Facility	Number of Additional Machines Needed by Service Area
Robeson	Southeastern Regional Medical Center	2			2	b	1,510	1.26	0	
Kobeson	TOTAL				2			2		0
Rowan	Novant Health Rowan Medical Center	1			1	b	1,027	0.86	0	
Kowan	TOTAL				1			1		0
Rutherford	Rutherford Regional Medical Center	1			1	с	54	0.05	0	
Kutileriöru	TOTAL				1			1		0
Scotland	Scotland Memorial Hospital	1			1	b	378	0.31	0	
Scottanu	TOTAL				1			1		0
Stanly	Atrium Health Stanly	1			1		0	0.00	0	
Stanty	TOTAL				1			0		0
Union	Atruim Health Union	1			1	b	380	0.32	0	
Childh	TOTAL				1			1		0
Vance/Warren	Maria Parham Medical Center	1			1	b	263	0.22	0	
v ance/ vv arren	TOTAL				1			1		0
	Duke Raleigh Hospital	3			3	b	847	0.71	0	
	Rex Hospital	6			6	b	7,486	6.24	0	
Wake	WakeMed	9			9	b	5,099	4.25	0	
	WakeMed Cary Hospital	1			1	b	624	0.52	0	
	TOTAL				19			12		0
Watauga	Watauga Medical Center	1			1	b	606	0.50	0	
watauga	TOTAL				1			1		0
Wayne	Wayne UNC Health Care	1			1	b	1,431	1.19	0	
w ayne	TOTAL				1			2		1
Wilkes	Wilkes Regional Medical Center	1			1		0	0.00	0	
TT IIKCS	TOTAL				1			0		0
Wilson	Wilson Medical Center	1			1	b	129	0.11	0	
	TOTAL				1			1		0
NORTH CAROLINA	TOTALS	145	6	4	155		118,538	121		3

^a Adult diagnostic procedures plus adult interventional procedures x 1.75 plus pediatric procedures x 2
 ^b Adult diagnostic procedures plus adult procedures interventional x 1.75

^c Adult diagnostic procedures

^d Adult interventional procedures x 1.75

Table 15A-4: Fixed Cardiac Catheterization Equipment Need Determination*

Service Area	Fixed Cardiac Catheterization Equipment Need Determination	Certificate of Need Application Deadline**	Certificate of Need Beginning Review Date
Cabarrus	1	February 15, 2024	March 1, 2024
Caldwell	1	June 17, 2024	July 1, 2024
Wayne	1	October 15, 2024	November 1, 2024
It is determined that there is no	need anywhere else in th	ne state and no other rev	views are scheduled.

- * Any person can apply for a CON to meet the need, not just the health service facility or facilities that generated the need.
- ** Application deadlines are absolute, pursuant to 10A NCAC 14C.0202(2). The filing deadline is <u>5:00</u> <u>p.m.</u> on the application deadline date.