

Here are the technical edits to Chapter 9, which will become Chapter 17. Dr. Jordan, Dr. Ullrich, and the staff have reviewed them. The edits have been written as if for the 2019 SMFP. We are striving for accuracy, consistency within and across chapters in formatting and organization of the narratives (to the extent possible), clarity of language, elimination of redundancies, and elimination of manual updates to the narratives (to the extent appropriate). In general, we have eliminated summaries of equipment and procedures from the narratives. The rationale is that this information is readily available in tables. In the few places where data is not in tables, we have left it in the narrative. For this draft document paper, I have included only the first page of multi-page tables to save on space and paper.

We also rearranged the chapter sections alphabetically.

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CHAPTER 17

TECHNOLOGY AND EQUIPMENT

Introduction

This chapter covers six of the nine types of medical equipment subject to the Certificate of Need Law: cardiac catheterization equipment, Gamma Knives, linear accelerators, lithotripters, magnetic resonance imaging scanners, and positron emission tomography scanners.

The reporting year for all types of equipment is October 1 through September 30. The “current” reporting year is October 1, 2016 through September 30, 2017.

The “inventory” is the number of units of equipment in operation, as reported at the end of the reporting year. The “planning inventory” is the inventory and any adjustments for certificates of need and prior need determinations.

Changes from the Previous Plan

No substantive changes in basic principles and methodologies have been incorporated into [this chapter](#). However, the chapter has had extensive technical edits.

Data Sources

Inventory and utilization data comes from the Hospital License Renewal Application for equipment located on a hospital campus or owned by a hospital. Data for equipment in freestanding facilities comes from the Registration and Inventory of Medical Equipment form for each type of equipment.

A. CARDIAC CATHETERIZATION EQUIPMENT

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 17A-1 and 17A-2 show the number of cardiac catheterization procedures performed during the reporting year.

Assumptions of the Methodology

1. A unit of fixed or shared cardiac catheterization equipment's service area is the same as 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 diagnostic-equivalent procedures per year, with the trigger of need at 80 percent of capacity. One interventional cardiac catheterization procedure is valued at 1.75 diagnostic-equivalent procedures. One cardiac catheterization procedure performed on a patient age 14 or younger is valued at two diagnostic-equivalent 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.

Application of the Methodology

The two standard methodologies used to determine need for additional fixed cardiac catheterization equipment in service areas with at least one unit of equipment currently in the inventory are:

Methodology 1 (Table 17A-3):

- Step 1: Determine the planning inventory for each facility with fixed cardiac catheterization equipment, to include the total of: existing equipment in operation, approved equipment for which a certificate of need was issued but is under development, and need determinations for which no certificate of need has yet been issued (Columns C – F).
- Step 2: Determine the number of adult and pediatric diagnostic and interventional procedures performed at each facility during the current reporting year (Column G). If mobile procedures are provided in a county that is part of more than one service area, the procedures will be divided 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 1.0, interventional cardiac catheterization procedures by 1.75, and pediatric procedures performed on patients age 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 percent of capacity, which is 1,500 procedures). 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 the sum to the nearest whole number (*Column J*).

Step 6: Subtract the number of units of fixed cardiac catheterization equipment required in each service area from the total planning inventory for each service area. The difference is the number of units of fixed cardiac catheterization equipment needed (*Column K*).

Methodology 2:

For cardiac catheterization equipment service an area in which a unit of fixed cardiac catheterization equipment is not located, 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 (300 procedures x 80 percent) procedures per year for each eight hours per week the mobile equipment is operated at that site during the current reporting year (*Table 17A-2*); and
2. No other fixed or mobile cardiac catheterization service is provided in the same service area.

Table 17A-1: Cardiac Catheterization Procedures by Facility and Type, 2017

County	Hospital	Diagnostic				Interventional				Total
		Adult		Pediatric		Adult		Pediatric		
		Fixed	Mobile	Fixed	Mobile	Fixed	Mobile	Fixed	Mobile	
Alamance	Alamance Regional Medical Center	577				238				815
Buncombe	Mission Hospital	3,441				1,583				5,024
Cabarrus	Carolinas HealthCare System NorthEast	1,328								1,328
Carteret	Carteret General Hospital	500								500
Columbus	Columbus Regional Healthcare System					36	13			49
Davidson	Novant Health Thomasville Medical Center						146			146
Durham	Duke University Hospital	3,445		247		1,030				4,722
Forsyth	N.C. Baptist Hospital	2,674		43		1,191				3,908
Guilford	Cone Health	3,116								3,116
Jackson	Harris Regional Hospital						8			8
Mecklenburg	Carolinas Medical Center	3,740		253		1,139				5,132
Orange	UNC Hospitals	1,863		72		901				2,836
Pitt	Vidant Medical Center	3,158		17		1,115				4,290
Wake	Rex Hospital	3,692				2,615	17			6,324
Wake	WakeMed	3,237								3,237
Haywood	Haywood Rgional Hospital	160								160
Henderson	Margaret Pardee Memorial Hospital	245								245
Iredell	Iredell Memorial Hospital	662								662
Lenoir	UNC Lenoir Health	598								598
Moore	FirstHealth Moore Regional Hospital	3,086								3,086
New Hanover	New Hanover Regional Medical Center	2,863								2,863
Pasquotank	Sentra Albermarle	989								989
Robeson	Southeastern Regional Medical Center	718								718
Rowan	Novant Health Rowan Medical Center	362								362
Scotland	Rutherford Regional Medical Center	51								51
Wake	Duke Raleigh Hospital	527								527
Wilson	Wilson Medical Center	361								361
Total		41,393	-	632	-	9,848	184	-	-	52,057

Table 17A-2: Mobile Cardiac Catheterization Capacity and Volume*

County	Service Site	Days/Week On Site	Procedure Capacity	Procedures
				Reported in 2017
Columbus	Columbus Regional Healthcare System	1.00	300	13
Davidson	Novant Health Thomasville Medical Center	1.00	300	146
Jackson	Harris Regional Hospital	2.00	600	8
Wake	Rex Hospital	7.00	2100	17
Total		11.00	3300	184

Table 17A-3: Fixed Cardiac Catheterization Equipment, Capacity and Volume

A	B	C	D	E	F	G	H	I	J	K
Cardiac Catheterization Equipment Service Areas	Facility	Current Inventory	CON Issued/ Pending Development	Pending Review or Appeal	Total Planning Inventory	Footnote	2017 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed
Alamance	Alamance Regional Medical Center	1			1	b	974	0.81	0	
	TOTAL				1			1		0
Buncombe/ Graham/ Madison/Yancey	Mission Hospital	4			4	a	6,211	5.18	1	
	TOTAL				4			5		1
Burke	Carolinas HealthCare System Blue Ridge	1			1	c	602	0.50	0	
	TOTAL				1			1		0
Cabarrus	Carolinas HealthCare System NorthEast	2			2	b	2,702	2.25	0	
	TOTAL				2			2		0
Caldwell	Caldwell Memorial Hospital [DLP Healthcare]	0	1		1	c, d	675	0.56	0	
	TOTAL				1			1		0
Carteret	Carteret General Hospital	1			1		843	0.70	0	
	TOTAL				1			1		0
Catawba	Catawba Valley Medical Center	1			1	b	914	0.76	0	
	Frye Regional Medical Center	4			4	b	2,960	2.47	0	
	TOTAL				5			3		0
Cleveland	Carolinas HealthCare System Cleveland [DLP Healthcare]	1			1	c	150	0.13	0	
	TOTAL				1			0		0
Craven/Jones/ Pamlico	CarolinaEast Medical Center	2	1		3	b	1,703	1.42	0	
	TOTAL				3			1		0
Cumberland	Cape Fear Valley Medical Center	3	1		4	b	4,552	3.79	0	
	TOTAL				4			4		0
Durham/ Caswell	Duke Regional Hospital	2			2	b	1,448	1.21	0	
	Duke University Hospital	7			7	a	5,824	4.85	0	
	TOTAL				9			6		0
Forsyth	North Carolina Baptist Hospital	5			5	a	4,862	4.05	0	
	Novant Health Forsyth Medical Center	8			8	b	3,881	3.23	0	
	TOTAL				13			7		0
Gaston	CaroMont Regional Medical Center	3			3	b	2,795	2.33	0	
	TOTAL				3			2		0
Guilford	Cone Health	7			7	b	5,433	4.53	0	

	High Point Regional Health	4		4	b	2,519	2.10	0	
	The Cardiovascular Diagnostic Center (closed)	1		1		0	0.00	0	
	TOTAL			12			7		0
Halifax/ Northampton	Halifax Regional Medical Center	1		1	c	352	0.29	0	
	TOTAL			1			0		0
Harnett	Central Harnett Hospital	1		1		0	0.00	0	
	TOTAL			1			0		0
Haywood	Haywood Regional Hospital	1		1	c	164	0.14	0	
	TOTAL			1			0		0
Henderson	Margaret R. Pardee Memorial Hospital [DLP Healthcare]	1		1	c	324	0.27	0	
	TOTAL			1			0		0
Iredell	Davis Regional Medical Center	1		1	c	16	0.01	0	
	Iredell Memorial Hospital	1		1	c	1,017	0.85	0	
	Lake Norman Regional Medical Center	1		1	c	69	0.06	0	
	TOTAL			3			1		0
Johnston	Johnston Health	1		1	c	1,112	0.93	0	
	TOTAL			1			1		0
Lee	Central Carolina Hospital	1		1		178	0.15	0	
	TOTAL			1			0		0
Lenoir	UNC Lenoir Health Care	1		1	c	714	0.59	0	
	TOTAL			1			1		0
Mecklenburg	Carolinas HealthCare System Pineville	3		3	b	2,976	2.48	0	
	Carolinas HealthCare System University	1		1	c	49	0.04	0	
	Carolinas Medical Center	8		8	a	6,429	5.36	0	
	Novant Health Matthews Medical Center	1		1	c	924	0.77	0	
	Novant Health Presbyterian Medical Center	3		3	b	2,769	2.31	0	
	TOTAL			16			11		0
Moore	FirstHealth Moore Regional Hospital	5		5	b	5,569	4.64	0	
	TOTAL			5			5		0
Nash	Nash General Hospital	2		2	c	1,456	1.21	0	
	TOTAL			2			1		0
New Hanover	New Hanover Regional Medical Center	5		5	b	6,136	5.11	0	
	TOTAL			5			5		0
Onslow	Onslow Memorial Hospital	1		1	c	0	0.00	0	
	TOTAL			1			0		0
Orange	UNC Hospitals	4		4	a	3,716	3.10	0	
	TOTAL			4			3		0
Pasquotank/	Sentara Albemarle Medical Center	1		1	c	989	0.82	0	

Camden/ Currituck/ Perquimans	TOTAL				1			1		0
Pitt/Greene/ Hyde/Tyrell	Vidant Medical Center	7			7	a	5,449	4.54	0	
	TOTAL				7			5		0
Randolph	Randolph Hospital	1			1	c	0	0.00	0	
	TOTAL				1			0		0
Robeson	Southeastern Regional Medical Center	2			2	b	1,231	1.03	0	
	TOTAL				2			1		0
Rowan	Novant Health Rowan Medical Center	1			1	c	777	0.65	0	
	TOTAL				1			1		0
Rutherford	Rutherford Regional Medical Center	1			1	c	51	0.04	0	
	TOTAL				1			0		0
Scotland	Scotland Memorial Hospital	1			1		466	0.39	0	
	TOTAL				1			0		0
Stanly	Carolinas HealthCare System Stanly	1			1		0	0.00	0	
	TOTAL				1			0		0
Union	Carolinas HealthCare System Union	1			1	c	630	0.53	0	
	TOTAL				1			1		0
Vance	Maria Parham Health	1			1	c	36	0.03	0	
	TOTAL				1			0		0
Wake	Duke Raleigh Hospital [DLP Healthcare]	3			3	c	730	0.61	0	
	Rex Hospital	5			5	b	8,268	6.89	2	
	WakeMed	9			9	b	6,182	5.15	0	
	WakeMed Cary Hospital	1			1	c	262	0.22	0	
	TOTAL				15			12		0
Watauga	Watauga Medical Center	1			1	c	606	0.50	0	
	TOTAL				1			1		0
Wayne	Wayne Memorial Hospital	1			1	c	805	0.67	0	
	TOTAL				1			1		0
Wilkes	Wilkes Regional Medical Center	1			1		0	0.00	0	
	TOTAL				1			0		0
Wilson	Wilson Medical Center	1			1	c	500	0.42	0	
	TOTAL				1			0		0
NORTH CAROLINA TOTALS		139	3	0	142		109,997	89		1

^a Adult procedures plus angioplasty x 1.75 plus pediatric procedures x 2

^b Adult procedures plus angioplasty x 1.75

^c Adult procedures

^d Procedures performed on mobile machine

Table 17A-4: Fixed Cardiac Catheterization Equipment Need Determination

Cardiac Catheterization Service Area	Fixed Cardiac Catheterization Equipment Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Buncombe/Graham/Madison/Yancey	1	June 17, 2019	July 1, 2019
It is determined that there is no need anywhere else in the state and no other reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. (see Chapter 3).

Table 17A-5: Shared Fixed Cardiac Catheterization Equipment Need Determination

Cardiac Catheterization Service Area	Shared Fixed Cardiac Catheterization Equipment Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
It is determined that there is no need anywhere in the state and no reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. (see Chapter 3).

Table 17A-6: Mobile Cardiac Catheterization Equipment Need Determination

Cardiac Catheterization Service Area	Mobile Cardiac Catheterization Equipment Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
It is determined that there is no anywhere in the state and no reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. (see Chapter 3).

B. GAMMA KNIVES

Introduction

"Gamma knife," as defined in G.S.131E-176(7c), means "equipment which emits photon beams from a stationary radioactive cobalt source to treat lesions deep within the brain and is one type of stereotactic radiosurgery." Two types of equipment, both using photon beams, perform this kind of radiosurgery. In one type, beams from a linear accelerator are focused from a device that rotates around the patient. The other type of equipment, gamma knife, emits 201 beams from stationary radioactive cobalt sources.

North Carolina has two gamma knife planning regions (service areas), the western region (HSAs I, II, and III) and the eastern region (HSAs IV, V, and VI). The gamma knife at North Carolina Baptist Hospital in Forsyth County (HSA II) serves the western region. This facility performed 457 procedures during the reporting year. The gamma knife at Vidant Medical Center in Pitt County (HSA VI) serves the eastern region. This facility performed 164 procedures during the reporting year.

Table 17B-1: Gamma Knife Need Determination

Gamma Knife Planning Region	HSA	Gamma Knife Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
It is determined that there is no need anywhere in the state and no reviews are scheduled.				

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. (see Chapter 3).

C. LINEAR ACCELERATORS

Introduction

G.S. 131E-176 (14g) defines a linear accelerator as “a machine used to produce ionizing radiation in excess of 1,000,000 electron volts in the form of a beam of electrons or photons to treat cancer patients.”

Table 17C-1 lists the facilities that have linear accelerators. Table 17C-2 lists the facilities that also provide stereotactic radiosurgery treatment using appropriately equipped linear accelerators.

Assumptions of the Methodology

1. The methodology incorporates: (a) a geographic accessibility criterion, which is a population base of 120,000 as suggested by the Inter-Society Council for Radiation Oncology ; (b) a criterion aimed at assuring efficient use of megavoltage radiation facilities (when Equivalent Simple Treatment Visit (ESTV) procedures divided by 6,750 minus the number of present linear accelerators equals .25+); and (c) a patient origin criterion that indicates when a service area has 45 percent or more of the patients coming from outside the service area. A need determination is generated when two of the three criteria are met within a service area.
2. The American College of Radiology recommends use of ESTVs because radiation treatments vary in complexity. In addition, ESTVs were recommended as part of the comments received during public hearings when the original methodology was developed. Providers report procedures by Current Procedural Terminology (CPT) code, which are converted to ESTVs (Table 17C-3).
3. Patient origin data from the current reporting year forms the basis for defining service areas (Table 17C-4). Counties are the basic units for the formation of linear accelerator service areas, based on proximity, utilization patterns, and patient origin data. A small percentage of the population lives some distance from a linear accelerator, but the sparsity of population in and around these areas does not provide the population required to support a linear accelerator. In these cases, two exceptions apply:
 - a. Where patient origin data indicates a county's residents primarily use a linear accelerator that is not the closest, the county is aligned with the county where at least 45 percent of its residents go for linear accelerator services.
 - b. When a county with a linear accelerator has a population less than 120,000, that county is combined with an adjacent county to which the largest percentage of patients go for linear accelerator services, based on patient origin data.
4. Three principal questions must be addressed when determining whether a service area needs an additional linear accelerator :
 - a. Do the linear accelerators in the service area perform more than 6,750 procedures (ESTVs) per accelerator per year?
 - b. Is the population of the service area greater than 120,000 per accelerator)?
 - c. Does the patient origin data show that more than 45 percent of the patients come from outside the service area?

Application of the Methodology

The standard methodology for determining need for linear accelerators is calculated as follows:

Criterion 1:

- Step 1: Using the 2018 North Carolina population estimate obtained from the North Carolina Office of State Budget and Management, sum the population estimates for counties that comprise each linear accelerator service area to determine the population for linear accelerator service areas (*Table 17C-4*).
- Step 2: For each linear accelerator service area, sum the number of operational linear accelerators acquired in accordance with G.S. 131E-175, et. seq., the number of approved linear accelerators not yet operational but for which a certificate of need has been awarded, and the linear accelerator need determinations from previous years (*Table 17C-1*).
- Step 3: Divide the service area population by the result of Step 2 to determine the population residing in the service area per linear accelerator. If the result is greater than or equal to 120,000 per linear accelerator, Criterion 1 is satisfied.

Criterion 2:

- Step 4: For each service area, use current patient origin data to count the number of patients who were served on linear accelerators located in the service area, and who reside in a county outside the service area.
- Step 5: For each service area, divide the results of Step 4 by the total number of patients served on linear accelerators located in the service area. If more than 45 percent of total patients served on linear accelerators located in a service area reside outside the service area, then Criterion 2 is satisfied (*Table 17C-5*).

Criterion 3:

- Step 6: For each linear accelerator service area, sum the number of reported ESTV procedures performed on the linear accelerators located in the service area.
- Step 7: Divide the results of Step 6 by the number of linear accelerators in the service area which are counted in Step 2 to determine the average number of ESTV procedures performed per linear accelerator in each linear accelerator service area.
- Step 8: Divide the results of Step 7 by 6,750 ESTV procedures.
- Step 9: Subtract the number of linear accelerators in the service area counted in Step 2 from the results of Step 8. If the difference is greater than or equal to positive 0.25, Criterion 3 is satisfied.
- Step 10: If any two of the above three criteria are satisfied in a linear accelerator service area, the service area has a need determination for one additional linear accelerator (*Table 17C-5*).

Criterion 4:

- Step 11: Regardless of the results of Steps 1-10 above, if a county has a population of 120,000 or more and there is not a linear accelerator counted in Step 2 for that county, a need is determined for one linear accelerator in that county. As a result, the county becomes a separate, new linear accelerator service area.

Table 17C-1: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2016-9/30/2017	Average Number of Procedures per Unit
Harris Regional Hospital	1	Jackson	1	1,496	1,496
NC Radiation Therapy - Franklin	1	Macon	1	1,472	1,472
21st Century Oncology	2	Buncombe	1	1,957	1,957
Mission Hospital - Main	2	Buncombe	3	19,176	6,392
NC Radiation Therapy - Asheville	2	Buncombe	2	5,311	2,655
NC Radiation Therapy - Clyde	2	Haywood	1	4,304	4,304
NC Radiation Therapy - Marion	2	McDowell	1	3,640	3,640
Watauga Medical Center	3	Watauga	1	2,951	2,951
Margaret R. Pardee Memorial Hospital	4	Henderson	1	5,706	5,706
NC Radiation Therapy - Hendersonville	4	Henderson	1	2,729	2,729
NC Radiation Therapy - Brevard	4	Transylvania	1	3,117	3,117
Carolinas HealthCare System Blue Ridge	5	Burke	2	5,796	2,898
Caldwell Memorial Hospital	5	Caldwell	1	1,932	1,932
Catawba Valley Medical Center	5	Catawba	2	12,049	6,024
Frye Regional Medical Center	5	Catawba	1	3,556	3,556
Carolinas HealthCare System Cleveland	6	Cleveland	1	5,628	5,628
CaroMont Regional Medical Center (CIS Belmont)*	6	Gaston	3	13,712	4,571
NC Radiation Therapy - Forest City	6	Rutherford	1	3,783	3,783
Carolinas HealthCare System University**	7	Mecklenburg	1	7,420	7,420
Carolinas Medical Center	7	Mecklenburg	3	18,946	6,315
Mathews Radiation Oncology Center	7	Mecklenburg	1	10,015	10,015
Novant Health Huntersville Medical Center	7	Mecklenburg	1	599	599
Novant Health Presbyterian Medical Center	7	Mecklenburg	2	9,746	4,873
Pineville Radiation Therapy Center	7	Mecklenburg	1	10,070	10,070
Carolinas HealthCare System Union	7	Union	1	8,072	8,072
Iredell Memorial Hospital	8	Iredell	2	5,927	2,963
Lake Norman Radiation Oncology Center	8	Iredell	1	6,841	6,841
Novant Health Rowan Medical Center	8	Rowan	1	5,693	5,693
Carolinas Healthcare System Northeast	9	Cabarrus	2	13,554	6,777
Carolinas HealthCare System Stanly	9	Stanly	1	3,802	3,802
North Carolina Baptist Hospital	10	Forsyth	4	26,608	6,652
Novant Health Forsyth Medical Center	10	Forsyth	5	23,060	4,612
Hugh Chatham Memorial Hospital	10	Surry	1	3,476	3,476
Lexington Medical Center	11	Davidson	1	3,415	3,415
Cone Health	12	Guilford	4	27,175	6,794
High Point Regional Health	12	Guilford	2	12,658	6,329
UNC Rockingham Health Care	12	Rockingham	1	4,614	4,614
Randolph Hospital	13	Randolph	1	3,911	3,911
University of North Carolina Hospitals	14	Orange	6	39,384	6,564

Table 17C-2: Stereotactic Radiosurgery Procedures

County	Facility	Number of Procedures
Alamance	Alamance Regional Medical Center	91
Buncombe	Mission Health	540
Buncombe	North Carolina Radiation Therapy Management Services-Asheville	80
Cabarrus	Carolinas HealthCare System NorthEast	374
Carteret	Carteret General Hospital	107
Catawba	Catawba Valley Medical Center	235
Catawba	Frye Regional Medical Center	69
Craven	CarolinaEast Health System	96
Durham	Duke Regional Hospital	47
Durham	Duke University Hospital	1,797
Forsyth	North Carolina Baptist Hospital	531
Forsyth	Novant Health Forsyth Medical Center	180
Gaston	CaroMont Regional Medical Center	226
Guilford	Cone Health	555
Guilford	High Point Regional Health	123
Henderson	Margaret R. Pardee Memorial Hospital	5
Henderson	North Carolina Radiation Therapy Management Services-Hendersonville	5
Iredell	Iredell Memorial Hospital	30
Lenoir	UNC Lenoir Health Care	57
McDowell	North Carolina Radiation Therapy Management Services-Marion	17
Mecklenburg	Carolinas HealthCare System University	69
Mecklenburg	Carolinas Medical Center	657
Mecklenburg	Novant Health Huntersville Medical Center	46
Mecklenburg	Novant Health Presbyterian Medical Center	306
Moore	FirstHealth Moore Regional Hospital	250
New Hanover	New Hanover Regional Medical Center	713
Orange	University of North Carolina Hospitals	749
Pitt	North Carolina Radiation Therapy Management Services-Greenville	685
Robeson	Southeastern Regional Medical Center	31
Rutherford	North Carolina Radiation Therapy Management Services-Forest City	45
Transylvania	North Carolina Radiation Therapy Management Services-Brevard	20
Union	Carolinas HealthCare System Union	57
Wake	Duke Raleigh Hospital	83
Wake	Rex Hospital	262
Wayne	North Carolina Radiation Therapy Management Services-Goldsboro	15
Total		9,153

Table 17C-3: Linear Accelerator Treatment Data - Hospital and Free-Standing

CPT Code	Description	ESTVs/ Procedures Under ACR
<i>Simple Treatment Delivery</i>		
77401	Radiation treatment delivery	1.00
77402	Radiation treatment delivery (<=5 MeV)	1.00
77403	Radiation treatment delivery (6-10 MeV)	1.00
77404	Radiation treatment delivery (11-19 MeV)	1.00
77406	Radiation treatment delivery (>=20 MeV)	1.00
<i>Intermediate Treatment Delivery</i>		
77407	Radiation treatment delivery (<=5 MeV)	1.00
77408	Radiation treatment delivery (6-10 MeV)	1.00
77409	Radiation treatment delivery (11-19 MeV)	1.00
77411	Radiation treatment delivery (>=20 MeV)	1.00
<i>Complex Treatment Delivery</i>		
77412	Radiation treatment delivery (<=5 MeV)	1.00
77413	Radiation treatment delivery (6-10 MeV)	1.00
77414	Radiation treatment delivery (11-19 MeV)	1.00
77416	Radiation treatment delivery (>= 20 MeV)	1.00
<i>Other CPT Codes</i>		
77417	Additional field check radiographs	.50
77418	Intensity modulated radiation treatment (IMRT) delivery	1.00
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multisource Cobalt 60 based (Gamma Knife)	3.00
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator	3.00
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions	3.00
G0339	(Image-guided) robotic linear accelerator-based stereotactic radiosurgery in one session or first fraction	3.00
G0340	(Image-guided) robotic linear accelerator-based stereotactic radiosurgery, fractionated treatment, 2nd-5th fraction	3.00
	Total body irradiation	2.50
	Hemibody irradiation	2.00
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linear accelerator)	10.00
	Neutron and proton radiation therapy	2.00
	Limb salvage irradiation	1.00
	Pediatric patient under anesthesia	1.50

Table 17C-4: Linear Accelerator Service Areas

Area	County	2018 Total Population
1	Cherokee	29,853
1	Clay	11,654
1	Graham	8,862
1	Jackson	43,662
1	Macon	35,779
1	Swain	15,142
	Total	144,952
2	Buncombe	264,666
2	Haywood	62,780
2	Madison	22,504
2	McDowell	45,915
2	Mitchell	15,216
2	Yancey	18,254
	Total	429,335
3	Ashe	27,262
3	Avery	18,087
3	Watauga	57,348
	Total	102,697
4	Henderson	117,902
4	Polk	21,273
4	Transylvania	34,814
	Total	173,989
5	Alexander	38,609
5	Burke	90,865
5	Caldwell	83,919
5	Catawba	157,424
	Total	370,817
6	Cleveland	98,862
6	Gaston	221,112
6	Lincoln	84,494
6	Rutherford	67,880
	Total	472,348
7	Anson	25,628
7	Mecklenburg	1,099,382
7	Union	232,425
	Total	1,357,435
8	Iredell	179,740
8	Rowan	142,862
	Total	322,602
9	Cabarrus	209,736
9	Stanly	63,069
	Total	272,805
10	Alleghany	11,264
10	Davie	43,244
10	Forsyth	376,314
10	Stokes	46,708
10	Surry	72,844
10	Wilkes	70,883
10	Yadkin	37,700
	Total	658,957

Table 9I: Linear Accelerator Service Areas

Area	County	2018 Total Population
11	Davidson	168,107
	Total	168,107
12	Guilford	527,696
12	Rockingham	91,731
	Total	619,427
13	Randolph	145,633
	Total	145,633
14	Chatham	76,383
14	Orange	143,873
	Total	220,256
15	Alamance	163,041
15	Caswell	23,692
	Total	186,733
16	Durham	310,847
16	Granville	60,566
16	Person	39,997
16	Vance	44,785
16	Warren	20,068
	Total	476,263
17	Hoke	54,679
17	Lee	59,486
17	Montgomery	27,957
17	Moore	99,112
17	Richmond	44,812
17	Scotland	35,598
	Total	321,644
18	Bladen	34,120
18	Cumberland	329,653
18	Robeson	131,384
18	Sampson	62,821
	Total	557,978
19	Brunswick	135,464
19	Columbus	56,904
19	New Hanover	230,919
19	Pender	62,551
	Total	485,838
20	Franklin	67,586
20	Wake	1,071,240
	Total	1,138,826
21	Harnett	133,065
	Total	133,065
22	Johnston	200,102
	Total	200,102
23	Duplin	59,446
23	Lenoir	57,366
23	Wayne	125,509
	Total	242,321

Table 9I: Linear Accelerator Service Areas

Area	County	2018 Total Population
24	Carteret	70,620
24	Craven	103,800
24	Jones	10,356
24	Pamlico	13,288
	Total	198,064
25	Onslow	197,455
	Total	197,455
26	Edgecombe	52,149
26	Halifax	51,468
26	Nash	94,420
26	Northampton	20,470
26	Wilson	82,408
	Total	300,915
27	Beaufort	47,444
27	Bertie	19,832
27	Greene	21,520
27	Hertford	23,855
27	Hyde	5,630
27	Martin	23,412
27	Pitt	176,920
27	Washington	12,272
	Total	330,885
28	Camden	10,416
28	Chowan	14,177
28	Currituck	27,109
28	Dare	37,172
28	Gates	12,008
28	Pasquotank	40,805
28	Perquimans	13,564
28	Tyrrell	4,137
	Total	159,388

Table 17C-5: Linear Accelerator Service Areas and Calculations

Service Area	2018 Population	Accelerators	Population within Service Area Per Accelerator	Percentage of Patients from Outside the Service Area	2016-2017 ESTV Procedures	Procedures Per Accelerator	ESTV Procedures Divided by 6,750 Minus # of Accelerators	Need Determinations
1	144,952	2	72,476	7.96%	2,968	1,484	-1.56	
2	429,335	8	53,667	20.03%	34,387	4,298	-2.91	
3	102,697	1	102,697	19.54%	2,951	2,951	-0.56	
4	173,989	3	57,996	9.11%	11,552	3,851	-1.29	
5	370,817	6	61,803	12.80%	23,332	3,889	-2.54	
6	472,348	5	94,470	7.24%	23,122	4,624	-1.57	
7*	1,357,435	10	135,744	22.85%	64,866	6,487	-0.39	
8	322,602	4	80,651	22.00%	18,460	4,615	-1.27	
9	272,805	3	90,935	21.65%	17,355	5,785	-0.43	
10*	658,957	10	65,896	26.74%	53,144	5,314	-2.13	
11	168,107	1	168,107	18.79%	3,415	3,415	-0.49	
12	619,427	7	88,490	22.07%	44,446	6,349	-0.42	
13*	145,633	1	145,633	17.57%	3,911	3,911	-0.42	
14**	220,256	6	36,709	77.81%	39,384	6,564	-0.17	
15	186,733	2	93,367	17.50%	7,080	3,540	-0.95	
16**	476,263	10	47,626	63.41%	47,949	4,795	-2.90	
17	321,644	3	107,215	22.76%	19,958	6,653	-0.04	
18	557,978	7	79,711	16.72%	31,030	4,433	-2.40	
19*	485,838	4	121,460	10.25%	24,892	6,223	-0.31	
20	1,138,826	11	103,530	12.04%	42,709	3,883	-4.67	
21*	133,065	1	133,065					
22**	200,102	2	100,051	46.53%	9,204	4,602	-0.64	
23*	242,321	2	121,161	9.64%	13,599	6,799	0.01	
24	198,064	3	66,021	13.11%	13,734	4,578	-0.97	
25*	197,455	1	197,455	10.26%	4,084	4,084	-0.39	
26	300,915	4	75,229	9.27%	11,977	2,994	-2.23	
27	330,885	7	47,269	33.01%	24,973	3,568	-3.30	
28	159,388	2	79,694	4.20%	8,974	4,487	-0.67	
Totals	10,388,837	126	82,451		603,450	4,789	-36.60	

* Service Area has at least 120,000 base population per accelerator.

** More than 45% of patients come from outside the service area.

Table 17C-6: Linear Accelerators Need Determination

Linear Accelerator Service Area	Linear Accelerator Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Service Area 18***	1	April 15, 2019	May 1, 2019
It is determined that there is no need anywhere in the state and no other reviews are scheduled.			

- * Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).
- ** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. (see Chapter 3).
- *** In response to a petition, the State Health Coordinating Council approved the adjusted need determination for one additional linear accelerator for Service Area 18, to be developed in Robeson County.

D. LITHOTRIPTERS

Introduction

A lithotripter, according to G.S. 131E-176(14i), means “extra-corporeal shockwave technology used to treat persons with kidney stones and gallstones.” Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. A technician places an emitter in contact with the patient's abdomen to focus the shock waves on the stone. The shock waves then shatter the stone, which can be expelled in the urine. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure to which this section pertains.

Data Sources

In addition to the standard data sources listed in the Introduction to this Chapter, this methodology also obtains the July 1 estimated population data from the North Carolina Office of State Budget and Management. The data is for the current SMFP publication year, which is two years beyond the current reporting year.

Assumptions of the Methodology

1. The incidence of urinary stone disease forms the basis of the methodology. The annual incidence of urinary stone disease is approximately 16 per 10,000 population. Lithotripsy is not an appropriate treatment for all cases of urinary stone disease . It has been estimated that lithotripsy is appropriate for 85 to 90 percent of kidney stone patients, when surgery is indicated¹. Therefore, the need determination methodology assumes that lithotripsy is appropriate in 90 percent of cases of urinary stone disease.
2. The annual treatment capacity of a lithotripter is 1,500 cases. The methodology considers 67% (or 1000 cases) to be full utilization for purposes of projecting need.
3. The lithotripter service area is the entire state.

Application of the Methodology

- Step 1: Divide the July 1 estimated state population by 10,000 and multiply the result by 16, which yields the estimated incidence of urinary stone disease per 10,000 population.
- Step 2: Multiply the result from Step 1 by 90 percent to get the number of patients in the state who have the potential to be treated by lithotripsy in one year.
- Step 3: Divide the result of Step 2 by 1,000 and round to the nearest whole number, to calculate the low range of the annual treatment capacity of a lithotripter. A remainder of 0.50 or greater rounds to the next highest whole number; a remainder of less than 0.50 rounds to the next lowest whole number.
- Step 4: Sum the number of existing lithotripters in the state (*Table 17D-1*), lithotripters not yet operational but for which a certificate of need has been issued , and lithotripter need determinations from previous years for which a certificate of need has yet to be issued .
- Step 5: Subtract the result of Step 4 from the result of Step 3 to calculate the number of additional lithotripters needed in the state (*Table 17D-2*).

¹ Pahiri, J.J. & Razack, A.A. (2001) “Chapter 9: Nephrolithiasis.” In *Clinical Manual of Urology*, 3rd edition, by Philip M. Hanno, Alan J. Wein, & S. Bruce Malkowicz. New York: McGraw-Hill.

Table 17D-1: Mobile and Fixed Lithotripsy Providers and Locations Served

MOBILE LITHOTRIPSY

Provider	Machines	Area Generally Served	Facility	Location	State	Number of Procedures		
Carolina Lithotripsy	2	Eastern NC	CarolinaEast Medical Center	New Bern	NC	82		
			Carteret General Hospital	Morehead City	NC	24		
			Columbus Regional Healthcare	Whiteville	NC	13		
			<i>OTHER LOCATIONS</i>					
Total Procedures						119		
Average Procedures per Lithotripter						59		
Catawba Valley Medical Center	2	Western and Central NC	Catawba Valley Medical Center	Hickory	NC	289		
			Frye Regional Medical Center	Hickory	NC	42		
			Rutherfordton Regional Medical Center	Rutherfordton	NC	47		
			<i>OTHER LOCATIONS</i>					
Total						378		
Average Procedures per Lithotripter						189		
Fayetteville Lithotripters - SC II	1	Western NC and SC	Gharles George VA Medical Center	Asheville	NC	27		
			The McDowell Hospital	Marion	NC	30		
			Oconee Medical Center	Secceca	SC	4		
			<i>OTHER LOCATIONS</i>					
Total						61		
Average Procedures per Lithotripter						61		
Fayetteville Lithotripters - VA I	1	Eastern NC and VA	Sentra Albermarle Hospital	Elizabeth City	NC	18		
			Vidant Chowan Hospital	Edenton	NC	36		
			<i>OTHER LOCATIONS</i>				VA	189
			Total					
Average Procedures per Lithotripter						243		

FIXED LITHOTRIPSY

Mission Hospital	1		Mission Hospital	Asheville	NC	232
TOTAL ALL PROVIDERS						xxx

Table 17D-2: Mobile and Fixed
Lithotripsy

Total Procedures Reported	(Total Procedures/Units Reported) Units Reported	Average Procedures Per Unit
9,253	15	617

Table 17D-3: Lithotripter Need Determination

Service Area	Lithotripter Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
It is determined that there is no need anywhere in the state and no reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. (see Chapter 3).

E. MAGNETIC RESONANCE IMAGING SCANNERS

Introduction

G.S. 131E-176 (14m) defines a magnetic resonance imaging (MRI) scanner as “medical imaging equipment that uses nuclear magnetic resonance.” The methodology designates MRI scanners as either fixed or mobile. A mobile MRI scanner means the MRI scanner and transporting equipment that is moved at least weekly to provide services at two or more host facilities. A fixed MRI scanner means an MRI scanner that is not a mobile MRI scanner.

Assumptions of the Methodology

1. An MRI procedure is a single MRI procedure performed on one patient on one defined body part during one visit. Each MRI procedure must be directly linked to a single billable CPT code associated with the MRI procedure. For example, an MRI brain scan with and without contrast is a single procedure with a single CPT code.
2. A fixed MRI service area is the same as an Acute Care Bed Service Area as defined in Chapter 5, and shown in Figure 5.1.
3. A placeholder of one MRI scanner appears in the inventory in Table 17E-1 for each new fixed MRI scanner for which a certificate of need has been issued even if the scanner is not yet operational.
4. The inventory shall exclude: MRI scanners used for research only, non-clinical MRI scanners, and MRI scanners awarded based on need determinations for a dedicated purpose or demonstration project (Table 17E-2).
5. Intraoperative Magnetic Resonance Imaging Scanners (iMRI), approved through Policy TE-2, shall not be counted in the inventory of fixed MRI scanners and the procedures performed on an iMRI will not be used in calculating the need methodology. Hospitals shall report intraoperative procedures and inpatient procedures performed on an iMRI separately (Table 17E-2). An iMRI scanner shall not be used for outpatients and may not be replaced with a conventional MRI scanner.
6. Need thresholds are arranged in tiers based on the number of scanners, weighting of procedures based on complexity, and a component addressing MRI service areas that have no fixed MRIs, but have mobile MRI scanners serving the area. The complexity of an MRI procedure is weighted based on whether the procedure is inpatient or outpatient and whether the procedure includes contrast or sedation. The methodology for determining need is based on fixed and mobile procedures performed at hospitals, fixed procedures performed at freestanding facilities, and procedures performed on mobile MRI scanners at mobile sites.

The tiers are based on the assumption that the time necessary to complete one MRI procedure (an outpatient procedure without contrast or sedation) is 30 minutes, or an average throughput of two procedures per hour on an MRI scanner. Capacity of a single MRI scanner is defined as that of an MRI scanner being available and staffed for use at least 66 hours per week for 52 weeks per year, which equals 6,864 procedures annually, at 30 minutes per procedure ($66 \times 52 \times 2 = 6,864$). This definition of capacity represents 100 percent of the procedure volume the equipment is capable of completing under ideal conditions.

7. The need determination for any one service area shall not exceed one MRI scanner per year, unless the SMFP includes an adjusted need determination for a specific MRI service area.

8. A facility that offers MRI services on a full-time basis pursuant to a service agreement with an MRI provider is not precluded from applying for a need determination to replace the existing contracted service with a fixed MRI scanner under the applicant’s ownership and control. It is consistent with the purposes of the Certificate of Need law and the State Medical Facilities Plan for a facility to acquire and operate an MRI scanner to replace such a contracted service, if the acquisition and operation of the facility’s own MRI scanner will allow the facility to reduce the cost of providing the MRI service at that facility.

Application of the Methodology

Use the following table to obtain the appropriate planning threshold, based on the number of fixed scanners in the service area. Multiply 6,864 by the Planning Threshold to obtain the Inpatient and Contrast Adjusted Threshold corresponding to the number of fixed scanners in the service area (e.g., for facilities with 4 or more MRIs, multiply 6,864 by 70% to obtain the Inpatient and Contrast Adjusted Threshold of 4,805).

Number of Fixed Scanners in Service Area	Planning Threshold	Inpatient and Contrast Adjusted Thresholds
4 and over	70.0%	4,805
3	65.0%	4,462
2	60.0%	4,118
1	55.0%	3,775
0	25.0%	1,716

The following below shows the weighting values to be assigned based on the complexity of the procedure type. Weights of 0.4 add 12 minutes to the standard 30-minute procedure time.

Procedure Type	Base Weight	Inpatient Weight	Contrast Weight	Procedure Time in Minutes
Outpatient/No Contrast/Sedation	1.0	0.0	0.0	30
Outpatient/With Contrast/Sedation	1.0	0.0	.4	42
Inpatient/No Contrast/Sedation	1.0	.4	0.0	42
Inpatient/With Contrast/Sedation	1.0	.4	.4	54

The standard methodology used to determine need for fixed MRI scanners is as follows, with results presented in Table 17E-1:

- Step 1: List the number of clinical fixed and mobile MRI scanners in each MRI service area by site to include: existing fixed or mobile MRI scanners in operation, approved fixed or mobile MRI scanners for which a certificate of need was issued but is pending development, and prior need determinations for which no certificate of need has yet been issued. The “total” is the number of fixed magnets in each service area (Column E).
- Step 2: Convert the number of fixed and mobile MRI scanners to fixed equivalent magnets as follows (Column F):
 - a. For each existing fixed MRI scanner, assign a value of one fixed equivalent magnet;
 - b. For each approved fixed MRI scanner, assign a value of one fixed equivalent magnet, even though the site may be receiving mobile services temporarily until the fixed

scanner is operational. [Table 17E-1](#) does not list mobile services separately from the approved fixed MRI scanner if the mobile unit will no longer be used when the fixed MRI scanner is operational.

- c. For each existing mobile MRI scanner site, calculate the fixed equivalent for each mobile site by dividing the number of MRI scans performed at each site by the threshold for the MRI service area, with the exception that the fixed equivalent shall be no greater than one; and

- Step 3: Sum the number of fixed equivalent magnets for each MRI service area ([Column F](#)).
- Step 4: Determine the total number of MRI [procedures](#) performed at each site regardless of whether the MRI scanner is fixed or mobile. If procedures are provided in a county that is part of more than one MRI service area, [divide](#) the procedures equally between the service areas ([Column G](#)).
- Step 5: Of the total number of [procedures](#) performed, determine the number performed by type (i.e., inpatient, outpatient, with contrast or sedation, [without](#) contrast or sedation) ([Columns H-K](#)).
- Step 6: For each site, multiply the number of inpatient [procedures](#) by 0.40 to calculate the inpatient adjustment.
- Step 7: For each site, multiply the number of contrast or sedation [procedures](#) by 0.40 to calculate the contrast adjustment.
- Step 8: For each site, sum the total number of [procedures](#) performed (Step 4), the inpatient adjustment (Step 6), and the contrast adjustment (Step 7) to calculate the total number of adjusted MRI procedures for each site ([Column L](#)).
- Step 9: For each service area, sum the number of adjusted total procedures for all sites in the service area ([Column L](#)).
- Step 10: Calculate the average number of adjusted total procedures per MRI scanner in the service area by dividing the adjusted total procedures for the service area (Step 9) by the sum of fixed equivalent magnets in the service area (Step 3) ([Column M](#)).
- Step 11: [Apply the MRI Tiered Planning Threshold \(see Assumptions of the Methodology\)](#) for the service area based on the number of existing, approved and pending fixed MRI scanners located in the service area as identified in Step 1 ([Column N](#)).
- Step 12: [In each service area, compare the average procedures per fixed equivalent magnet \(Step 10\) with the threshold for the service area \(Step 11\). If the average procedure per magnet is greater than or equal to the service area threshold, the service area has a need determination for one additional MRI scanner \(Column O\).](#)

Table 17E-1: MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Service Area	Service Type	CON #	Service Site (Provider/Owner)	Fixed Magnet	Fixed Equiv	Total MRI Scans	Outpt No Contrast	Outpt Contrast	Inpt No Contrast	Inpt Contrast	Adjusted Total	Area Avg Procs	Threshold	MRI Need
Alamance	Hospital Fixed	G-006214-00	Alamance Regional Medical Center	2	2.00	5,496	3,184	1,269	760	283	6,534			
Alamance	Mobile		Alamance Regional Outpatient Imaging Center	0	0.19	774	541	233	0	0	867			
Alamance	Mobile		MedCenter - Mebane	0	0.20	805	595	210	0	0	889			
Alamance	Mobile	G-007038-04	UNC Hospitals-Burlington (Alliance Healthcare Services)	0	0.06	249	192	57	0	0	272			
Alamance	Mobile	Grandfathered	University of North Carolina (Alliance Healthcare Services)	0	0.01	36	28	8	0	0	39			
Alamance	Mobile	Grandfathered	University of North Carolina (Alliance Healthcare Services)	0	0.08	349	252	97	0	0	388			
Alamance				2	2.54	7,709					8,989	3,539	4,118	0
			No Service Site											
Alexander													1,716	0
Alleghany	Mobile	Grandfathered	Alleghany Memorial Hospital (Alliance Healthcare Services)	0	0.06	110	94	16	0	0	116			
Alleghany				0	0.06	110					116	116	1,716	0
Anson	Mobile	F-006868-03	Carolinas HealthCare System Anson (Carolinas Imaging Services, LLC)	0	0.02	37	32	4	1	0	39			
Anson				0	0.02	37					39	39	1,716	0
Ashe	Hospital Fixed	D-008162-08	Ashe Memorial Hospital, Inc.	1	1.00	904	535	181	171	17	1,058			
Ashe				1	1.00	904					1,058	1,058	3,775	0
Avery	Mobile	Grandfathered	Charles A Cannon Memorial Hospital (Alliance Healthcare Services)	0	0.19	327	238	78	11	0	363			
Avery				0	0.19	327					363	363	1,716	0
Beaufort	Hospital Fixed	Q-005992-99	Vidant Beaufort Hospital	1	1.00	2,104	1,265	527	153	159	2,503			
Beaufort				1	1.00	2,104					2,503	2,503	3,775	0
			No Service Site											
Bertie													1,716	0
Bladen	Mobile	M-006605-02	Bladen Healthcare, LLC (Mobile Imaging of North Carolina, LLC)	0	0.24	420	293	127	0	0	471			
Bladen				0	0.24	420					471	471	1,716	0
Brunswick	Hospital Fixed	Grandfathered (Alliance)	J. Arthur Doshier Memorial Hospital	1	1.00	1,218	858	332	11	17	1,369			
Brunswick	Hospital Fixed	O-006658-02	Novant Health Brunswick Medical Center	1	1.00	3,774	2,522	795	342	115	4,321			
Brunswick	Freestanding Fixed	O-011125-16	J. Arthur Doshier Memorial Hospital	1	1.00	0	0	0	0	0	0			
Brunswick	Mobile	F-007001-04	NHRMC Health & Diagnostics - Brunswick Forest (Alliance Healthcare Services)	0	0.21	934	482	452	0	0	1,115			
Brunswick	Mobile	O-006434-01	Novant Health Imaging South (Cape Fear Diagnostic Imaging, Inc.)	0	0.07	313	313	0	0	0	313			
Brunswick				3	3.28	6,239					7,117	2,170	4,462	0
Buncombe	Hospital Fixed		Mission Hospital - Carolina Spine & Neurosurgery	1	1.00	2,213	1,388	825	0	0	2,543			

Table 17E-2: Existing and Approved Specialized MRI Scanners, Excluded from Inventory

Scanner Use	County	Provider	CON Project ID	Number of Scanners
Cardiovascular Clinical Use (Policy AC-3)	Durham	Duke University Hospital	J-006511-01	3
Dedicated Breast Scanning	Mecklenburg	Charlotte Radiology Breast Center	F-006725-02	1
Dedicated Breast Scanning	Forsyth	Breast Clinic MRI	G-007601-06	1
Dedicated Pediatric Use	Mecklenburg	Carolinas Medical Center (Levine Children's Hospital)	F-007219-05	1
Extremity Scanner	Wake	Bone & Joint Surgery Clinic	J-007605-06	1
Radiation Oncology	Durham	Duke University Hospital	J-006295-00	1
Radiation Oncology	Forsyth	North Carolina Baptist Hospital	G-006816-03	1
Use in Operating Room Suite	Durham	Duke University Hospital	J-008030-07	1
Intraoperative MRI (iMRI) - <i>Approved</i>	Mecklenburg	Carolinas Medical Center	F-011210-16	1

Note: These scanners shall be used only for the purposes indicated above. They shall not be used for general clinical purposes.

Table 17E-3: Fixed MRI Scanner Need Determination

Services Areas	Fixed MRI Scanners Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Durham	1	April 15, 2019	May 1, 2019
Forsyth	1	October 15, 2019	November 1, 2019
Mecklenburg	1	August 15, 2019	September 1, 2019
Wake	1	November 15, 2019	December 1, 2019
It is determined that there is no need anywhere else in the state and no other reviews are scheduled. ***/****			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. (see Chapter 3).

*** The need determination in the Davie County service area for one fixed MRI scanner was removed in response to a petition approved by the State Health Coordinating Council.

****The need determination in the Pasquotank/Camden/Currituck/Perquimans County service area for one fixed MRI scanner was removed in response to a petition approved by the State Health Coordinating Council.

F. POSITRON EMISSION TOMOGRAPHY SCANNERS

Introduction

A positron emission tomography (PET) scanner, as defined in G.S. 131E-176(19a), means “equipment that utilizes a computerized radiographic technique that employs radioactive substances to examine the metabolic activity of various body structures.”

The first PET scanners were dedicated machines performing only that service, supported by cyclotrons on-site. However, PET scanners also include hybrid machines, performing a variety of nuclear medicine studies and supported by new tracer production facilities housing cyclotrons in stand-alone facilities. Many PET scanners are configured with a single gantry to accommodate computed tomography (CT) to acquire sequential PET and CT images during the same exam. All of these machines are PET scanners as defined in G.S. 131E-176 (19a), but they vary widely in their capabilities.

Dedicated PET scanners can be fixed or mobile. “Mobile PET scanner” means a dedicated PET scanner and its transporting equipment that is moved to provide services at two or more host facilities.

Assumptions of the Methodology

1. The methodology concerns dedicated PET scanners only. Dedicated scanners do not perform other nuclear medicine procedures.
2. A dedicated fixed PET scanner's service area is the Health Service Area (HSA) in which the scanner is located (Table 17F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.
3. A dedicated mobile PET scanner has a statewide service area (Table 17F-2).
4. There is a need for one additional fixed dedicated PET scanner when each existing fixed dedicated PET scanner was utilized at or above 80 percent of capacity during the current reporting year. For the purposes of need determination calculations, the annual capacity of a fixed dedicated PET scanner is 3,000 procedures; 80 percent capacity is 2,400 procedures.

Application of the Methodology

Part 1 (Table 17F-1):

Determine the planning inventory of all fixed PET scanners in the state, to include existing fixed PET scanners in operation, approved fixed PET scanners for which a certificate of need was issued but is pending development, and need determinations in prior SMFPs for which a certificate of need has not yet been issued (Column C).

- Step 1: For each facility that operates a PET scanner, determine the total number of procedures performed on all fixed PET scanners located at the facility for the current reporting year (Column D).
- Step 2: Multiply the number of fixed PET scanners at each facility by 3,000 procedures to determine the PET scanner capacity at each facility (Column E).
- Step 3: Divide the total number of PET scanner procedures performed at each facility, as determined in Step 2, by the capacity calculated in Step 3. Multiply the results by 100 to convert the numbers to a utilization percentage (Column F).

Step 4: A [service area has a need determination](#) for an additional fixed PET scanner if the utilization percentage is 80 percent or greater at a facility, except as provided in Step 8 for both parts of the methodology combined.

Part 2:

Step 5: Identify each major cancer treatment facility, program or provider in the state, [defined as providers that operate two linear accelerators and performed over 12,500 ESTV procedures during the current reporting year \(Table 17C-5\)](#).

Step 6: A [service area has a need determination](#) for one additional fixed PET scanner if a major cancer treatment facility, program, or provider identified in Step 6 is hospital-based ([i.e., on a hospital's license](#)) and does not own or operate a fixed dedicated PET scanner, except as provided in Step 8 for both parts of the methodology combined.

Step 7: The maximum need determination for a single HSA in any one year will be no more than two additional fixed PET scanners regardless of the numbers generated individually by each part of the methodology ([Table 17F-1, Column F](#)).

Table 17F-1: Utilization of Existing Dedicated Fixed PET Scanners

A	B	C	D	E	F
HSA	Center	Planning Inventory	2016-2017 Procedures	Utilization Rate	Need Determination
I	Catawba Valley Medical Center / Frye Regional Medical Center	1	1,190	39.67%	0
	Mission Hospital	1	2,040	68.00%	0
II	Alamance Regional Medical Center	1	791	26.37%	0
	High Point Regional Health	1	815	27.17%	0
	Cone Health	1	1,726	57.53%	0
	North Carolina Baptist Hospital *	2	2,610	43.50%	0
	Novant Health Forsyth Medical Center **	2	2,969	49.48%	0
III	Carolinas HealthCare System NorthEast	1	1,026	34.20%	0
	Carolinas HealthCare System Union	1	579	19.30%	0
	Carolinas Medical Center	2	4,134	68.90%	0
	CaroMont Regional Medical Center	1	652	21.73%	0
	Iredell Memorial Hospital	1	531	17.70%	0
	Novant Health Presbyterian Medical Center	1	1,711	57.03%	0
IV	Duke Raleigh Hospital***	1	-	0.00%	0
	Duke University Hospital	2	4,774	79.57%	0
	Rex Hospital	1	2,556	85.20%	1
	UNC Hospitals	2	4,152	69.20%	0
	Wake PET Services, Wake Radiology Oncology, Wake Radiology	1	469	15.63%	0
V	Cape Fear Valley Medical Center	1	1,301	43.37%	0
	First Imaging of the Carolinas	1	1,120	37.33%	0
	New Hanover Regional Medical Center	1	2,044	68.13%	0
VI	CarolinaEast Medical Center	1	828	27.60%	0
	Nash General Hospital	1	390	13.00%	0
	Vidant Medical Center	1	2,277	75.90%	0
	TOTAL	29	40,685	46.76%	1

* CON issued on May 28, 2014 converting research only PET to clinical use. Project closed on February 28, 2017. *CON Project ID: G-010133-13*

** CON issued to convert fixed PET scanner to mobile PET scanner. Mobile scanner put into operation on February 27, 2017. Reporting period for fixed scanner 10/01/2016 - 02/26/2017. *CON Project ID: G-011051-15*

*** CON issued for new PET August 21, 2018. *CON Project ID: J-011384-17*

Table 17F-2: PET Scanner Provider of Mobile Dedicated Scanners

Mobile Provider	Procedures	Utilization Rate
		Year 2016-2017 Procedures, 2600 as Capacity
Alliance Imaging I	2,767	106%
Alliance Imaging II	3,668	141%
Novant Health Forsyth Medical Center (NHFC)*	830	32%
TOTAL	7,265	

*Placed in service 2/27/2017. Reporting period 2/27/2017-9/30/2017.

Table 17F-3: PET Scanner Sites Utilization of Existing Mobile Dedicated Scanners

Mobile Site	Mobile Provider	Number of Sites	Procedures
			2016-2017
Caldwell Memorial Hospital	Alliance I	1	102
Carolinas HealthCare System Blue Ridge	Alliance I	2	280
Carolinas HealthCare System Cleveland	Alliance I	1	786
Carolinas HealthCare System Stanly	Alliance I	1	226
Columbus Regional Healthcare System	Alliance II	1	3
Carteret General Hospital	Alliance II	1	249
Cone Health	Alliance I	1	0
Duke Raleigh Hospital	Alliance II	1	1,092
Harris Regional Hospital	Alliance I	1	263
Haywood Regional Medical Center	Alliance I	1	39
Johnston Health	Alliance II	1	195
Lake Norman Regional Medical Center	Alliance I	1	253
Lenoir Memorial Hospital	Alliance II	1	126
Margaret R. Pardee Memorial Hospital	Alliance I	1	180
Maria Parham Medical Center	Alliance II	1	75
Northern Hospital of Surry County	Alliance I	1	89
Novant Health Huntersville Medical Center	Alliance I	1	18
Novant Health Huntersville Medical Center	NHFMC	1	217
Novant Health Kernersville Medical Center	NHFMC	1	174
Novant Health Matthews Medical Center	Alliance I	1	19
Novant Health Matthews Medical Center	NHFMC	1	198
Novant Health Rowan Medical Center	Alliance I	1	0
Novant Health Rowan Medical Center-Julian Road	NHFMC	1	134
Novant Health Thomasville Medical Center	Alliance I	1	7
Novant Health Thomasville Medical Center	NHFMC	1	107
Onslow Memorial Hospital	Alliance II	1	503
Park Ridge Health	Alliance I	1	126
Randolph Hospital	Alliance I	1	135
Rutherford Regional Medical Center	Alliance I	1	127
Sentara Albemarle Medical Center	Alliance II	1	216
Scotland Memorial Hospital	Alliance II	1	115
Southeastern Regional Medical Center	Alliance II	1	281
The Outer Banks Hospital	Alliance II	1	159
Vidant Chowan Hospital	Alliance II	0	9
Watauga Medical Center	Alliance I	1	117
Wayne Memorial Hospital	Alliance II	1	238
Wilson Medical Center	Alliance II	1	407
TOTAL		37	7,265

Table 17F-4: Fixed Dedicated PET Scanners Need Determination

Service Area	Fixed Dedicated PET Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
HSA IV	1	February 15, 2019	March 1, 2019
It is determined that there is no need anywhere else in the state and no other reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. (see Chapter 3).

Table 17F-5: Mobile Dedicated PET Scanners Need Determination

Service Area	Mobile Dedicated PET Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
It is determined that there is no need anywhere in the state and no reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. (see Chapter 3).