

Proposed Policy TE-4: Plan Exemption for Linear Accelerators Agency Recommendation

Proposal:

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.” Radiation therapy using a linear accelerator (LINAC) is a common treatment for many types of cancers, as well as some benign tumors. The National Cancer Institute defines “standard of care” as “[t]reatment that is accepted by medical experts as proper treatment for a certain type of disease and that is widely used by health care professionals...”¹ In 2022, the State Health Coordinating Council (SHCC), in discussing and approving a petition from WakeMed for an adjusted need determination for a LINAC in Service Area 20 in the 2023 State Medical Facilities Plan (SMFP), noted that the use of LINAC technology is the standard of care for cancer treatment. In 2023, the SHCC approved a similar petition submitted by FirstHealth of the Carolinas to include an adjusted need for a LINAC in Service Area 17 in the 2024 SMFP on the same basis. Therefore, the Agency proposes that the SHCC develop a policy allowing cancer/oncology programs/centers that do not have a LINAC to obtain one without regard to a need determination in the SMFP.

The rationale for this proposal is similar to that for Policy TE-3. Policy TE-3 allows acute care hospitals with 24-hour emergency care that do not have a magnetic resonance imaging (MRI) scanner to obtain one without regard to a need determination because access to and use of MRI technology is considered standard of care for such facilities.

Policy TE-4: Plan Exemption for Linear Accelerators

The applicant proposing to acquire a linear accelerator (LINAC) under this policy shall demonstrate in its certificate of need (CON) application that:

1. it is or proposes to be a cancer center/program as defined in one of the categories used by the American College of Surgeons Commission on Cancer;² and
2. the proposed LINAC will not be located at a site where the inventory in the SMFP reflects that there is an existing or approved LINAC obtained in the five years immediately preceding the filing of the CON application; and
3. it has at least one radiation oncologist affiliated with the center; and
4. it has at least one medical physicist affiliated with the center or available by referral; and
5. if the service area has at least one LINAC, the average ESTVs across all LINACs in the applicant’s service area is at least 3,375.

The performance standards in 10A NCAC 14C .1903 are not applicable.

¹ National Cancer Institute. [Standard of Care Definition](#)

² If the policy is approved, the CoC categories will appear in Chapter 15 of the 2025 SMFP.

Background Information:

Currently, the prerequisite to the acquisition of a new LINAC is a need determination in the SMFP. The LINAC methodology projects need based on the number of procedures performed in each of the state’s 28 service areas, patient origin, and population. The methodology evaluates the service areas annually to ascertain whether the previous year’s configuration is still accurate based on changes in county population. The service areas have remained stable for quite a few years.

LINACs serve patients in a total of 72 facilities located across 54 of North Carolina’s 100 counties. The state has a total of 131 LINACs and need determinations to develop two additional LINACs are pending.³ The SMFP does not provide ownership information for facilities that have LINACs, but of the existing facilities, 58 are hospital-based, hospital-owned, or hospital-affiliated (i.e., bear a hospital name); and 14 are free-standing (i.e., do not bear a hospital name). All but two of the free-standing facilities are part of GenesisCare (North Carolina Radiation Therapy Management). The remaining facilities are Lake Norman Radiation Oncology and Matthews Radiation Oncology. These two are part of the SERO network, as are some other facilities in the larger Charlotte metropolitan area that bear hospital names.

Table 1 shows the need determinations for the past five SMFPs and the 2024 SMFP. Each need is for one LINAC. Of the last six need determinations, two were derived from the methodology. The remaining four were based on summer petitions.

Table 1. Linear Accelerator Need Determinations, 2019-2024⁴

SMFP	Service Area	Notes
2019	18	Based on petition and designated for Robeson County
2020	0	
2021	19	
2022	7	
	24	Based on petition and designated for Carteret County
2023	20	CON application under appeal. Applications received for Wake County.
2024	17	Based on petition

The proposed policy concerns individual facilities and, thus, does not advocate changing the way that service areas are defined. The specific location of the facility is also not a consideration. In other words, it does not matter how many other facilities in the service area may have LINACs or the number of procedures currently performed.

³ 2024 SMFP. https://info.ncdhhs.gov/dhsr/ncsmfp/2024/2024_SMFP.pdf; The 2024 SMFP shows 73 locations and 132 LINACs because it includes the placeholder in Wake County for the 2023 need determination. The 2023 need determination in Wake County is under appeal. There is a 2024 need determination in Service Area 17.

⁴ 2019 – 2024 SMFP. <https://info.ncdhhs.gov/dhsr/ncsmfp/index.html>

Discussion:

Before crafting a policy, it is necessary to define the type of facility to which the proposed policy would apply. The terms “cancer center,” “cancer program,” “oncology center,” and “oncology program” are often used to describe the types of settings that would be likely to provide LINAC treatment. However, neither the SMFP, Certificate of Need (CON) Regulations, nor the CON law define these terms or describe the types of facilities or settings eligible to provide LINAC treatment.

In looking for guidance, the Agency examined the classification system that the American College of Surgeons’ (ACS) Commission on Cancer (CoC) uses to accredit cancer programs. While the SHCC may not wish to adopt this classification system, it may inform development of a policy (See Table 2). The ACS website shows that NC has 51 accredited programs.⁵ Not all the CoC-accredited program names parallel the names of facilities in Table 15C-1 of the SMFP (See Appendix), so it is difficult to compare the listing to the SMFP directly.

⁵ <https://www.facs.org/hospital-and-facilities/?searchTerm=&address=+north+carolina&page=1>

Table 2. American College of Surgeons (ACS) Commission on Cancer (CoC) Categories⁶

- **Academic Comprehensive Cancer Program (ACAD):** The facility participates in postgraduate medical education in at least four program areas, including internal medicine and general surgery. The facility accesses more than 500 newly diagnosed cancer cases each year.
- **Community Cancer Program (CCP):** The facility accesses more than 100 but fewer than 500 newly diagnosed cancer cases each year.
- **Comprehensive Community Cancer Program (CCCP):** The facility accesses 500 or more newly diagnosed cancer cases each year.
- **Free Standing Cancer Center Program (FCCP):** The facility is a nonhospital-based program and offers at least one cancer-related treatment modality. The full range of diagnostic and treatment services is available by referral. Referral to CoC-accredited cancer program(s) is preferred. There is no minimum caseload requirement for this category.
- **Hospital Associate Cancer Program (HACP):** The facility accesses 100 or fewer newly diagnosed cancer cases each year and has a limited range of diagnostic and treatment services available on-site. Other services are available by referral. Clinical research is not required.
- **Integrated Network Cancer Program (INCP):** Facilities belonging to an organization that owns a group of facilities that offer integrated and comprehensive cancer care services and is overseen by a centralized governance structure/board and CEO.
- **NCI-Designated Comprehensive Cancer Center Program (NCIP):** The facility secures a National Cancer Institute (NCI) peer-reviewed Cancer Center Support Grant and is designated a Comprehensive Cancer Center by the NCI. A full range of diagnostic and treatment services and staff physicians are available. Participation in the training of resident physicians is optional, and there is no minimum caseload requirement for this category.
- **NCI-Designated Network Cancer Program (NCIN):** Facilities belonging to an organization that owns a group of facilities that offer integrated and comprehensive cancer care services and is overseen by a centralized governance structure/board and CEO. Additionally, the facilities secure a National Cancer Institute (NCI) peer-reviewed Cancer Center Support Grant and are designated a Comprehensive Cancer Center Consortium by the NCI. To be included in the NCIN, all facilities must be included within the NCI grant.
- **Pediatric Cancer Program (PCP):** The stand-alone pediatric facility provides care to children and adolescents below the age of 18 (a center that cares only for teens and older is excluded). The pediatric facility offers the full range of diagnostic and therapeutic services for pediatric patients. The pediatric facility is required to participate in cancer-related clinical research, including the enrollment of patients in cancer-related clinical trials. There is no minimum caseload requirement for this category.
- **CoC Pediatric Specialty Accreditation (CoC-PS):** The pediatric oncology program within an existing CoC-accredited facility provides care to children and adolescents below the age of 18 (a program that cares only for teens and older is excluded). The pediatric oncology program offers the full range of diagnostic and therapeutic services for pediatric patients separate from the adult services. The pediatric oncology program is required to participate in cancer-related clinical research, including the enrollment of patients in cancer-related clinical trials. There is no minimum caseload requirement for this category.
- **Veterans Affairs Cancer Program (VACP):** The facility provides care to military veterans and offers the full range of diagnostic and treatment services either on-site or by referral, preferably to CoC-accredited cancer program(s). There is no minimum caseload requirement for this category.

⁶ American College of Surgeons Commission on Cancer Accreditation. [Cancer Program Categories](#)

Potential Impact:

Figure 1 shows the incidence of new cancer diagnoses in North Carolina for the most recent ten years for which final data are available from the Central Cancer Registry (CCR). All health care providers are required by law to report cases to the CCR (as in nearly all other states), but the primary data source is hospitals with CoC-accredited cancer programs. For cases that are not reported by the hospital cancer registry, the CCR supplements data with reports from physician offices, free-standing treatment centers and clinics, pathology laboratories and other sources.⁷ It is possible that the COVID-19 pandemic affected new diagnoses (or their reporting) in 2020. Therefore, the downturn may not be the beginning of a trend.

Figure 1. Cancer Incidence in North Carolina 2011-2020⁸

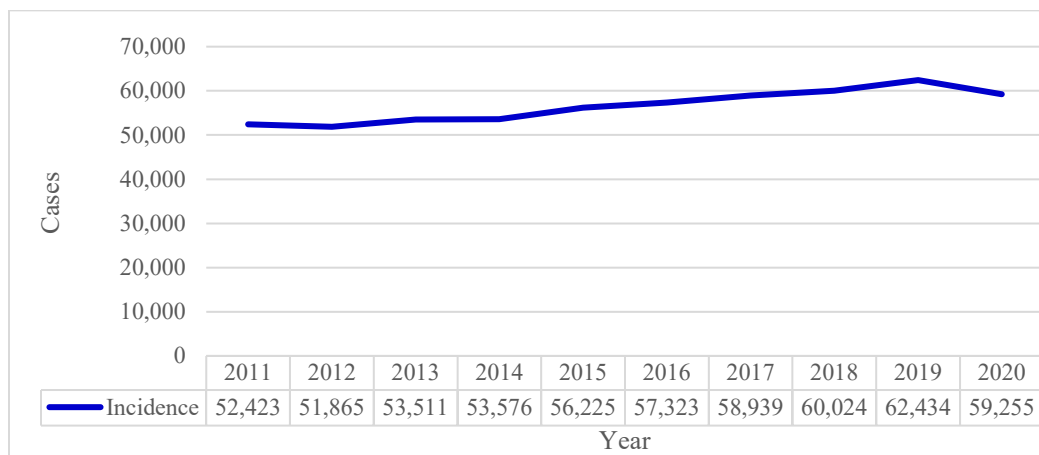


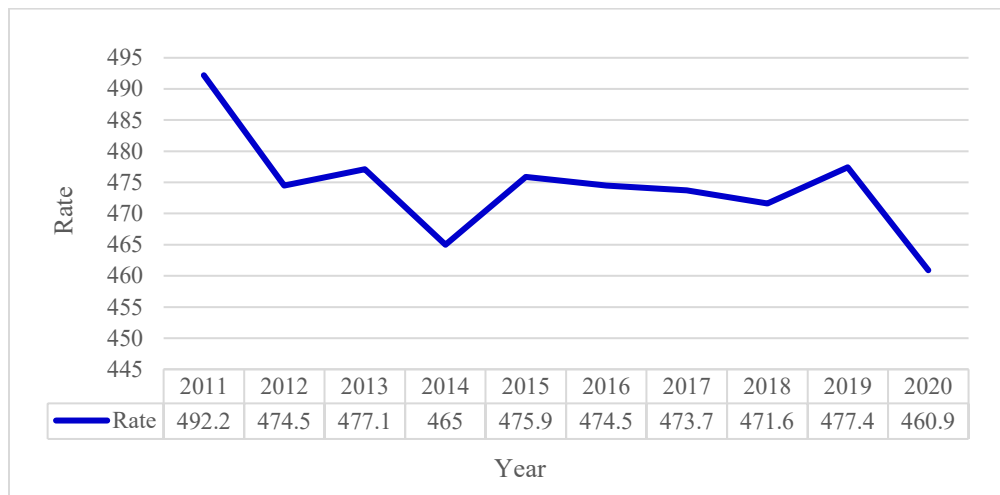
Figure 2 shows the incidence rates over the same period. Based on these findings, the incidence of cancer has increased by about 13% over that time, compared to a 9.5% increase in the state population.⁹ However, the cancer rate has decreased over the same period.

⁷ North Carolina State Center for Health Statistics. [NC SCHS: Central Cancer Registry \(ncdhhs.gov\)](http://ncdhhs.gov)

⁸ North Carolina Central Cancer Registry. NC DHHS, Division of Public Health, [NC SCHS: Statistics and Reports: Cancer: Incidence Rates \(ncdhhs.gov\)](http://ncdhhs.gov)

⁹ North Carolina Office of State Budget and Management. [NC Census Data | NC OSBM](http://ncosbm.gov)

Figure 2. Rate of New Cancer Diagnoses per 100,000 Population, 2011-2020¹⁰



Overall LINAC utilization was about 70% for the 2021-2022 reporting year. Six service areas have an average of less than 50% utilization (3,375 procedures per LINAC) (See Table 3). These are service areas 1 (Jackson and Macon counties), 3 (Watauga County), 11 (Davidson County), 21 (Harnett), 25 (Onslow), and 26 (Halifax, Wilson, and Nash counties).

The Agency has no data on the proportion of cancer patients that receive LINAC treatment. Regardless, it is unlikely that the proposed policy would lead to the proliferation of LINACs. LINACs are highly specialized equipment that require considerable financial, physical, and professional resources. Rather, the Agency anticipates that a providers may develop new or additional oncology programs/cancer centers. In addition, new centers may be developed in a few of the 46 counties that do not currently have a LINAC. As always, it is possible that new centers may be developed to compete with existing centers.

¹⁰North Carolina Central Cancer Registry. [NC SCHS: Statistics and Reports: Cancer: Incidence Rates \(ncdhhs.gov\)](https://www.ncdhhs.gov/ncschs-statistics-reports-cancer-incidence-rates). Rates are age-adjusted to the 2000 U.S. standard population.

Appendix: LINAC Providers and Average Number of Procedures per Service Area, 2024 SMFP¹¹

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2021-9/30/2022	Average Number of Procedures per Service Area
Harris Regional Hospital	1	Jackson	1	1,355	
North Carolina Radiation Therapy Management Services - Franklin	1	Macon	1	1,984	
			2	3,339	1,670
North Carolina Radiation Therapy Management Services - Asheville	2	Buncombe	1	7,828	
North Carolina Radiation Therapy Management Services - Asheville	2	Buncombe	1	0	
North Carolina Radiation Therapy Management Services - Clyde	2	Haywood	1	4,308	
North Carolina Radiation Therapy Management Services - Marion	2	McDowell	1	2,872	
North Carolina Radiation Therapy Management Services - Weaverville	2	Buncombe	1	2,915	
Mission Hospital	2	Buncombe	3	15,170	
			8	33,093	4,137
Watauga Medical Center	3	Watauga	1	2,336	2,336
			1	2,336	2,336
Margaret R. Pardee Memorial Hospital	4	Henderson	1	6,194	
North Carolina Radiation Therapy Management - Brevard	4	Transylvania	1	1,521	

¹¹ 2024 SMFP. [Table 15C-1](#). Note: the values for the total number of procedures and the average number of procedures per service area in Table 15C-1 are rounded.

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2021-9/30/2022	Average Number of Procedures per Service Area
North Carolina Radiation Therapy Management Services - Hendersonville	4	Henderson	1	3,536	
			3	11,251	3,750
Caldwell UNC Health Care	5	Caldwell	1	0	
Frye Regional Medical Center - Main Campus	5	Catawba	1	2,737	
Catawba Valley Medical Center	5	Catawba	2	13,250	
UNC Health Blue Ridge - Valdese Campus	5	Burke	2	5,506	
			6	21,493	3,582
Atrium Health Cleveland	6	Cleveland	1	6,561	
North Carolina Radiation Therapy Management Services - Forest City	6	Rutherford	1	3,642	
CaroMont Regional Medical Center *	6	Gaston	3	21,210	
			5	31,413	6,283
Atrium Health Union	7	Union	1	8,279	
Atrium Health University City	7	Mecklenburg	1	7,918	
Novant Health Huntersville Medical Center	7	Mecklenburg	1	4,263	
Atrium Health Pineville	7	Mecklenburg	2	13,016	
Matthews Radiation Oncology Center	7	Mecklenburg	2	11,087	
Novant Health Presbyterian Medical Center	7	Mecklenburg	2	12,699	
Atrium Health Carolinas Medical Center	7	Mecklenburg	3	19,496	
			12	76,758	6,397
Lake Norman Radiation Oncology	8	Iredell	1	7,994	
Novant Health Cancer Institute-Rowan	8	Rowan	1	6,041	
Iredell Memorial Hospital, Inc.	8	Iredell	2	6,307	
			4	20,342	5,086
Atrium Health Stanly	9	Stanly	1	3,661	
Atrium Health Cabarrus	9	Cabarrus	3	12,954	

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2021-9/30/2022	Average Number of Procedures per Service Area
			4	16,615	4,154
Hugh Chatham Memorial Hospital	10	Surry	1	0	
Wake Forest Baptist Medical Center	10	Forsyth	4	23,199	
Novant Health Forsyth Medical Center	10	Forsyth	5	10,631	
			10	33,830	3,383
Lexington Medical Center	11	Davidson	1	3,181	
			1	3,181	3,181
UNC Rockingham Hospital	12	Rockingham	1	2,505	
High Point Medical Center	12	Guilford	2	9,977	
Cone Health	12	Guilford	4	30,468	
			7	42,950	6,136
Randolph Health	13	Randolph	1	3,884	
			1	3,884	3,884
University of North Carolina Hospitals at Chapel Hill, DBA UNC Hospitals	14	Orange	6	39,067	
			6	39,067	6,511
Alamance Regional Medical Center	15	Alamance	2	9,630	
			2	9,630	4,815
Duke Regional Hospital	16	Durham	1	3,497	
Maria Parham Health	16	Vance	1	6,203	
Duke University Hospital Main Campus	16	Durham	8	40,503	
			10	50,203	5,020
Scotland Memorial Hospital	17	Scotland	1	2,991	
FH Moore Regional Hospital	17	Moore	2	17,364	
			3	20,355	6,785
North Carolina Radiation Therapy Management Services - Clinton	18	Sampson	1	3,473	

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2021-9/30/2022	Average Number of Procedures per Service Area
Southeastern Regional Medical Center	18	Robeson	2	6,525	
Cape Fear Valley Medical Center	18	Cumberland	5	19,399	
			8	29,397	3,675
New Hanover Regional Medical Center **	19	New Hanover	5	34,506	
			5	34,506	6,901
Franklin County Cancer Center	20	Franklin	1	0	
UNC Hospital Radiation Oncology -Holly Springs	20	Wake	1	0	
UNC Rex Cancer Center of East Raleigh	20	Wake	1	4,240	
Duke Raleigh Hospital	20	Wake	4	23,733	
Rex Hospital	20	Wake	4	21,356	
			11	49,329	4,484
Central Harnett Hospital	21	Harnett	1	0	0
			1	0	0
Johnston Health Clayton Professional Plaza	22	Johnston	1	6,319	
Smithfield Radiation Oncology	22	Johnston	1	5,239	
			2	11,558	5,779
UNC Lenoir Health Care	23	Lenoir	1	7,653	
North Carolina Radiation Therapy Management Services - Goldsboro	23	Wayne	1	6,017	
			2	13,670	6,835
CarolinaEast Medical Center	24	Craven	2	9,746	
Carteret Health Care	24	Carteret	2	6,980	
			4	16,726	4,182
Onslow Radiation Oncology, LLC	25	Onslow	1	2,694	
			1	2,694	2,694
North Carolina Radiation Therapy Management Services - Roanoke Rapids	26	Halifax	1	2,484	

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2021-9/30/2022	Average Number of Procedures per Service Area
Wilson Radiation Oncology	26	Wilson	1	1,377	
Nash Hospitals Inc.	26	Nash	2	7,706	
			4	11,567	2,892
ECU Health Beaufort Hospital	27	Beaufort	1	4,354	
Vidant Radiation Oncology	27	Hertford	1	2,026	
Vidant Radiation Oncology	27	Pitt	1	6,604	
Vidant Radiation Oncology	27	Pitt	3	14,375	
			6	27,359	4,560
Outer Banks Health Hospital	28	Dare	1	3,029	
Sentara Albemarle Medical Center	28	Pasquotank	1	5,584	
			2	8,613	4,307
Total All Facilities			131	625,159	4,772

* CaroMont Regional Medical Center has two linear accelerators in Gaston County and one linear accelerator in Lincoln County.

** New Hanover Regional Medical Center has four linear accelerators in New Hanover County and one linear accelerator in Brunswick County.