Linear Accelerator Services Workgroup

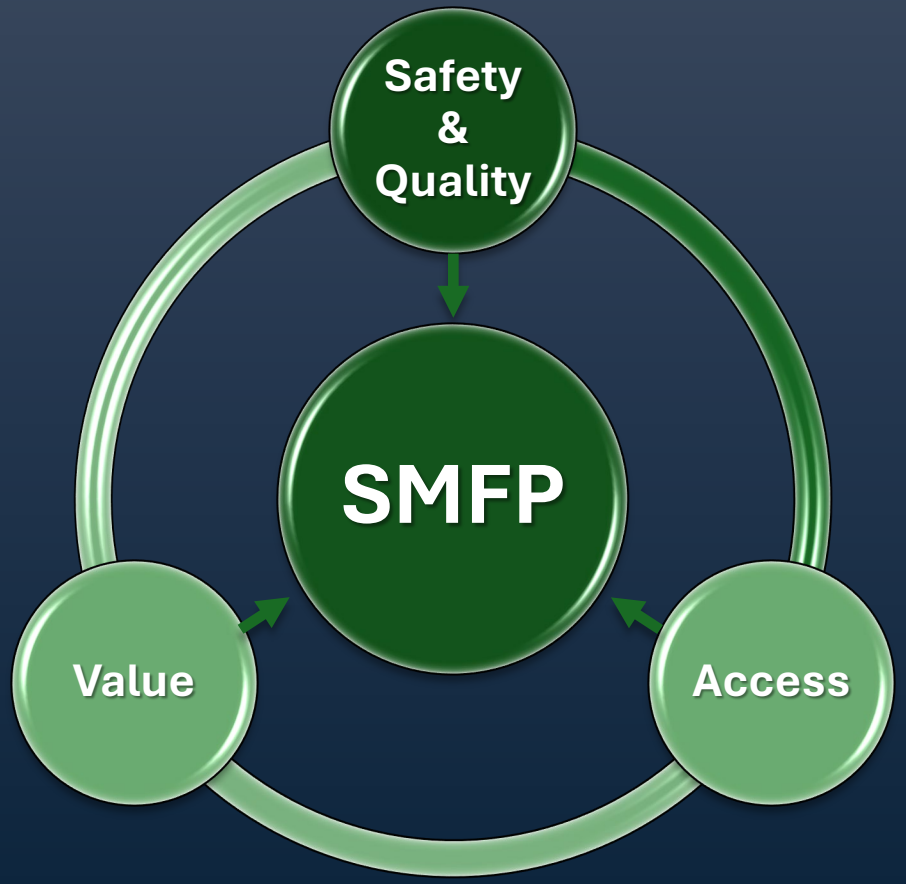
Meeting 1

October 22, 2025

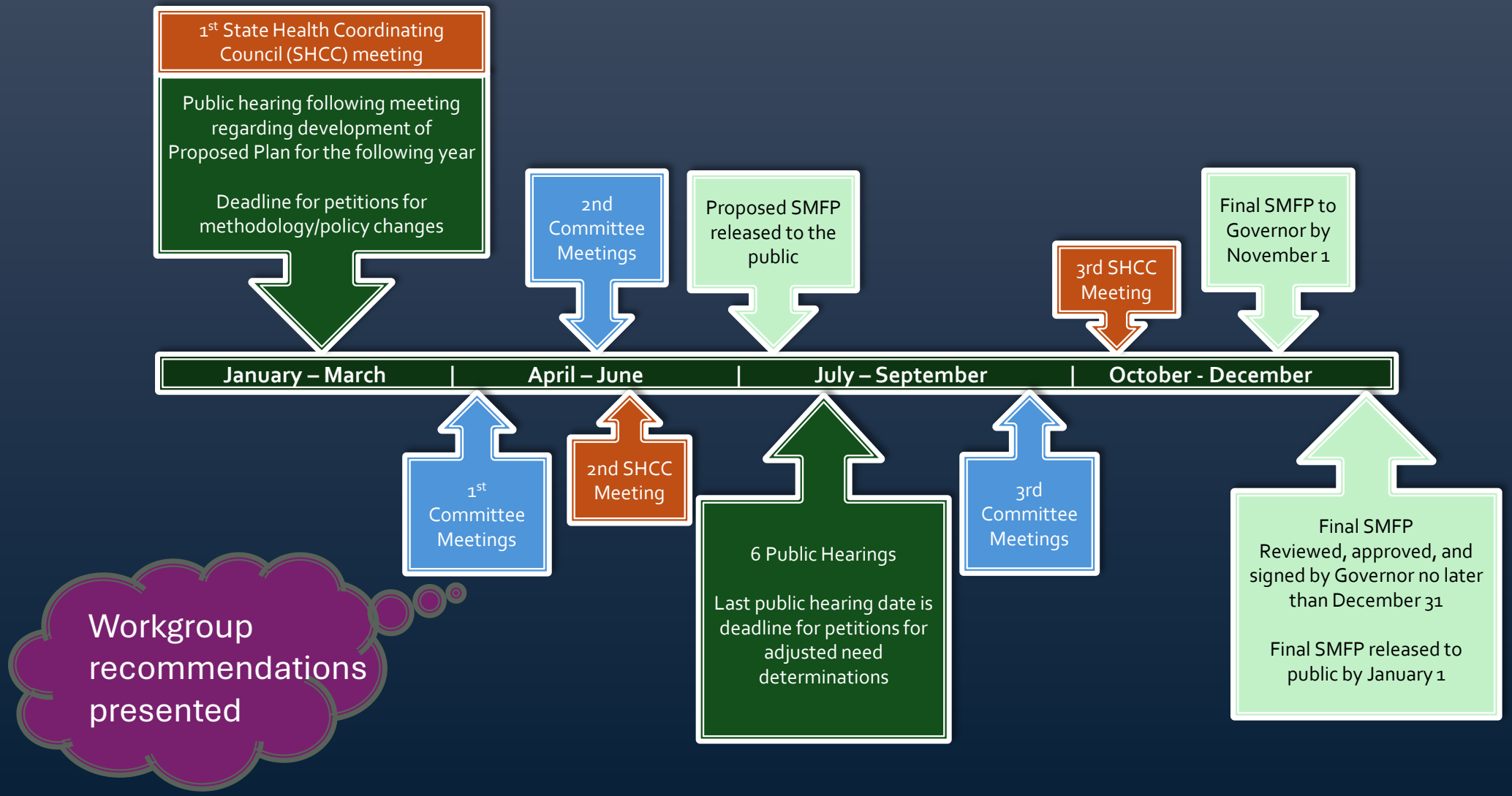
Workgroup Charge

- Review the current concerns around achieving an adequate supply of LINACs in the state.
    - Review recent activity from the Interested Parties meeting held on February 18, 2025.
    - Review comments from providers regarding the issue of LINAC as standard of care specifically reassess in the current and future oncology practice paradigm what the role and quality standards are for LINAC as part of a comprehensive oncology center/program.
    - Review petitions for LINACs submitted to DHSR in the past 10 years.
    - Gather input from constituencies to understand how the current methodology works and to identify potential problems.
    - Assess whether new policies or a revised methodology are warranted.
- If deemed necessary, develop findings and recommendations for revisions to the SMFP policies and/or the LINAC methodology, and present them to the Technology and Equipment Committee of the SHCC for consideration in Spring 2026.

Basic Principles Governing the Development of the SMFP [Chapter 1]



The SHCC/SMFP Annual Planning Cycle



Summary of Certificate of Need (CON) Process

- While the SMFP for the next year is being developed, the CON staff implements the SMFP developed for the current year
  - In 2025, CON continues to review applications based on 2024 SMFP needs

- Anyone desiring a certificate of need must:
  - Complete an application by the established deadline and pay the application fee
  - Furnish information upon which the CON staff can evaluate conformity with the statutory review criteria

- CON may:
  - Approve an application with conditions
  - Deny an application

Methodology

LINAC Methodology Criteria

Two of three must be satisfied for a need determination

1. Geography
2. Patient Origin
3. Utilization

also used to define service areas

Defining LINAC Service Areas

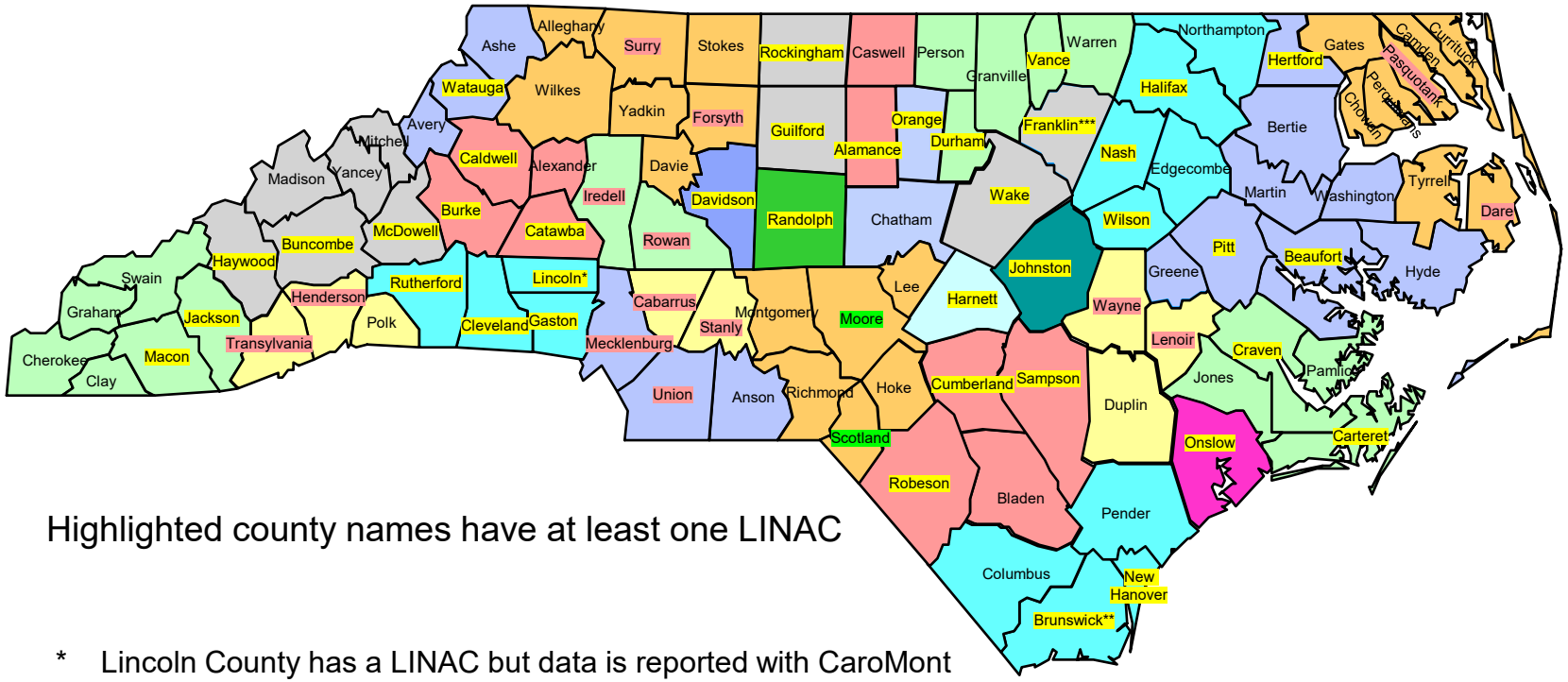
Do >=45% of patients go outside home county ?

Service Areas (SA)

- LINACs do not have “divided” SAs. No county is split between two or more multi-county SAs.

- NC has 28 LINAC SAs.
  - NOT all SAs have > 120,000 population.
  - Seven SA have no single county with > 120,000 population.
  - Five SAs contain only one county.
    - Have > 120,000 population
    - Do not serve at least 45% of patients from any other single county

LINAC Service Areas



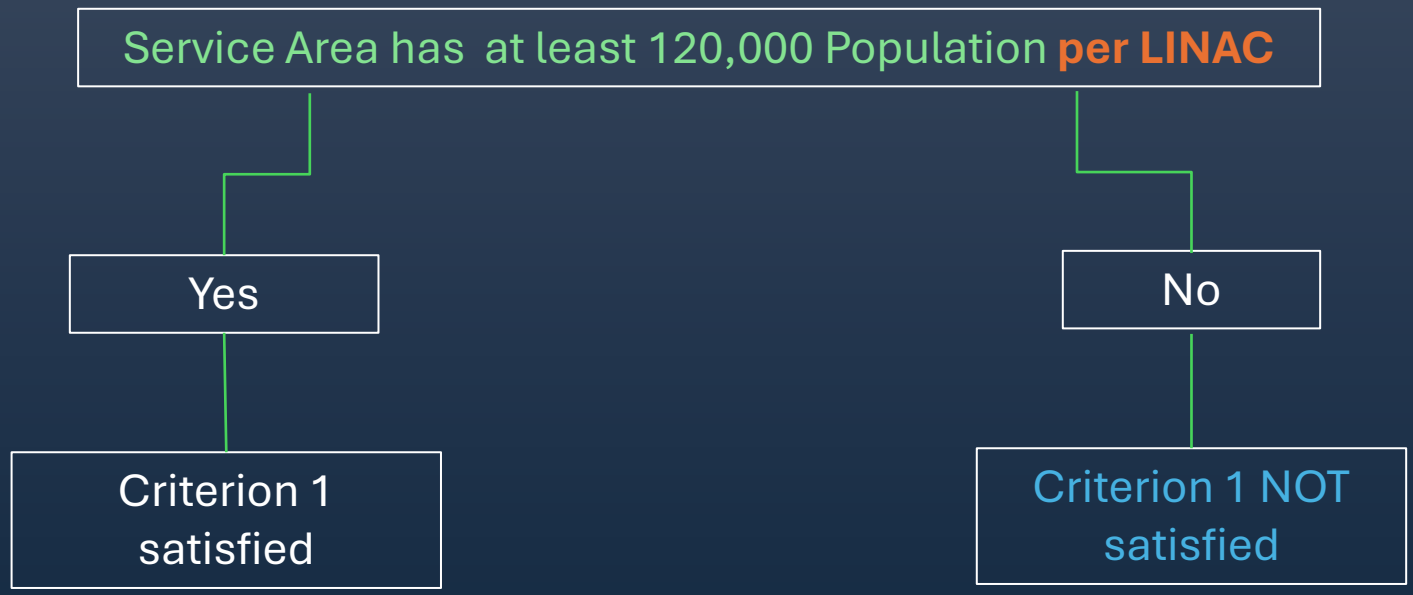
Highlighted county names have at least one LINAC

* Lincoln County has a LINAC but data is reported with CaroMont Hospital in Gaston County

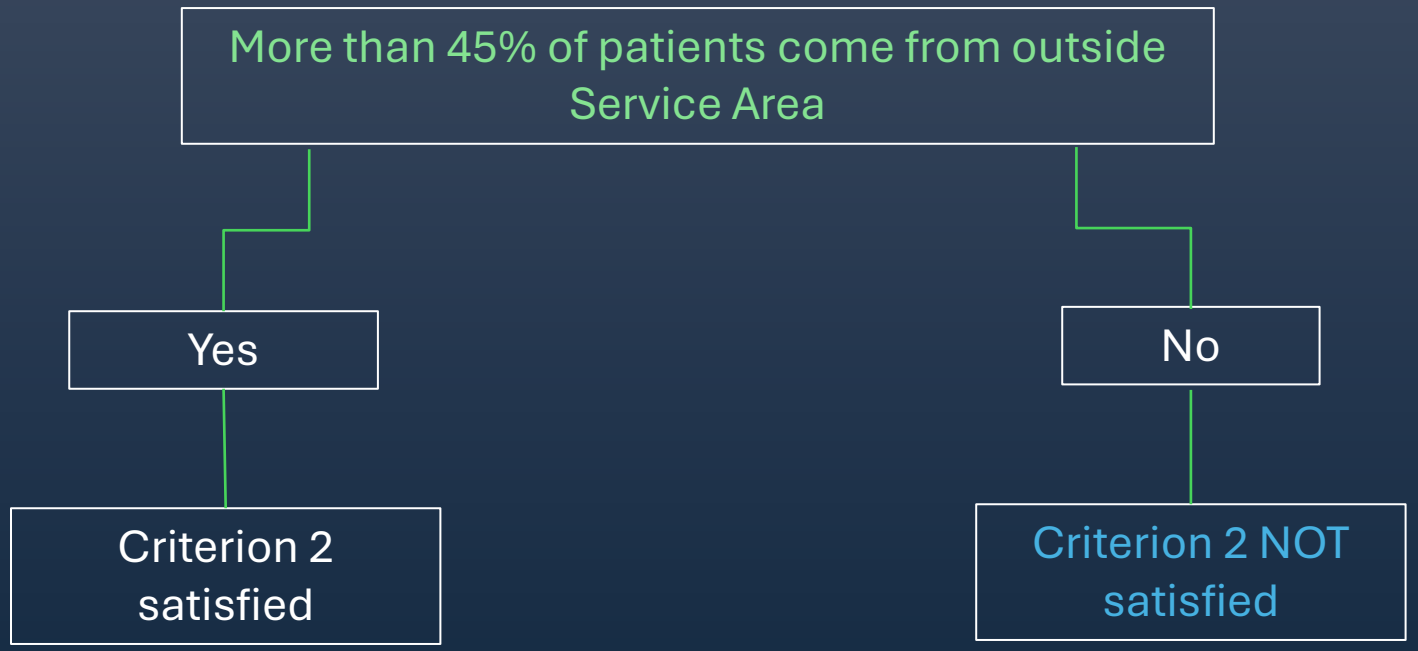
** Brunswick County has a LINAC but data is reported with NewHanover Regional Medical Center in New Hanover County

*** Duke has CON to relocate LINAC to Wake County

Criterion 1


Service Area has at least 120,000 Population per LINAC
Yes
No
Criterion 1 satisfied
Criterion 1 NOT satisfied

Criterion 2


More than 45% of patients come from outside Service Area
Yes
No
Criterion 2 satisfied
Criterion 2 NOT satisfied

Criterion 3:

Utilization Threshold

1. X = total ESTVs in SA ÷ 6,750
2. Y = X – Number of LINACs in SA
3. If Y >= 0.25 → Criterion 3 is satisfied

Need Determination Calculation Example – Service Area 12

Table 15C-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) 10/1/2023-9/30/2024	Average Number of Procedures per Unit
Atrium Health Wake Forest Baptist - High Point Medical Center	12	Guilford	2	8,775	4,387
Cone Health Wesley Long Hospital	12	Guilford	4	31,476	7,869
UNC Rockingham Hospital	12	Rockingham	1	3,301	3,301

Table 15C-1 shows LINAC locations. Table 15C-4 lists each SA with its counties and their populations.

Table 15C-4: Linear Accelerator Service Areas

Area	County	2025 Total Population
11	Davidson	180,480
	Total	**180,480**
12	Guilford	560,760
12	Rockingham	92,415
	Total	**653,175**

Instructive Calculation Examples

Two criteria must be satisfied

1. Minimum 120,000 population per LINAC
2. > 45% of patients are from out of SA
3. >= 0.25

SA 19-New Hanover & Brunswick

1. 108,576 population per LINAC - NO
2. 10.42% of patients are from outside SA - NO
3. = 0.77 – or 7,790 ESTVs per LINAC - YES

SA 22-Johnston

1. 128,088 population per LINAC - YES
2. 39.3% of patients are from outside SA – NO – but pretty close
3. = -0.3 – or 5,730 ESTVs per LINAC - NO

Criterion 4

- Not part of calculations

- When county reaches population >= 120,000 and has no LINAC
  - a need determination for one LINAC is created
  - the county also becomes a new service area

Need Determinations, 2007-2026

SMFP	Petition	Service Area	Constituent Counties (red = county issued CON)
2007		20	Franklin, Harnett, Wake
2008		18	Bladen, Cumberland, Robeson, Sampson
2014	Yes	20	Franklin, Wake
2015		21	Harnett (created new service area in 2014)
2019	Yes	18	Bladen, Cumberland, Robeson, Sampson
2021		19	Brunswick, Columbus, New Hanover, Pender
2022	Yes	24	Carteret, Craven, Jones, Pamlico
2022		7	Anson, Mecklenburg
2023	Yes	20	Franklin, Wake (under appeal)
2024	Yes	17	Hoke, Lee, Montgomery, Moore, Richmond, Scotland
2026*		7	Anson, Mecklenburg
2026*	Yes	6	Cleveland, Gaston, Lincoln, Rutherford
2026*	Yes	12	Guilford, Rockingham
2026*	Yes	23	Duplin, Lenoir, Wayne

* Pending Governor's approval

What happens when the methodology doesn’t work for every service area or provider?

- ✓ *Petition process*
- ✓ *Policies that allow exceptions to the methodology*
- ✓ *Specific methodology exceptions included in the SMFP*

Procedure for Petitions

Spring – changes to policy and/or methodology

Summer – adjusted need determinations

Spring Petitions

- 2006 Change to original 1998 methodology
  - If a county has >= 120,000 population, becomes separate service area. If it has no LINAC, a need determination is created. Several new services areas were created.
- 2008 Petitions to change methodology – both denied
  - Include need determination for integrated cancer care providers (i.e., provide chemotherapy and LINAC) where utilization exceeds 9,000 ESTVs
  - Treat total body radiosurgery by robotic LINAC as unique service
- 2010 Petition for demonstration project for prostate cancer center – approved
- 2012 Implemented annual updates of service areas

Adjusted Need Determination (Summer) Petitions

SMFP	Service Area	Counties	Petitioner	Rationale	Result
2013	20	Franklin, Harnett, Wake	Duke Raleigh Hospital	• Adequate LINACs in service area	Denied
2014	20	Franklin, Wake	Duke Raleigh Hospital	• Not all LINACs in SA are operational	Denied
2019	**18**	**Bladen, Cumberland, Robeson, Sampson**	**Southeastern Medical Center**	• **High utilization** • **Challenges in serving rural population**	**Approved**
2022	20	Franklin, Wake	WakeMed	• Not all LINACs in SA are operational	Denied
2023	**20**	**Franklin, Wake**	**WakeMed**	• **Not all LINACs in SA are operational** • **LINAC as standard of care**	**Approved Under appeal**
2024	**17**	**Hoke, Lee, Montgomery, Moore, Richmond, Scotland**	**FirstHealth Moore**	• **Increase in patients.** • **FirstHealth Moore serves considerably more patients than national average**	**Approved, for a cancer center**
2025	20	Franklin, Wake	WakeMed	• Not all LINACs in SA are operational • LINAC as standard of care	Denied
2026*	20	Franklin, Wake	WakeMed	• Not all LINACs in SA are operational • LINAC as standard of care	Denied
2026*	**6**	**Cleveland, Gaston, Lincoln, Rutherford**	**CaroMont Health**	• **High utilization at hospital** • **Low utilization elsewhere is suppressing need**	**Approved**
2026*	**12**	**Guilford, Rockingham**	**Cone Health**	• **High utilization at hospital** • **Decreasing utilization elsewhere** • **Long distance to facility with capacity**	**Approved**
2026*	**23**	**Duplin, Lenoir, Wayne**	**UNC Health Wayne**	• **LINAC as standard of care.** • **Petitioner has oncology program but no LINAC**	**Approved**

* Pending Governor's approval of 2026 SMFP

LINAC-Related Policies

- No policies specific to LINAC
- Policy AC-3: Academic Medical Center Teaching Hospitals
- LINAC-related PET policy
  - TE-4 : obtain dual-functioning fixed PET/LINAC simulator for mid-size cancer centers without regard to PET need determination
- Also
  - Part 2 of PET methodology. A need determination for 1 PET scanner exists when a major cancer treatment facility/program/provider, owns or operate 2 LINACs and has over 12,500 ESTVs.

Areas of Consideration for the Need Determination Methodology and Policies

Assure Adequate Number of LINACs

- Methodology should not result in excess capacity but should be “generous” enough to assure sufficient number of LINACs
  - All methodologies have a planning “buffer”
- Statewide geographical coverage
- Reflect number needed for general population
  - Based on some accepted metric (e.g., number of LINACs per population or per patient)
- Measure LINAC utilization appropriately and completely
  - How to measure “traffic” on the LINAC
  - Measures must be readily available to providers
- Project into future
  - Planning horizon - how long it takes to put a LINAC into operation
- Consider need for policies or exceptions to methodology (e.g., emerging technologies or applications)
  - May not be immediately apparent at implementation of new methodology

Data Availability

Available and Collected

- Number of existing and CON-approved LINACs
- Current and prior utilization (ESTVs)
- CPT codes
- Number of patients (# of courses of treatment)
- Prior need determinations for which no CON has yet been issued
- County population, current and projected

Not Available or Problematic

- Data system does not “talk” to other state or provider data systems (only imports LRA data from Enterprise)
- Periodic updates to CPT codes
- Other measures of utilization
- Changes to data collected on hospital License Renewal Application take a long time
- Timely data on cancer incidence, conditions, patient characteristics
  - Most current data is too old
  - 5-year rates are more stable
  - No prevalence data

Statewide Geographical Coverage

- Definition of service areas
  - County – based
    - County definitions are stable over time and well defined

- Underserved populations
  - Assumption: If there is an adequate supply of LINACs in SA, then that enables services to geographically underserved populations
  - For underserved populations based on social determinants of health (e.g.,), the provider determines how best to address access to services by people who are underserved

Reflect Number Needed for Population

- ESTRO/QUARTS – European Union - recommendations
  - 1 LINAC per 180,000 population
  - 1 LINAC per 400 patients per year: 1 patient = 1 new course of treatment
- Bates, et al. – United States – 2020 – observations
  - 88,000 population per LINAC or 11.4 LINACs per million people
- LINACs per population in NC
  - 1.2 LINACs per 100,000
  - 1.4 LINACs per 120,000
  - 2.1 LINACs per 180,000
  - 84,146 people per LINAC or 11.8 LINACs per million
- Patients per LINAC (41,025 total patients) in NC: 1 patient = 1 “course of treatments”
  - 311 per existing or CON-approved LINAC
  - 326 per operational LINAC
- May not have data to examine other measures of adequacy of supply
- Using cancer incidence data is problematic

The Cancer Incidence Data Problem

- Central Cancer Registry, State Center for Health Statistics
  - Do not have direct access to data
- County level incidence data
  - No data on where cancer patients receive treatment
- No prevalence data
- Age of data
  - During 2025, in preparation of 2026 SMFP
    - March 2025, published 5-year incidence rates, 2018-2023.
      - 2023 data is preliminary
    - July 2025
      - 2022 incidence, single year data
      - Too late for inclusion in next year's SMFP

Measure Utilization Appropriately and Completely

- What is important in measuring “how much” a LINAC is used?
  - Hours per day
    - ESTVs
    - Treatment fractions?
- How do you record “how much” treatment is administered?

- Use Equivalent Simple Treatment Visit (ESTV) based on weighted CPT codes
- Current use of CPT codes
  - Agency does not have ability to update codes
- Can we make ESTVs work better than currently?
  - Are we missing CPT codes for treatment that should be included?
    - Brachytherapy?
    - Pain management?

Projecting Need

- Methodology should project need beyond the reporting year to account for typical amount of time it takes for a LINAC to become operational after CON approval.
  - Differs for hospitals and free-standing centers

- On what basis?
  - Growth in population
  - Growth in utilization

- Reporting year is two years behind SMFP publication year

What's Next?

- Obtain and review public comments
  - Due November 7

- For the next meeting, staff will present some options for revisions to methodology based on today's discussion
  - **Any ideas for what you'd like to see that we haven't discussed?**

- Discuss possible exceptions to methodology