Petition to State Health Coordinating Council

Adjustment to the Linear Accelerator Need Determination Included in the Proposed 2026 State Medical Facilities Plan

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Statement of Requested Change

Raleigh Neurosurgical Clinic ("RNC") requests an adjusted statewide need determination for one (1) linear accelerator demonstration project, specifically a self-shielded, stereotactic radiosurgery ("SRS")-dedicated linear accelerator in the *2026 State Medical Facilities Plan* ("*SMFP*").

Background

The development of radiation oncology in North Carolina reflects a long-standing commitment to improving cancer outcomes through innovation, accessibility, and patient-centered care. Since the early 20th century, radiation has been a critical modality in the treatment of cancer, and its evolution has mirrored advances in medical technology and healthcare infrastructure. The linear accelerator, now the standard of care for external beam radiation therapy, fundamentally transformed cancer treatment by enabling clinicians to deliver highly targeted doses while preserving surrounding healthy tissue.

North Carolina's leadership in this field dates back to the mid-20th century, when academic medical centers such as Duke University and the University of North Carolina at Chapel Hill introduced megavoltage radiation therapy and medical physics programs. These institutions helped pioneer the use of early linear accelerator technology and trained generations of radiation oncologists, medical physicists, and dosimetrists who would go on to establish and expand radiation services across the state. Their impact remains visible today in the distribution of radiation therapy services and clinical expertise throughout North Carolina.

As the clinical benefits of linear accelerators became more evident, healthcare providers across North Carolina sought to increase availability outside of academic centers. By the 1980s and 1990s, community hospitals in urban and rural settings alike began investing in linear accelerator infrastructure to meet growing cancer care demands. This expansion was guided by the North

Carolina CON process, which helped balance service growth with equitable geographic distribution and ensured that new installations aligned with actual need. By 1999, 83 linear accelerators were operated by 47 providers in 36 counties.

Over the past 25 years, North Carolina has experienced significant progress in expanding linear accelerator access statewide. Cities such as Asheville, Chapel Hill, Charlotte, Durham, Fayetteville, Greensboro, Greenville, Raleigh, Wilmington, and Winston-Salem are now home to three or more linear accelerators. Currently, providers in the 23 North Carolina urban counties, defined as counties with a population over 125,000, operate 93 of the 132 linear accelerators in North Carolina. These providers support a broad spectrum of services including intensity-modulated radiation therapy ("IMRT"), image-guided radiation therapy ("IGRT"), and stereotactic radiosurgery. More recently, stereotactic body radiation therapy ("SBRT") has emerged as a key modality for treating tumors in the lungs, liver, spine, and prostate, further enhancing the clinical value of linear accelerator platforms.

In more rural and underserved counties, expansion has followed a slower trajectory than in urban counties due to capital costs, staffing limitations, and infrastructure needs. Currently, North Carolina urban counties, defined as counties with a population less than 125,000, operate 39 of the 132 linear accelerators in 32 counties. This represents a doubling of the rural counties offering linear accelerator services since 1999. As a result, many North Carolinians can now access high-quality radiation oncology services within reasonable driving distance, a major improvement compared to past decades.

Currently, all linear accelerators in North Carolina are located in hospitals or freestanding oncology treatment centers. These linear accelerators all require housing in specially constructed radiation-shielded vaults due to the emitted high energy photon beams, typically 6 to 18 megavolts. Vaults are often placed at ground level or below-grade to support the heavy shielding and equipment weight, as well as the up to 3 million pounds of concrete and extensive rebar reinforcement. Construction of a vault can take 6 to 9 months and cost $1.5 million to $2.5 million.

Reason for the Proposed Change

Raleigh Neurosurgical Clinic is submitting this petition to the State Health Coordinating Council requesting an adjustment to the need determination for linear accelerators in North Carolina to include an adjusted statewide need determination for one self-shielded, SRS-dedicated linear accelerator.

Benefits of a Self-Shielded Linear Accelerator

The following are some of the benefits of a self-shielded, SRS-dedicated linear accelerator:

Eliminates the Need for a Radiation Vault

- Traditional linear accelerators require heavy shielding, often 3–7 feet of concrete or lead, to contain high-energy radiation. Self-shielded linear accelerators have integrated shielding to meet all regulatory radiation protection standards.
- Vault construction often costs $1.5 million to $2.5 million and can take 6–9 months. Self-shielded linear accelerators are installed in standard medical office or outpatient spaces, reducing setup time and expense.
- Without a vault, these self-shielded linear accelerators can be installed in existing exam rooms, surgical suites, or converted spaces.

Lower Total Cost of Ownership

- The elimination of the radiation vault and related infrastructure significantly lowers upfront capital costs.
- Unlike cobalt-based systems, self-shielded linear accelerators use standard X-ray beam technology, eliminating recurring costs and safety protocols associated with radioactive source replacement and disposal.
- With less shielding infrastructure and a compact footprint, operating expenses, such as HVAC, structural reinforcement, and shielding compliance testing, are reduced.

Greater Flexibility in Deployment

- Self-shielded linear accelerators can be installed in physician offices, medical clinics, outpatient centers, or community hospitals.
- Approvals and commissioning are quicker since less structural radiation shielding and permitting are required.

Improved Patient Access and Experience

- Treatments can be delivered in compact, comfortable environments, often alongside surgical, imaging, or medical oncology services.
- Unlike traditional vaults with thick doors and maze entries, self-shielded linear accelerators can offer open layouts, integrated audio/video communication, and even allow staff to remain near the patient.

Advanced Technology Integration

- Self-shielded linear accelerators are designed specifically for SRS and feature short source-axis distances, gyroscopic motion, and fine beam collimation for exceptional dose targeting.
- These self-shielded linear accelerators are engineered with shielding that keeps radiation leakage well below IEC and NCRP safety limits, ensuring safety for nearby personnel and adjacent facilities.
- Designed for frameless, outpatient-based SRS without general anesthesia, enhancing patient convenience and reducing care complexity.

Statement of the Adverse Effects on Providers or Consumers if the Change is Not Made

Not approving an adjusted statewide need determination for a self-shielded, SRS-dedicated linear accelerator would have negative consequences for both radiation therapy providers and the patients they serve. Without this adjustment, a provider is effectively blocked from bringing more flexible, lower-cost, and patient-centered technologies into communities served by traditional linear accelerator models. The resulting limitations would widen access disparities, constrain innovation, and prolong avoidable inefficiencies in cancer care delivery.

From a consumer perspective, the most immediate impact is reduced access to innovative, high-quality, precision radiation therapy. Traditional linear accelerators require construction of costly and space-intensive radiation vaults, which most physician practices, ambulatory settings, and outpatient clinics cannot afford or accommodate. Without the ability to introduce self-shielded, SRS-dedicated linear accelerators, patients must continue to travel to larger hospital campuses for daily radiation treatments that often span four to six weeks. This barrier to timely care increases the risk of treatment delays, lower adherence rates, and worse clinical outcomes, especially for the elderly, disabled, or low-income patients with limited transportation options.

For providers, the lack of an approved statewide pathway for a self-shielded, SRS-dedicated linear accelerator imposes substantial operational and financial barriers. Healthcare organizations that seek to improve local access or expand outpatient oncology services are forced to pursue high-cost infrastructure projects that may not be feasible in leased buildings, shared medical office space, or smaller healthcare campuses. The inability to offer SRS and other advanced modalities in decentralized settings undermines provider efforts to embrace modern, value-based care models.

Clinically, the absence of self-shielded, SRS-dedicated linear accelerators limits the ability of providers to adopt new technologies that improve patient outcomes. These systems offer enhanced beam precision, reduced leakage radiation, and compact treatment environments tailored for neurological and stereotactic procedures.

Not approving this adjusted need determination effectively stifles access to safer, more comfortable, and technologically advanced treatments that are already available in other states and internationally.

Furthermore, without an adjusted need determination, North Carolina risks falling behind national trends in outpatient cancer care delivery. Several states are embracing vault-free linear accelerators as a way to expand access without expanding hospital infrastructure. In contrast, maintaining current assumptions in the SMFP may inadvertently favor large institutional systems at the expense of smaller, community-based providers trying to deliver innovative, patient-focused solutions.

Statement of Alternatives Considered and Found Not Feasible

In developing this petition for an adjusted need determination for a self-shielded, SRS-dedicated linear accelerator, two alternatives were considered. However, under the current linear accelerator need determination methodology outlined in the SMFP, they were found to be neither feasible or appropriate to meet the unique benefits, access needs, and technology characteristics associated with self-shielded, SRS-dedicated linear accelerators.

Reliance on Standard Need Methodology

The most direct alternative would be to rely on the existing standard need determination methodology in the SMFP. However, this method is built around traditional vault-based, hospital-installed linear accelerators. It is structured primarily on historical utilization patterns, capacity metrics, and service area–based volume thresholds, which do not capture the operational differences, clinical applications, or geographic flexibility offered by self-shielded, SRS-dedicated linear accelerators.

Self-shielded, SRS-dedicated linear accelerators are designed for SRS and are not intended to replace general-purpose linear accelerators used for all cancer modalities including prostate, breast, and head and neck cancers. As such, self-shielded, SRS-dedicated linear accelerators operate under a different clinical model, typically with a lower total patient volume but higher precision per case.

Therefore, using standard methodology does not accommodate the clinical or deployment characteristics of self-shielded, SRS-dedicated linear accelerators and results in an effective exclusion of this technology from consideration.

Mobile Radiation Therapy Unit Need Determination

Mobile radiation therapy has been deployed in select US rural regions, but mobile units are typically configured for conventional fractionated therapy and require periodic transportation, large logistical investments, and fixed shielding strategies. They are not suitable for the high precision, high-stability requirements of cranial SRS and cannot match the dosimetric or safety performance of a dedicated self-shielded, SRS-dedicated linear accelerator installed in a fixed outpatient location.

No Unnecessary Duplication of Health Resources

The proposed adjusted statewide need determination for a self-shielded, SRS-dedicated linear accelerator will require any applicant to meet the utilization performance standards in 10A NCAC 14C .1903(3). As a result, the adjusted need determination would not result in unnecessary duplication of health resources.

Based on the performance standard required to operate an additional linear accelerators, 10A NCAC 14C .1903(5)(a) and (b) requires an applicant to project that the linear accelerators identified in Items (1) and (2) of this Rule and the proposed linear accelerator shall perform during the third full fiscal year of operation following completion of the project either: 6,750 or more ESTVs per linear accelerators; or serve 250 or more patients per linear accelerators.

Currently, self-shielded, SRS-dedicated linear accelerators are designed specifically for SRS focused on tumors, lesions, and conditions in the brain, head, and neck. This limited radiation patient population requires a larger service area, as compared to traditional linear accelerators.

Evidence that the Proposed Change is Consistent with the Three Basic Principles Governing the Development of the SMFP: safety and quality, access, and value.

The request for an adjusted need determination for a self-shielded, SRS-dedicated linear accelerator is fully aligned with the three basic principles governing the development of the SMFP: safety and quality, access, and value. By enabling the strategic deployment of a vault-free, self-shielded linear accelerator technology, North Carolina can modernize its cancer care infrastructure while advancing equity, reducing costs, and improving clinical outcomes.

Safety and Quality

Self-shielded, SRS-dedicated linear accelerators are engineered to meet and often exceed national and international radiation safety standards. These linear accelerators are designed with integrated shielding that contains leakage radiation to levels far below the thresholds set by the International Electrotechnical Commission and the National Council on Radiation Protection and Measurements. With beam energies tailored for SRS (typically ≤3 MV), these linear accelerators exhibit significantly lower scatter radiation and penumbra than traditional high-energy linear accelerators, enabling precise dose delivery with better protection of healthy tissue.

Clinical studies have demonstrated that self-shielded, SRS-dedicated linear accelerators provide superior dose gradients, especially in cranial SRS applications, with fewer monitor units, reduced normal brain exposure, and minimized treatment time. These improvements directly enhance patient safety and treatment quality, particularly for brain metastases, meningiomas, and functional disorders requiring high-conformity, high-precision therapy.

Access

Approving a self-shielded, SRS-dedicated linear accelerator need determination directly improves access by allowing installations in a setting that cannot support conventional linear accelerator infrastructure. Traditional linear accelerators require multi-ton concrete vaults requiring a location within a hospital or oncology treatment center, while self-shielded, SRS-dedicated linear accelerators can be placed in physician offices, ambulatory surgical centers, outpatient clinics, and outpatient clinics.

Value

From a fiscal and strategic standpoint, self-shielded, SRS-dedicated linear accelerators offer a high-value solution to growing cancer care demands. They eliminate the need for vault construction, reducing capital costs by $1.5 million to $2.5 million per installation. They require less physical space, shorter construction timelines, and lower ongoing facility maintenance, making them financially viable for both independent practices and health systems seeking to expand without the burden of full-scale hospital infrastructure.

Furthermore, these self-shielded, SRS-dedicated linear accelerators support value-based care goals by enabling efficient, localized treatment delivery, reducing unnecessary referrals, and improving the patient experience, all while maintaining or exceeding clinical standards.

Summary

Raleigh Neurosurgical Clinic is requesting an adjusted statewide need determination for one (1) linear accelerator demonstration project, specifically a self-shieled, SRS-dedicated linear accelerator in the *Proposed 2026 SMFP*.

Raleigh Neurosurgical Clinic appreciates the SHCC and staff's time and attention and is pleased to answer any questions.