Petition to the State Health Coordinating Council Regarding a Policy for Dual Function Fixed PET Scanners in Mid-Size Cancer Centers

2025 State Medical Facilities Plan

March 6, 2024

Petitioner:		*Contact:*	
Name:	Carteret Health	**Name:**	Kyle Marek
Address:	3500 Arendell Street Morehead City, NC 28557	**E-mail:**	kmarek@carterethealth.org
		Phone:	252.499.6000

STATEMENT OF REQUESTED ADJUSTMENT

Carteret Health respectfully requests a change in the *2025 State Medical Facilities Plan* to allow American College of Surgeons designated Community Cancer Centers to acquire a Positron Emission Therapy ("PET") scanner irrespective of the need calculated by the Standard Methodology in the State Medical Facilities Plan. The policy requires that the PET scanner function in two roles: as both a fixed PET scanner and as a simulator for planning treatments on the cancer center's linear accelerators. This dual use efficiency would reduce the performance requirement of 2,080 scans for a Fixed PET scanner to 1,040 scans. Suggested wording follows:

Policy TE-4: Plan Exemption for Fixed PET Scanners in Mid-Size Cancer Centers

The applicant proposing to acquire a fixed Positron Emission Therapy (PET) scanner shall demonstrate in its certificate of need (CON) application that:

1. it is a licensed North Carolina acute care hospital or hospital campus that has the following characteristics:
    a. has licensed acute care beds;
    b. provides emergency care coverage 24 hours a day, seven days a week.
    c. offers external beam radiation therapy on a linear accelerator on the date of the CON application;
    d. has Certificate of Need approval for at least two linear accelerators;
    e. offers mobile PET scanning through a third-party contract; and
    f. does not own or have a Certificate of Need to own a Fixed PET scanner.
2. the proposed Fixed PET Scanner equipment will have capacity to function as both a linear accelerator simulator and a PET scanner;
3. the proposed PET Scanner installation will provide both linear accelerator simulator and PET scan functions in an American College of Surgeons Community Cancer Program or Comprehensive Community Cancer Program,
4. the Proposed PET scanner will perform at least 1,040 PET procedures during the third full operating year.
5. The proposed fixed PET scanner will be located:
    a. on the main campus of the hospital as defined in G.S. § 131E-176(14n); or

b. on an acute care hospital campus that operates under the main hospital's license.

The proposed fixed PET scanner cannot be located at a site where the inventory in the SMFP reflects that there is an existing or approved fixed PET scanner. The proposed scanner may operate as part of the hospital, a diagnostic center, or an independent diagnostic testing facility (IDTF) location that does not currently provide fixed PET scanner services.

The performance standards in 10A NCAC 14C .3703 are not applicable.

REASON FOR THE PROPOSED ADJUSTMENT

The standard methodology for PET scanners generates a need only when existing scanners reach a performance standard of 2,400 annual procedures. (Translation of Step 3 p 363)

The Standard Methodology provides imperfect access

Part 2 of the standard methodology grants an exemption for "major cancer centers," defined as hospital cancer centers with two or more linear accelerators doing a combined total of 12,500 ESTVs a year. Such centers, which do not have a fixed PET scanner, can apply for a CON for a fixed PET scanner, regardless of the calculated need in the SMFP. However, a smaller center offering comprehensive cancer services may have two approved linear accelerators but may not reach the 12,500 ESTV threshold. For reference purposes, we note that 12,500 ESTV's justifies a third linear accelerator. Capacity of a linear accelerator is 6,750 ESTV's according to the methodology in Chapter 15F of the 2024 SMFP.

PET scanning is now a standard component of cancer treatment.

PET scanners produce images of metabolic activity by taking radiographic images of patients who have been given short life isotopes. At one time only one isotope, FDG was routinely available, and it demonstrated only glucose metabolism. Many new isotopes now available show a wider range of metabolic activity. As a result, PET scanners are now more versatile and have become routine elements of managing cancer treatment. See Attachment A for more discussion of new isotopes and their role in cancer treatment. At one time, these short half-life isotopes were only available in a limited number of places. That too has changed.

Technology advances make a dual function Fixed PET Scanner feasible

The technology of PET scanning equipment has advanced, as well. Several manufacturers make equipment that *can function as both a diagnostic PET scanner and as a simulator for developing linear accelerator treatment plans*. Linear accelerators deliver high intensity external beam radiation to destroy cancer cells. To function, they need digital images of the cancer relative to the patient and patient position on the linear accelerator platform. Simulators produce these, exposing the patient to minimal radiation. Data from the simulator feeds electronically to the linear accelerator to establish the dimensions of the treatment beam relative to the tumor(s) and the patient position on the linear accelerator table. Most simulators are CT scanners. See Attachment B for a glossary of PET scanner terms.

A cancer center that has two linear accelerators can function more efficiently with more than one but less than two simulators. Dual function equipment that can function as either simulator or fixed PET scanner provides this efficiency.

The SMFP, as written, does not consider the needs of a mid-size cancer center. A cancer center can have enough patient demand to justify two linear accelerators, but not enough to require 2,400 annual PET scans. Economically, it is more cost effective to acquire a single piece of equipment that can perform two functions – as both a simulator for the linear accelerator and a Fixed PET scanner.

According to the 2024 SMFP, two North Carolina cancer centers located in smaller communities have PET scanners and two linear accelerators, Nash General Hospital and Southeastern Regional Medical Center. Neither provides close to 12,500 annual ESTVs on their two linear accelerators, or close to 2,400 PET scans. However, both PET scanners serve important roles in the respective cancer centers.

Because PET scanning is now a routine component of cancer care staging, the SMFP should have provisions for a cancer center that has two linear accelerators and no fixed PET scanner to add this important capacity efficiently.

The PET/CT simulator has features for radiation therapy planning that are not available on a standard oncology CT simulator. The addition of PET images, obtained in treatment position at the time of simulation, increases sensitivity, specificity, and accuracy of radiation target delineation for patients with head and neck, lung, cervix, anal, esophageal, and prostate cancers. While it is not perfect for all patients, due to the narrower CT bore size and reduced size range for metallic artifact attenuation, the fused PET/CT simulator would be the ideal treatment planning platform for a sizable portion of CHC patients, particularly among patients receiving definitive-intent therapy. These patients may be leaving the county for all their treatment, because one element is missing.

The standard SMFP methodology does not anticipate the option of a dual purpose, Fixed PET scanner/ linear accelerator simulator. However, when Fixed PET scanner technology serves more than one function, it requires fewer PET scan procedures to be financially viable. The double function equipment makes it possible for mid-size cancer centers to offer a full range of cancer services.

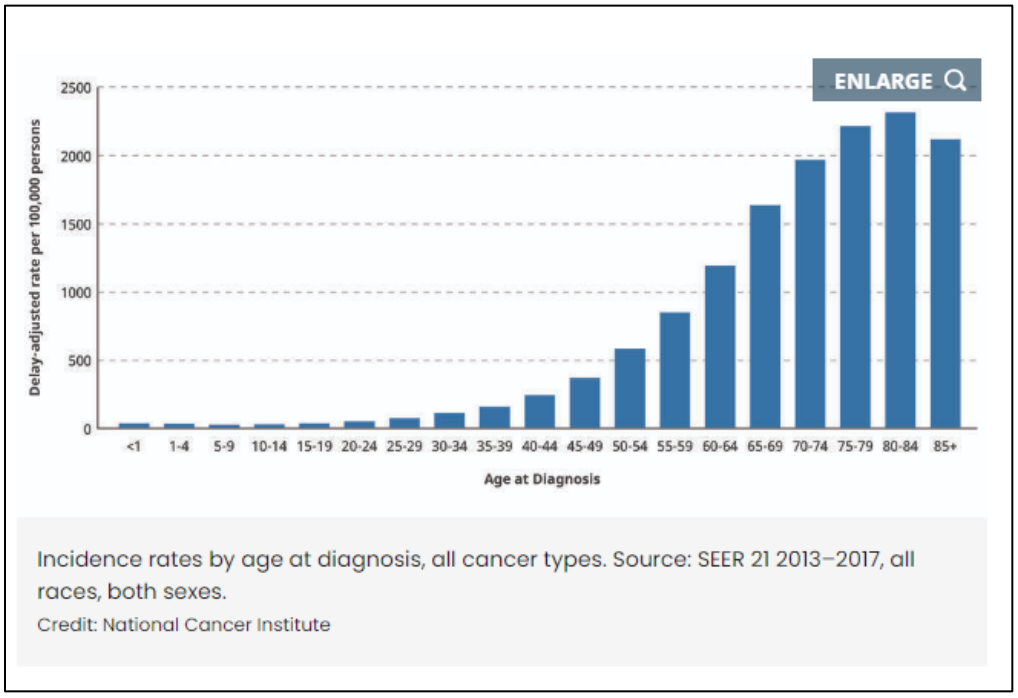
Mobile PET scanners provide limited access

The requirement that applicants offer mobile PET scanning will confirm an applicant's commitment to including the modality in its cancer program. However, mobile PET scanners are an imperfect solution. They are not available every day, they offer a limited range of isotopes, and they involve the added cost of the mobile management company. Locations with mobile scanners may still refer out half of their cancer center patient PET scans. The mobile scanners typically offer only the FDG isotope.

An Aging North Carolina population will have more cancer

Age and cancer rates have a direct correlation, with cancer rates rising as people age. SEER data indicate that cancer rates increase exponentially with age, between age 45 and 75.

Figure 1: New Cancer Diagnosis Rates by Age



Incidence rates by age at diagnosis, all cancer types. Source: SEER 21 2013–2017, all races, both sexes.

Credit: National Cancer Institute

Challenges of geography and demographics of North Carolina are a consideration in access to PET scans

Carteret General Hospital exemplifies a community cancer center that would benefit from this policy. County population is much older than the state, its geography includes waterways that separate many communities by long distances from major cancer centers. It has CON approval for two linear accelerators. It has mobile PET service from a third-party vendor, but only one day a week, on Sunday. It is in HSA VI. However, the American College of Surgeons community and comprehensive cancer centers may also qualify.

STATEMENT OF ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS IF THE ADJUSTMENT IS NOT MADE

Cancer treatment is taxing for the patient and the patient's family / support group. The person with cancer cannot transport themselves to treatment or to the screenings. Thus, at least two people have disrupted schedules for every test and every treatment.

PET scans are a routine part of treatment planning for cancer treatment. When the treatment and the screening for planning the treatment are in two separate places, the logistics are more complicated. The SMFP policies support eliminating barriers to service access.

Residents of larger communities are not as likely to experience as large an access barrier. In a larger community the patient may be getting linear accelerator simulation and treatment in one place and go elsewhere for PET scans. However, that community may have a PET scanner closer to the cancer patient's home. In a smaller community (county) if the PET scanner is not at the cancer center – and likely there will be only one – the patient and support person must plan for a whole new set of logistics and the providers must take extra coordination steps – both add to cost and risk communication errors in the transition.

With improved cancer treatment, the state has more cancer survivors. And cancer survivors are at risk for re-occurrences that require treatment. Attachment # provides a summary of selected Cancer Survival rates in North Carolina.

STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

Wait for Standard Methodology

Waiting for the SMFP to produce a need without the policy is unreasonable. In Health Service Area VI, for example, PET scanners operate at about 50 percent capacity. The threshold for a new PET scanner is 80 percent of capacity. HSA IV has the largest land mass in North Carolina, 29 counties and 3,000 square miles. Patients should not be penalized for living too far from services when alternatives – efficient ones – are available.

Expand the eligible group

Restricting eligible applicants to hospitals provides consistency with Step 2 of the standard methodology for Fixed PET Scanners. It also assures that the provider of this expensive technology also participates in the community safety net role required by EMTALA. Step 2 of the Standard Methodology is less restrictive. It does not require that the hospital have an emergency room.

The ACS requirement provides third party quality oversight. ACS has a rigorous program for accreditation of these two levels of cancer centers. See Attachment C.

Require fewer linear accelerators

The requirement for two linear accelerators is also consistent with Step 2 of the Standard Methodology. It also assures that demand for the linear accelerator simulator function of the Fixed PET Scanner equipment will be sufficient to justify what will a second, though part-time linear accelerator simulator.

Some asked why not permit this exemption for a cancer center that offers brachytherapy or chemotherapy. Brachytherapy is highly specialized and can be offered at limited scale in a physician office, or in a radiation oncology cancer center as an adjunct therapy. Brachytherapy does not require a simulator and could not benefit from the efficiency of the dual function PET Scanner/ Simulator equipment. A radiation therapy simulator supports only a linear accelerator

Repeat a Summer Petition

Carteret Health filed a special need petition in Summer 2023. In discussion of the petition, SHCC members suggested that the need may be broader than Carteret. The Agency noted that the proposal would require adjustments to the Performance Standard rules for PET Scanners and recommended that Carteret Health consider a petition that does not involve a change in Administrative Rules. This option provides a systematic path for mid-size cancer centers to develop.

EVIDENCE OF NO UNNECESSARY DUPLICATION OF SERVICES

The narrow definition of eligible applicants will limit the number of additional PET scanners in the state. A cancer center that has two linear accelerators and is already offering limited PET scanning should have an opportunity to demonstrate that it can provide better and more efficient access for patients.

Extending the provision only to dual use equipment will make it possible to offer PET scanning cost effectively in mid-size cancer centers. It is impossible to purchase a partial PET scanner or a partial linear accelerator simulator. A Fixed Scanner allows the cancer center to schedule patients on any day of the week. By contrast, for example, Carteret's mobile unit is available only on Sundays.

With age comes new cancer cases. Counts of new cancer cases typically do not include cancer survivors. These patients currently represent about 25 percent of CHC's cancer patients. The number of survivor patients will increase as systemic therapy has become more effective in prolonging the survival of patients with advanced or metastatic cancer. Data in Attachment D show North Carolina cancer survival rates by cancer type. Retreatments represent 25 percent of Carteret Health Cancer patients. Effective care means people live longer, but metastatic cancers do reoccur and are effectively retreated.

EVIDENCE OF CONSISTENCY WITH NORTH CAROLINA STATE MEDICAL FACILITIES PLAN

Basic Governing Principles

1. *Safety and Quality*

This basic principle notes:

> "*…priority should be given to safety, followed by clinical outcomes, followed by satisfaction.*
> "*…As experience with the application of quality and safety metrics grows, the SHCC should regularly review policies and need methodologies and revise them as needed to address any persistent and significant deficiencies in safety and quality in a particular service area*."

PET scanning is now a standard element of cancer care. Equipment and isotopes have advanced significantly since Massachusetts General introduced this modality in the 1950's. Adopting a policy that permits cancer centers that have two linear accelerators but falls short of the definition of "major cancer center" to adopt dual purpose simulator / scanner technology provides North Carolina with a natural and systematic progression and maintains safety and quality while increasing access.

Requiring American College of Surgeons designation as a comprehensive community cancer center or a community cancer center, provides assurance of third-party oversight.

Restricting the policy to hospitals assures that the PET scanner will operate in a setting governed by North Carolina licensure.

2. *Access*

This basic principle notes:

> "*…The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers.*
> *"…The SHCC planning process will promote access to an appropriate spectrum of health services at a local level, whenever feasible under prevailing quality and value standards."*

Adopting a policy that accommodates the cancer center that does not have a PET scanner and is in a small county addresses this basic principle. North Carolina has 10.5 million people. With more people comes more traffic congestion and longer travel distances from major health centers. Mid-sized health care centers are growing, as they should, to fill in that gap.

Step 1 of the Standard Methodology permits additional PET scanners only when existing centers reach 80 percent of capacity. It provides an exception in Step 2 for "major cancer centers." However, the definition of "major" does not provide for the reasonable needs of mid-size cancer centers. This proposed policy would bridge that gap.

Using Carteret Health as an example, it is easy to see that mobile scanner limitations regarding schedule and radiotracers means that treating physicians must send about half of the county's cancer patients out of the county for their PET/CT imaging. The Carteret Health Cancer Program Needs Assessment has repeatedly identified transportation as one of the most significant barriers to care for patients getting cancer care in Carteret County. Transportation problems only get worse when the necessary diagnostic PET/CT imaging is unavailable near where they live. This often leads to delays in care, particularly for patients with disability or those facing financial hardship.

3. *Value*

This basic principle notes:

> *"The SHCC defines health care value as the maximum health care benefit per dollar expended.*
> *"…Cost per unit of service is an appropriate metric…*
> *" …At the same time overutilization of more costly and/or highly specialized low-volume services without evidence-based medical indication may contribute to escalating health costs without commensurate population-based health benefit."*

A dual function piece of equipment – simulator / PET scanner will enable the cancer center to keep its costs closer to those of a larger center that has a dedicated fixed PET scanner. Restricting the exemption to a hospital will assure provision of the service by an entity that participates in the county's health care safety net.

CONCLUSION

The proposed policy would close a substantial gap in the SMFP with regard to PET scanners. It will provide a cost-efficient solution and still provide reasonable limits on the number of Fixed PET scanners in the state.

ATTACHMENTS:

PET Radioisotopes ..... A

Glossary of Terms PET Scanners ..... B

Glossary of Terms ACS Cancer Centers C

Cancer Survival Rates ..... D

Attachment A: PET Radioisotopes

PET scanning technology involves radiopharmaceuticals that have extremely short half-lives. The mobile PET scanner contract very specifically restricts scans to one common isotope, FDG. However, PET scanning has advanced, and other organ specific isotopes are now available and better for certain types of PET scans. Because the mobile unit cannot provide specialized isotopes, such as PSMA, Ximum, Amyvid, and Cerianna, CHC cannot offer brain, breast, or prostate cancer scans. As a result, a cancer center that relies on a mobile PET scanner must refer almost half its cancer patients who need PET scans out of the county.

Stand-alone PET/CT scans are critical tools for staging cancer and evaluating treatment effectiveness. The PET/CT simulator has features for radiation therapy planning that are not available on a standard oncology CT simulator. The addition of PET images, obtained in treatment position at the time of simulation, increases sensitivity, specificity, and accuracy of radiation target delineation for patients with head and neck, lung, cervix, anal, esophageal, and prostate cancers. While it is not perfect for all patients, due to the narrower CT bore size and reduced size range for metallic artifact attenuation, the fused PET/CT simulator would be the ideal treatment planning platform for a significant portion of CHC patients, particularly among patients receiving definitive-intent therapy. These patients may be leaving the county for all their treatment, because one element is missing.

Newer radioisotopes specific for brain, breast and prostate scans are not available on mobile PET scanners. Yet, together, these three cancer types represent about half of new cancer patients.

Attachment B: Glossary of PET Equipment Terms

PET Scanner

PET scans measure metabolic activity within the body's tissues. By injecting a small amount of radioactive material (tracer), PET scans can visualize how tissues and organs are functioning in real-time. This is particularly useful for detecting cancer, monitoring cancer treatment, evaluating brain abnormalities, and more.

The tracer's positrons collide with electrons in the body, producing gamma rays that are detected by the scanner to create images. The images highlight areas of high tracer absorption, indicating higher levels of chemical activity, which often correlate with disease areas. Focuses on the metabolic or chemical activity in the body, providing functional imaging. This involves exposure to radioactive tracers, but the amount of radiation is generally low and considered safe. The radioactive material decays quickly and leaves the body within a few hours to days.

CT Scanner

CT scans use X-rays to create detailed cross-sectional images of the body's internal structures, such as bones, blood vessels, and soft tissues. It provides a more detailed image than standard X-rays, making it valuable for diagnosing diseases, injuries, and monitoring the progression of certain conditions. CT scanners emit a series of narrow beams through the human body as it moves through an arc, creating a series of images from different angles that a computer then reconstructs into cross-sectional slices of the body. It provides detailed anatomical information, offering structural imaging. It excels at visualizing the shape, size, and location of structures in the body. It exposes patients to ionizing radiation from X-rays, which is a concern with repeated exposure. Radiologists work to minimize dose without compromising image quality.

Combination PET/CT Scanner

In practice, PET and CT scans are often combined into a single PET/CT scan to provide both functional and structural information in one imaging session. This combination offers a more comprehensive diagnostic tool, allowing for accurate localization and characterization of abnormalities.

Linear Accelerator

A linear accelerator, also referred to as LINAC, is a machine that aims external radiation at cancer tumors with pinpoint accuracy, sparing nearby healthy tissue. It is used to deliver several types of external beam radiation therapy.

Simulator for external radiation therapy

A machine called a simulator takes images or scans to give the healthcare team a picture of the part of the body to be treated by the external beam radiation therapy linear accelerator. The most common type of simulator used is a CT (computed tomography) simulator. An X-ray simulator may also be used in some situations. A simulator is not a treatment machine. These simulations help the radiation therapy team decide where and how to direct the radiation.

PET/CT equipment can also be designed for use for certain cancer simulations for the linear accelerator. The PET simulator may be involved in cancer treatment.

Attachment C: Glossary of American College of Surgeons Cancer Center Terms

Community Cancer Program (CCP) The facility accessions 100 but fewer than 500 newly diagnosed cancer cases each year.

C**omprehensive Community Cancer Program (CCCP)** the facility accessions 500 or more newly diagnosed cancer cases each year.

Source: https://www.facs.org/quality-programs/cancer-programs/commission-on-cancer/coc-accreditation/categories/

Attachment D: Survival Rates Selected Cancers North Carolina

2016-2020 Cumulative Observed and Relative Survival of 6 Selected Cancer Sites in North Carolina						
	NORTH CAROLINA					
	Cumulative observed survival	Lower 95% CI for observed survival	Upper 95% CI for observed survival	Cumulative relative survival	Lower 95% CI for relative survival	Upper 95% CI for relative survival
COLON/RECTUM	50.2%	49.4%	51.0%	58.4%	57.5%	59.3%
LUNG/BRONCHUS	21.7%	21.3%	22.2%	25.6%	25.1%	26.1%
MELANOMA (SKIN)	84.6%	84.1%	85.0%	97.8%	97.2%	98.3%
FEMALE BREAST	82.8%	82.4%	83.2%	92.6%	92.1%	93.0%
CERVIX UTERI	56.5%	53.8%	59.0%	59.9%	57.1%	62.6%
PROSTATE	81.6%	81.1%	82.1%	92.5%	91.9%	93.0%
ALL CANCERS	56.6%	56.4%	56.8%	65.0%	64.7%	65.2%

Produced by the NC Central Cancer Registry, 03/2023
Numbers are subject to change as files are updated.
The Ederer II method is used to estimate expected survival.
Cumulative Relative Survival: survival rates among cancer cases compared to survival rates of general population during the analysis years.
Note: Cancer cases were presumed to be alive at the time of analysis unless indicated as dead by National Death Index,
Social Security Death Index or North Carolina Death Records by the end of 2021 during follow-up.
This method of follow-up is passive. Thus survival rates may be higher than expected. Please use with caution.
Cancer survival statistics are typically expressed as the proportion of patients alive at some point subsequent to the diagnosis of their cancer.
Relative survival is an estimate of the percentage of patients who would be expected to survive the effects of their cancer when compared to the death rate of general population.
Observed survival is the actual percentage of patients still alive at some specified time after diagnosis of cancer. It considers deaths from all causes, cancer or otherwise. Overview of Population-based Cancer Survival Statistics describes the methodologies involved in calculating cancer survival statistics. http://seer.cancer.gov/statistics/types/survival.html
For example, the cumulative observed suruvial for colorectal cancer was 50.2%, meaning that as obeserved in cancer registry data, 50.2% of people with colorectal cancer survived at the end of 2021 since their cancer diagnosed between 2016 and 2020.
As for cumulative relative suvival of 58.4% in colorectal cancer, it can be interpreted as: compared to the overall survival of general population, 58.4% of people with colorectal cancer survived at the end of 2021 since their cancer diagnosed between 2016 and 2020.