

Technology and Equipment Committee
Agency Report
Change the Methodology for Fixed PET Scanners or Develop a Policy for
Dual-Function Fixed PET Scanners in Mid-Size Cancer Centers
Proposed 2025 State Medical Facilities Plan

Petitioner:

Carteret Health
3500 Arendell Street
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Contact:

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Request:

Carteret Health requests either modifications to the fixed positron emission tomography (PET) scanner methodology or the addition of a policy exemption for dual-functioning fixed PET scanners in “mid-sized” cancer centers in the *2025 State Medical Facilities Plan (SMFP or “Plan”)*.

Background Information:

Chapter Two of the *North Carolina 2024 SMFP* provides that “[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” The *Plan’s* annual planning process and timeline allows for the submission of spring petitions for changes to policies and methodologies in the *SMFP* and summer petitions requesting adjustments to need projections in the *SMFP* to the State Health Coordinating Council. It should be noted that any person may submit a certificate of need (CON) application for a need determination in the *SMFP*.

The standard need determination methodology for fixed PET scanners establishes a service area need under two conditions. The first condition is specific to service areas with facilities that have a deficit of PET scanners. A deficit occurs when a facility’s overall utilization of dedicated fixed scanners is 2,400 or more scanner procedures, which is at least 80% of a scanner’s capacity. The service area’s need determination will be the number of all facility deficits minus the number of placeholders for need determinations from previous SMFPs. In the second condition, a service area has a need determination for one additional fixed scanner if a major cancer treatment center - defined as a hospital-based provider that does not operate or own a dedicated fixed PET scanner: 1) operates two linear accelerators (LINACs); and 2) performed over 12,500 Equivalent Simple

Treatment Visit (ESTV) procedures during the current reporting year. A fixed PET scanner's service area is the health service area (HSA) in which it is located. The *2024 SMFP* does not have any policies specific to the acquisition of fixed PET scanners.

Carteret Health operates Carteret General Hospital (CGH) in Carteret County, which is located in PET service area HSA VI. CGH does not own a fixed PET scanner; rather, PET scanning services are provided once a week through a third-party vendor. In HSA VI, three fixed PET scanners are currently in operation, and one is under development. Specifically, CarolinaEast Medical Center in Craven County and Nash General Hospital in Nash County each operate one fixed PET scanner. Vidant Medical Center in Pitt County operates one scanner and has a CON for a second scanner. The *2024 SMFP* does not show a need determination for a fixed PET scanner in HSA IV.

In the *SMFP*, counties are grouped into 28 LINAC planning service areas. CGH is located in LINAC service area 24. It operates one LINAC, and it has a CON for a second LINAC, which is not yet in operation. There are three additional LINACS in service area 24: one operated by Onslow Radiation Oncology in Onslow County and two operated by CarolinaEast Medical Center.

The Petitioner submitted a 2023 summer petition requesting to lower the Performance Standard in Certificate of Need Regulation 10A NCAC 14C .3703, which states that applicants proposing to acquire a fixed PET scanner shall project that the proposed fixed scanner will perform at least 2,080 procedures by the third full year of operation. The Petitioner requested that the Performance Standard be reduced to 1,040 procedures. In their Petition, they asserted that the modification would make it easier for CGH to acquire a single piece of equipment that functions as both a fixed PET scanner and a LINAC simulator. The SHCC denied the petition on the basis that: 1) the attempts to modify the Performance Standard would need to undergo the rulemaking process; 2) such a modification would have a statewide impact; and 3) because the need methodology for fixed PET scanners addresses only fixed PET/CT scanners, a spring petition would be required to establish either a new methodology or a new policy for a PET scanner/LINAC simulator.

Analysis/Implications:

The Petitioner has submitted two spring petitions as alternative pathways to allow "...American College of Surgeons designated Community Cancer Centers to acquire a [PET] scanner irrespective of the need calculated by the Standard Methodology in the [SMFP]." According to the Petitioner, either modifying the fixed PET scanner need methodology or adding a policy for fixed PET scanners would address the need for scanners in "mid-sized cancer centers". Mid-sized cancer centers are not defined in the *SMFP*. The Petitioner describes such centers as ones that have enough patient demand for two LINACs, but not enough to require 2,400 or more PET procedures. The Petitioner asserts that a PET scanner/LINAC simulator machine requires fewer scans to be financially viable, and in facilities with two LINACs, a second simulator would also allow two patients to be in simulation at the same time. Further, the Petition highlights that the PET scanner function of this machine includes more advanced, and other organ-specific isotopes that are not provided on the mobile scanner it utilizes, and therefore, brain, breast and prostate cancer scans cannot be offered on it.

Proposal to Modify the Fixed PET Scanner Methodology

As described above, there are two conditions by which a service area need determination for a fixed PET scanner can be generated. The Petitioner proposes a revision to the second condition so that more hospitals with cancer treatment programs can be considered “major” cancer centers. To achieve this, the Petitioner requests to change one methodology step and to add a step. The Petitioner’s language is in blue text and underlined below:

Part 2, Step 5: Identify each major cancer treatment facility, program, or provider in the state, defined as providers that operate two [LINACs] that performed over ~~12,500~~ 7,000 ESTV procedures during the current reporting year (Table 15C-5).

Part 2, Step 8: A Fixed PET Scanner in a “major cancer center” defined in Part 2 shall be exempt from the Performance Standards for Fixed PET Scanners if the proposed equipment will be a Fixed PET Scanner designed and used for dual-function as a linear accelerator simulator, and a fixed PET scanner and the number of diagnostic and treatment PET scans proposed is at least 1,040 in the third year of operation.

Changing the methodology as recommended presents multiple challenges. Any efforts to reduce performance standard thresholds must be addressed through the rulemaking process. Also, changes to need methodologies require a collaborative study undertaken by Agency staff, SHCC members, and field experts through workgroups or meetings of interested parties.

Proposal to Add a Policy for Fixed PET Scanners

The Petitioner has proposed the inclusion of the policy below in the *2025 SMFP* as an alternative to their above proposal to change the fixed PET scanner methodology.

Proposed 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.

Regarding the first requirement of the proposed policy, Agency review of the fixed PET scanner data provided on 2023 Hospital LRAs and 2023 Equipment R&I forms revealed that 26 facilities operated fixed PET scanners, and 92% of them are located on a campus of a licensed acute care hospital. The remaining fixed PET scanners are at two free-standing facilities. Hospitals that currently operate fixed PET scanners also operate at least two LINACs – except for Atrium Health Union, which operates one LINAC. In sum, there is support for most elements of the first requirement. However, the Agency finds no reason why the applicant must already offer PET services before being eligible for a fixed PET scanner under this policy. There is also support for the second requirement of the proposed policy based on the Petitioner's description of the benefits of dual-functioning machines.

Additionally, Agency staff examined data pertaining to the policy's third requirement which uses the American College of Surgeons (ACS) Commission on Cancer's¹ categories of cancer programs to define the facilities that would be eligible under the policy. They are:

- **Community Cancer Program (CCP):** The facility accessions more than 100 but fewer than 500 newly diagnosed cancer cases each year.
- **Comprehensive Community Cancer Program (CCCP):** The facility accessions 500 or more newly diagnosed cancer cases each year.

While the Petitioner defines mid-sized cancer centers according to these categories, the Agency does not collect data on the number of newly diagnosed cancer cases. Therefore, we would be unable to determine which cancer centers would be eligible to apply for a fixed PET scanner under the policy on that basis. One way to identify mid-sized cancer centers may be to examine the number of ESTV procedures performed at each facility with at least two LINACs. The *SMFP* describes major cancer treatment facilities, programs or providers as those that “operate two [LINACs] that performed over 12,500 ESTV procedures during the current reporting year”. This

¹ American College of Surgeons Commission on Cancer Accreditation. [Cancer Program Categories](#)

suggests that a major cancer center with at least two LINACs would perform an average of 6,250 ESTV procedures or more per LINAC. It might be reasonable, then, to define a mid-sized cancer center, as one that owns two LINACs and performed an average of more than 3,125 ESTV procedures per LINAC, or half the ESTV procedures required to be classified as a major cancer center, and up to an average of 6,249 ESTV procedures per LINAC. Table 1 demonstrates the ranges in volume on LINACs and fixed PET scanners during the 2022 data year at hospitals that can be placed in either of these categories.

Table 1. Performance Data of Hospitals that Own Two LINACs, 2022 Data Year

Category	Number of Hospitals in this Category	Average ESTV Procedures/LINAC	Number of fixed PET scanners per Hospital	Average PET scans/ fixed PET scanner
Major Cancer Centers	4	6,350 - 8,682	1 - 2*	1,382 – 2,085
Mid-size Cancer Center	7	3,154 – 4,989	1**	526 – 1,223

Source: 2023 Hospital LRAs and 2023 Equipment Registration and Inventory (R&I) Forms

* Atrium Health Pineville is categorized as a major cancer center, but it does not own a fixed PET scanner.

** Carteret General Hospital is categorized as a mid-sized cancer center, but it does not own a fixed PET scanner.

It is worth noting that of the mid-sized centers, CGH is currently the only hospital-based cancer center that does not operate a fixed PET scanner. The only other hospital with two LINACs that does not own or operate a fixed scanner is UNC Health Blue Ridge of Burke County in HSA I. Based on data submitted on its 2023 LRA, it would need to perform an average of 373 more ESTV procedures per LINAC to qualify as a mid-size cancer center that could apply under a policy that defines these centers as described above.

Agency staff further examined data related to the fourth requirement of the policy that says the applicant must demonstrate that the proposed PET scanner will perform at least 1,040 PET procedures during the third full operating year. There are nine hospitals with two LINACs that also have PET scanners; these hospitals operate one fixed PET scanner each. In 2022, on average, they performed 1,139 PET scan procedures (Table 2). Except for Southeastern Regional Medical Center, all hospitals have operated their LINACS for more than three years. This observation suggests that reducing the procedure requirement for a PET scanner/LINAC simulator to 1,040 is not unreasonable. If this requirement in a policy were approved, then the performance standards outlined in 10A NCAC 14C .3703 could no longer apply.

Table 2. Fixed PET Procedures in Hospitals with Two LINACs, 2022 Data Year

Facility	County of Service	PET Procedures/ Fixed PET Unit	> 3 Years in Operation	HSA
Alamance Regional Medical Center	Alamance	809	✓	II
Catawba Valley Medical Center	Catawba	1,382	✓	I
CarolinaEast Medical Center	Craven	1,149	✓	VI
High Point Regional Health	Guilford	1,223	✓	II
Iredell Memorial Hospital	Iredell	628	✓	III
Novant Health Presbyterian Medical Center	Mecklenburg	2,085	✓	III
FirstHealth Moore Regional Hospital and Pinehurst Treatment	Moore	1,658	✓	V
Nash General Hospital	Nash	526	✓	VI
Southeastern Regional Medical*	Robeson	791	✗	V

* Southeastern Regional Medical Center began operating its fixed PET scanner in data year 2022.

In the proposed policy, the factor that follows the enumerated items says that the proposed scanner cannot be located at a site where there is an existing or approved fixed PET scanner, and it may operate as part of the hospital, a diagnostic center, or an IDTF. If an applicant under the proposed policy cannot own a fixed PET scanner or have a CON for one, then it is unnecessary to state that the proposed scanner cannot be located on a site where there is an existing or approved fixed scanner. Further, the North Carolina Certificate of Need Statute defines a diagnostic center as “[a] freestanding facility, program, or provider, including but not limited to physicians’ offices, clinical laboratories, radiology centers, and mobile diagnostic programs....”² Also, the Medicare Learning Network³ defines IDTFs as facilities independent of both an attending or consulting physician's office and of a hospital. Therefore, including diagnostic centers and IDTFs as potential locations for a proposed scanner is contrary to elements of the policy that indicate it must be located at a hospital’s main campus or a campus that operates under the hospital license.

Agency Recommendation:

The Agency supports the standard methodology and current policies for dedicated fixed PET scanners. Given the available information submitted by the March 20, 2024 deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition to modify the need determination methodology for fixed PET scanners, but approval of the Petition to add a policy for fixed PET scanners. The recommendation is to add the policy proposed in the petition with the following edits (in blue and underlined):

² 2024 State Medical Facilities Plan, Appendix E. https://info.ncdhhs.gov/dhsr/ncsmfp/2024/2024_SMFP.pdf

³ Medicare Learning Network Booklet. <https://www.cms.gov/files/document/mln909060-independent-diagnostic-testing-facility.pdf>

Proposed Policy TE-4: Plan Exemption for Dual-Functioning 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~~
 - e. ~~£~~ 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;~~
3. the proposed PET scanner will provide both linear accelerator simulator and PET scan functions in a cancer center that performed an average of between 3,126 and 6,249 ESTV procedures on a LINAC during the most recent data year; and
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.