Petition to the State Health Coordinating Council Regarding a Special Need Petition for a PET Scanner/CT Simulator In HSA VI

2024 State Medical Facilities Plan

July 26, 2023

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STATEMENT OF REQUESTED ADJUSTMENT

Carteret Health Care ("CHC") requests an adjusted need determination in the 2024 State Medical Facilities Plan (SMFP) for one additional Fixed Positron Emission Tomography (PET) Scanner that would function in a dual role as a linear accelerator simulator, to be designated for a licensed acute care hospital in Carteret County in Health Service Area VI. CHC also requests an adjustment in the performance standard for the third year of operation from 2,080 PET scans to 1,040 scans.

Table 15F-4: Fixed PET Scanner Need Determination

(Scheduled for Certificate of Need Review Commencing in 2024)

It is determined that the service areas listed in the table below need an additional fixed PET scanner.

Service Areas	Replacement MRI Scanner Need Determination	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date	
HSA VI	1***	TBD	TBD	

^{*} Need determination shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

^{**} Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).

^{***} Provided that in response to this need, a scanner should be located in Carteret County in a community acute care hospital that does not own, or whose parent company does not own fixed PET equipment in this area, and that will use this equipment in a dual role as a simulator for radiation therapy on a linear accelerator.

REASONS FOR THE PROPOSED ADJUSTMENT

FIRST POINT: UNIQUE CANCER PROGRAM AT CARTERET HEALTH CARE

Carteret Health Care ("CHC"), a non-profit community health care system, operates Carteret General Hospital, a 135-bed acute care hospital, which has a Comprehensive Cancer Center. Carteret Cancer Center offers both medical and radiation therapy and complementary support services and cares for about 1,000 patients a year including new and retreated cancers. Carteret General medical staff has dedicated medical and radiation oncologists and the Cancer Center will soon have two linear accelerators operating in newly renovated space. In addition to clinical growth, the Cancer Center has experienced meaningful recent improvements in quality assurance and certification. The American College of Surgeons Committee on Cancer designated the CHC a Community Cancer Center in 2013. In 2019 it was awarded with Silver commendation.

Today, CHC provides PET scan services through a third-party owned and operated mobile unit that comes <u>once a week on Sunday</u>. PET scanning technology involves radiopharmaceuticals that have extremely short half-lives. The mobile PET scanner contract very specifically <u>restricts scans to one common isotope</u>, 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, <u>almost half of CHC cancer patients who need PET scans must be referred out</u> of the county.

Even with the limitations, this one-day mobile service is busier than three of North Carolina's full-time PET scanners¹. This year, CHC is on track to provide about 600 PET scans – the maximum available on the mobile unit. The mobile contract also limits CHC to twelve scans a day. Typically, even with the limitations, CHC has a two-week backlog. CHC is grateful to have the mobile PET scanner available – but it is no longer enough to meet demand. The nearest PET scanner in New Bern is about an hour away. Recall that these are cancer patients for whom travel is difficult.

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.

Carteret Health Care is in a unique position today. PET/CT simulator technology has advanced, and the price is down. CHC is midway through construction plans for major improvements to the Cancer Center. Construction should be complete by mid-2025. CHC's single radiation therapy CT simulator is a dual work engine already, serving as the backup CT scanner for the Emergency Department and the simulator for the single linear accelerator. During peak season, it cannot meet demand. The Emergency Department takes precedence, and simulations will be delayed. More simulator capacity is needed, but

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¹ Table 15F-1: Nash General Hospital, Messino Cancer Center, and First Imaging of the Carolinas

there is not enough demand for another full-time simulator. Even when the second linear accelerator comes online, a second dedicated simulator would have excess capacity.

However, CHC has enough current and forecast need to support a single piece of fixed equipment that could function part time as both a simulator and part time as a PET scanner. North Carolina statute requires a Certificate of Need to purchase either a simulator or a PET scanner.

There is a piece of equipment that can meet this need, a PET/ CT simulator scanner. Two vendors produce such equipment – GE and Siemens. The dual function equipment is not new technology; large cancer centers have been using it for more than a decade. The price is now affordable for the community. PET/ CT scanner simulators provide refined information for the linear accelerator simulation, but they cannot accommodate all patient simulations, because some patients need a bigger bore, or opening. They are an ideal means to relieve simulator overflow.

SECOND POINT: SMFP METHODOLOGY WILL NOT GENERATE A NEED IN HSA VI

The fixed PET methodology in Chapter 15F will not address the needs of Carteret County. The Proposed 2024 SMFP limits the number of PET scanners by HSA, triggering a need when the number of PET scans completed by existing PET scanners in FY2022 equals or exceeds 2400 times the number of PET scanners plus one. The Proposed 2024 plan shows no need in HSA VI. PET scanners in this HSA operated at 17.5 to 54.7 percent of what the methodology identifies as capacity. Need occurs when the average for the service area is 80 percent of capacity. Capacity is defined as 3,000 annual PET scans.

HSA VI is the largest in total land mass and number of counties in the state. It has 3,000 more square miles than the next largest. It has 29 counties; most are rural and close to half are carved up by coastal waterways. This geography makes it difficult to bring advanced technology close to residents.

The standard SMFP methodology does not anticipate the option of a dual function fixed PET scanner. However, when technology can offer more than one function, it can be supported by fewer procedures and new opportunities open up for rural areas like HSA VI.

The Proposed 2024 SMFP has a second method for generating need. Carteret Health Care has two linear accelerators and offers medical and radiation therapy, but it is not a "major cancer center," so methodology Option 2 is not available.

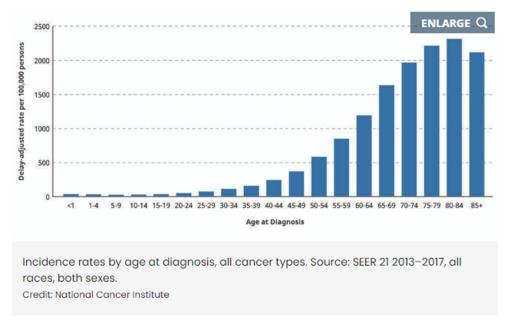
A similar situation occurred at Southeastern Regional Medical Center in HSA V and the SHCC granted a special need for an additional Fixed PET scanner for Robeson County in the 2020 SMFP. That scanner provided 791 PET scans last year, according to Table 15F-1.

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THIRD POINT: AN OLDER POPULATION WILL SUSTAIN MORE DEMAND FOR PET/CT SERVICE

According to the NC Office of State Budget and Management {"NCOSBM"}, Carteret has fewer residents than Robeson County, but Carteret's population is older. The median age in Robeson is 37.8 in 2023 and trending younger. Carteret County's median age is 49 and trending older, which puts Carteret in very rare company. Carteret is also unique in HSA VI. Residents are 10 years older than the state; the state's Median age is 39.8. 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: Incidence Rates by Age by Type



Carteret County is older, on average, than neighboring counties and is aging more quickly than most of Eastern North Carolina. Carteret is 12 years older than its neighbor to the north, Craven County, and 23 years older than Onslow County to the west.

Unlike many aging counties, Carteret is experiencing substantial population growth. Per US Census data, Carteret Country grew by 2.5% between April 1, 2020, and July 1, 2022, and NCOSBM forecasts another 3.1 percent increase between 2023 and 2028². Demographic forecasts are not yet reflecting the number of people who shifted their permanent addresses and settled into their second homes during the pandemic. None of the demographic projections include the tourists who live in the County for two thirds of the year, or the military associated with Cherry Point Marine Air Station and Camp Lejeune, who live in the area and get some of their health care from local health care providers.

By 2025, according to the State Center for Health Statistics, there will be <u>587 new cancer</u> cases in Carteret County alone³. Internal data indicate that Carteret Health Care's Cancer Center treats about 96

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²NC Office of State Budget and Management, Demographic Projections by Age and Sex https://www.osbm.nc.gov/facts-figures/population-demographics/state-demographer/countystate-population-projections accessed July 2023.

³ Projected Cancer Cases and Deaths for Selected sites 2023, Produced by NC Central Cancer Registry https://schs.dph.ncdhhs.gov/schs/CCR/CancerProjectionsByCounty-2023.pdf

percent of the county's new cancer cases. Forecast new cancer cases for 2023 may also be low, because they are based on people who were diagnosed during the pandemic years.

New cancer cases do not include patients who have survived cancer but are maintained by retreatment. These patients currently represent about 25 percent of CHC's cancer patients. These patients will increase as systemic therapy has become more effective in prolonging the survival of patients with advanced or metastatic cancer. Data in Attachment A show statewide 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.

FOURTH POINT: CARTERET COUNTY HAS A UNIQUE GEOGRAPHY

Carteret County borders the Atlantic Ocean; supports a major state port, research labs, marine industry, agriculture, and tourism. Carteret General also supports support many military service members and family from the Cherry Point Marine Air Station in Havelock and Marine Airfields in eastern Onslow County.

This request is important to CHC's Board and the community. New Bern looks close on a map, but it is not in peak season, when traffic jams Route 70 and the two-lane roads. A one-way trip from Morehead City can take more than an hour. Down East – the eastern of the two county peninsulas – is agricultural and slow-moving farm equipment can double and triple travel time.

Carteret County has the coast and many remote rural areas connected by bridges. Some still lift and stop traffic to let the marine vessels through. Others just support winding 2-lane roads through a maze of waterways. These rural areas are home to some of the lower income communities that have only one vehicle. A trip from Beaufort, the County Seat, to New Bern can take 1.5 hours each way; a trip from Sea Level is 2+ hours each way.

On the books, NCOSBM shows 69,000+ Carteret residents. On the street the population is much larger. Not yet included in Official State Projections, Carteret County is experiencing new population growth following the Pandemic – with a surge of second homeowners now making Carteret County their new primary home. Though many try, no one has a good count of the tourist population. They start arriving in March and stay until October, and the service industry sees the surge, but they are elusive to count. They affect the cancer center because they can continue their treatments locally. Local retirement communities also mean more survivors who need retreatments.

As part of the State's transportation network development, Route 70, which connects the mountains to the coast, is becoming Interstate 42 in eastern North Carolina. That will mean a four-lane highway that can support more shipping and more military industry between Carteret and Craven County. It is expected to add another 25,000 residents in the next five years. So, traffic to New Bern will not get easier, but demand for services will increase. Significant planned investments by private sector military companies will be part of that growth. Morehead City has one of the state's two deep water international shipping container ports. It will get busier when the transportation is easier.

In short, the community served by CHC is small enough for citizens to keep an informed and close eye on what happens in the health care system. They want quality at a fair price. Hospital revenue stays in the community to expand and support local services. CHC leadership and board are held accountable

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because the Board of Directors are elected by residents of the county and leadership serves at the pleasure of the board.

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

The adverse effects on patients are obvious:

- Mobile PET one day a week means CHC will continue to refer out about half of the patients who need PET scans.
- Some people will opt to avoid the scan, rather than travel.
- Those who do leave will be inconvenienced and have the added cost of extra transportation.

STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

OVERVIEW

Three other alternatives do not really address the need in a cost-effective way.

ALTERNATIVE 1

A dedicated fixed scanner would be more expensive, and the service area may not need the required 2,080 PET scans that current performance standards require of a stand-alone fixed PET scanner in its third operating year. A fixed PET scanner at CHC would expand the range of isotopes and would increase the number of PET scans from the current 600 to approximately 1,000.

ALTERNATIVE 2

Waiting for the standard methodology to show a need in HSA VI means waiting for something that may never happen because existing PET scanners in HSA VI are not close to the threshold.

ALTERNATIVE 3

More mobile PET days are not available, and even if available would only provide FDG isotopes.

BEST ALTERNATIVE

The best alternative for this geography is a PET scanner simulator. It can provide the marginal extra simulator capacity needed for the second linear accelerator without the cost of a full simulator and it can provide full-time PET service for about 95% of patients. Dual use will be more cost effective and limited capacity will put any temptations for over-use in check.

This alternative also requests a lower performance threshold for the dual use scanner, reducing it from 2,080 scans in the third year to 600 to 1,040 scans. That is reasonable and achievable in Carteret County.

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This proposed alternative would allow Carteret Health to offer a wider range of radioisotopes, which CHC's supplier can provide and radiologists at Eastern Radiology are prepared to support and interpret the PET scans as they do now for the mobile unit.

EVIDENCE OF NO UNNECESSARY DUPLICATION OF SERVICES

The proposed solution, a PET/CT simulator / scanner will be the only such equipment in the cancer community served by Carteret Health. The nearest PET scanners are hours away. Though not used to capacity, they are not really accessible to Carteret County residents.

Dual use will reduce the capacity threshold requirement. It is impossible to purchase half a scanner. The mobile unit is only available on Sundays.

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."

It would provide information essential to refining simulation plans for radiation therapy that would not otherwise be available in this cancer center.

Simulator capacity is only one of the reasons for this request. A PET/CT simulator has features for radiation therapy planning that are not available on a standard oncology CT simulator. PET images, obtained in treatment position at the time of simulation, increase sensitivity, specificity, and accuracy of radiation target delineation for patients with cancers of the head and neck, lung, cervix, anus, esophagus, prostate, and lymphoma. While it is not perfect for all patients, due to the narrower CT bore size and reduced size range for metallic artifact attenuation compared to a standard simulator, the fused PET/CT simulator would be the ideal treatment planning platform for a significant portion of patients, particularly those receiving definitive-intent therapy.

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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."

This is tested technology and improved access would reduce travel for fragile patients. The restrictions on schedule and radiotracers, means that approximately half of CHC patients are sent out of the county for their PET/CT imaging. CHC's Cancer Program Needs Assessment has repeatedly identified transportation to be one of the most significant barriers to care for patients in Carteret County, which is further exacerbated when the necessary diagnostic PET/CT imaging is unavailable in 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."

CHC has highly competitive Medicare rates because it is rural. It has competitive rates with commercial providers. In some cases, its PET scans cost insured patients half of what other providers are paid.

The proposed solution, a shared PET/CT simulator would be ideal. CHC's existing CT simulator is at capacity many days a month, requiring rescheduling of patients to a later date. Between 2015 and 2022, the number of radiation therapy plans per year more than doubled, from 243 to 514. A single Plan involves 1 to 3 simulations. The upward trend in the number of CT simulations per patient will likely continue as image guidance and treatment monitoring technology in Radiation Oncology continue to improve. Each regular CT simulation takes an average of an hour. Simulations performed with 4D technique, with IV contrast, or when multiple sites are being treated, take 90 minutes. The increasing demand for CT simulator time risks an operational bottleneck in radiation planning.

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CONCLUSION

The proposed changes are consistent with and support the Basic Principles that govern the *SMFP*. This is the right time for this special need for a fixed PET/CT simulator / scanner for Carteret County in HSA VI, to be located in an acute hospital that has two linear accelerators, no PET scanner, and no more than one simulator. Reduction in the performance standard to 1,040 annual PET scans in the third year of operation is reasonable and consistent with dual use of the proposed equipment and the Plan's treatment of other dual use technology and equipment.

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ATTACHMENTS:

2016-2020 Survival Rates of Selected Cancer Sites in North Carolina	A
Copies of Public Hearing Speeches July 20, 2023	В
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Attachment A

2016-2020 Survival Rates of Selected Sites in North Carolina

2016-2020 Cumulative Observed and Relative Survival of 6 Selected Cancer Sites in North Carolina									
	NORTH CAROLINA								
	Cumulative observed	Lower 95% CI for observed	Upper 95% CI for observed		Lower 95% CI for relative	Upper 95% CI for relative			
	survival	survival	survival	Cumulative relative survival	survival	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.

Attachment B

Copies of Public Hearing Speeches

July 20, 2023

Presentation of Special Needs Petition for PET/CT,

Carteret County,

Proposed 2024 State Medical Facilities Plan

July 20, 2023

Presented by: Kyle Rusthoven, MD

Introduction

Good afternoon, my name is Dr. Kyle Rusthoven. I am a radiation oncologist certified by the American

Board of Radiology. I have been the Medical Director of Radiation Oncology at Carteret Health since

2015 and am now one of two full-time radiation oncologists at our hospital.

Comprehensive Cancer Care at Carteret Health

Cancer care is a major priority at Carteret Health. By 2025, we expect 634 new cancer cases for the

County alone; and we treat about 96 percent of those new cases. I have been here for 8 years. During

my tenure, annual Radiation Oncology consultations have increased by 25 percent. These numbers

exclude existing cancer patients who are being maintained with retreatment. They currently represent

about 25 percent of our patient volume, a figure which will increase because systemic therapy has

become more effective in prolonging the survival of patients with advanced or metastatic cancer.

In addition to clinical growth, Carteret Healthcare has achieved meaningful quality recognition. Since

2013, our cancer program, which I chair, has been accredited by the American College of Surgeons

Committee on Cancer. In 2019 we achieved accreditation with Silver commendation. Undergirding these

successes, our cancer program is fortunate to have strong backing from administration and our Board.

Importance of Full-Time PET at Carteret Health

An important part of developing a cancer treatment plan is a PET scan. Carteret Health has very

restricted PET/CT service on a mobile unit. It comes only on Sunday, we are limited to 12 scans a week,

and only one radioisotope, FDG. Newer radioisotopes specific for brain, breast and, in particular,

prostate scans, are not available. Yet, together, these three cancer types represent about half of new cancer patients.

The restrictions on schedule and radiotracers means that approximately half of our patients are sent out of the county for their PET/CT imaging. Our Cancer Program Needs Assessment has repeatedly identified transportation to be one of the most significant barriers to care for patients in Carteret County, which is further exacerbated when the necessary diagnostic PET/CT imaging is unavailable in near where they live. This often leads to delays in care, particularly for patients with a disability or those facing financial hardship.

The proposed solution, a shared PET/CT simulator would be ideal. Our existing CT simulator is at capacity many days a month, requiring us to reschedule patients for a later date. Between 2015 and 2022, the number of radiation therapy plans per year more than doubled, from 243 to 514. Each regular CT simulation takes an average of an hour. Simulations performed with 4D technique, with IV contrast, or when multiple sites are being treated, take 90 minutes. To keep costs down, we also use our existing CT simulator as a back-up diagnostic CT for radiology or acute presentations in the emergency room. These factors have led to increasing demand for our CT simulator time, which risks an operational bottleneck in radiation planning.

In addition to population growth, the increase in radiation plans is related to the expanding use of stereotactic radiation for patients with oligometastatic disease and to the increasing use of dynamic and adaptive radiation planning. Patients may be re-simulated during treatment for a variety of reasons, including weight loss, tumor response, or changes to their internal anatomy around the treatment target. Re-planning, in these settings, improves treatment accuracy and safety and optimizes the therapeutic ratio of radiation therapy. Depending on the disease site, patients will undergo 1 to 3 simulations during a course of treatment. As image guidance and treatment monitoring technology in Radiation Oncology continue to improve, the mean number of simulations performed during treatment is also likely to increase.

Simulator capacity is only one of the reasons for this request. A PET/CT simulator has features for radiation therapy planning that are not available on a standard oncology CT simulator. PET images, obtained in treatment position at the time of simulation, increase sensitivity, specificity, and accuracy of radiation target delineation for patients with cancers of the head and neck, lung, cervix, anus, esophagus, prostate, and lymphoma. While it is not perfect for all patients, due to the narrower CT bore size and reduced size range for metallic artifact attenuation compared to a standard simulator, the fused PET/CT simulator would be the ideal treatment planning platform for a significant portion of our patients, particularly those receiving definitive-intent therapy.

A PET/CT simulator is more expensive than a standard CT simulator, but, as Kyle Marek explained, we can justify the additional cost if we can make dual use of the same equipment to do fixed PET scans. We could schedule patients for weekday PET scans and could use specialized brain, breast, and prostate isotopes. In doing so, we would reduce delays in care and retain the 50% of patients who are currently leaving the county for their diagnostic PET/CT imaging. We estimate that full time PET capacity would mean in the range of 450-500 additional annual PET/CT scans performed in Carteret County.

Having studied our cancer numbers, we know that, despite how busy our cancer program at Carteret Health Cancer Center is, we would not likely reach the Performance standard for a fixed PET scanner – 2,080 annual scans by the third year of operation. We feel confident, however, that we would do over 1,000 diagnostic PET scans per year, nearly doubling the number of scans which are currently performed on our mobile unit. With a dual PET/CT scanner/simulator, the scanner would pay for itself with the combination of PET scans and additional radiation therapy simulations. Even with this dual use, however, the sum of simulations and diagnostic scans is not likely to reach 2,080. As such, the second part of our special need petition is to reduce the performance standard by half, from 2,080 to 1,040 combined scans and simulations. This would be efficient. It would truly serve as the ideal dual-purpose unit to address multiple oncology service line needs at our community hospital. Without question, a shared scanner/simulator would help optimize the coordination of care amongst the treating physicians and reduce unnecessary travel and treatment delays for our patients.

I believe this shared function PET/CT scanner would be a first for North Carolina. This technology has evolved at the perfect time for Carteret Health Care. With a need in the 2024 Plan, we could apply for a CON and conceivably have a decision in time to include it in our current major Cancer Center improvements.

We appreciate your thoughtful consideration of this important request.

I am happy to answer any questions.

Presentation of Special Needs Petition for PET/CT

Carteret County

Proposed 2024 State Medical Facilities Plan

July 20, 2023

Presented by: Julius Taylor, Vice Chair, Carteret Health Board of Directors

<u>Introduction</u>

Good afternoon. My name is Julius Taylor, and I am Vice Chair of the Carteret Health Care Board of Directors. I have been a member of the Board for 5 years and am a lifelong resident of Carteret County. I am also a cancer survivor.

I am here to add support for Carteret Health's request to include a <u>special need for a new shared PET scanner/ CT simulator in Carteret County and to reduce the performance standard for PET scans by half.</u>

Background

Since being appointed to the Board of Directors, I have had the opportunity to become aware of the dedicated and conscientious medical professionals our county is fortunate to have at Carteret Health Care. I have observed firsthand their work as both a board member and as a cancer patient and I believe this experience has afforded me a unique perspective of our local medical professionals. It has instilled in me a sense of deep responsibility for doing what I, as a board member, can do to assist these professionals in providing the best medical care for our citizens while always keeping in mind the fiscal restraints. I have concluded that our board should do all it can to provide these hard-working medical professionals with the tools they need, such as a PET/CT scan unit, to carry out their vital mission. These are some of the reasons why I strongly favor this petition.

Carteret Health has been providing quality care to Carteret and surrounding counties since 1967. The hospital is county owned and the Board of Directors is elected by residents. Carteret County borders the Atlantic Ocean; supports a major state port, research labs, marine industry, agriculture, and tourism. We

also support military families from the Cherry Point Marine Air station and Camp LeJeune. Our mission is "to provide Quality Healthcare with exceptional compassion and respect." We are small enough for citizens to keep a close eye on what happens in the Carteret Health Care system, and they want quality at a fair price. Hospital revenue stays in the community to expand and support local services and we are fortunate to have an award-winning Cancer Center that is:

- Accredited by Commission on Cancer (CoC) of the American College of Surgeons since 2013.
- Recognized for Medical Oncology by the Quality Oncology Practice Initiative.
- Achieved recognition for Excellence in breast health as a Pink Ribbon Facility for 3D Breast Imaging.

Current Situation

This request is important to our Board and the community. The nearest fixed PET scanner in New Bern looks close on a map. It is not during the tourist peak season, when traffic jams Route 70 and the two-lane roads. A one-way trip from Morehead City can take more than an hour and from Down East – the eastern part of the two county peninsulas – agricultural and slow-moving farm equipment can double and triple travel times.

Carteret County has the coast and many remote rural areas connected by bridges. A few still lift and stop traffic to let the marine vessels through. Others just support winding 2-lane roads through a maze of waterways. Typically, these rural areas are home to some of the lower income communities that have only one vehicle. A trip from Beaufort, the County Seat, to New Bern can take 1.5 hours each way and a trip from Sea Level is 2+ hours each way.

Age is another unique feature in Carteret. While the State's Median age is 39.8, Carteret County's is 49 and going up, which puts Carteret in rare company. Age and cancer rates have a direct correlation, with cancer rates rising as people age. On the books, NCOSBM shows 69 thousand residents. On the street we know the population is much larger. Not yet included in official state projections, the County is experiencing new population growth following the Pandemic – with a surge of second homeowners now making Carteret County their new primary home. Though many try, no one has a good count of the

additional huge tourist population. We know they start arriving in March and stay until October, and we see the surge in the service industry, but they are elusive to count. They affect our cancer center because they can continue their treatments locally. They come to the coast for comfort or to be with family. Our retirement communities also mean more survivors who need retreatments.

As part of the State's transportation network development, Route 70, which connects the mountains to the coast, is becoming Interstate 42 in eastern North Carolina. That will mean a four-lane highway that can support more shipping and more military industry between Carteret and Craven County. We expect it will add another 25,000 residents in the next five years. So, traffic to New Bern will not get any easier, but demand for services will increase. Significant planned investments by private sector military companies will be part of that growth. Morehead City has one of the state's two deep water international shipping container ports. It will also get busier when the transportation improves.

Consistent with the past 5 years, The NC State Center for Health Statistics expects 1.3% annual growth in new cancer patients within our primary service area which translates to over 2,200 new cancer cases in Carteret, Craven and Onslow by 2028.

Conclusion

I know what it is like to arrange help traveling out of the county for tests when you are getting cancer treatment. It is exhausting and you are at the mercy of other people's schedules. I ask that you help us and approve our request for a special need determination for a shared fixed PET scanner/CT simulator in Carteret County. I will be submitting a formal petition in the required format later this month.

Presentation of Special Needs Petition for PET/CT

Carteret County

Proposed 2024 State Medical Facilities Plan

July 20, 2023

Presented by: Kyle Marek, President, Carteret Health

Introduction

Good afternoon. My name is Kyle Marek, I am President of Carteret Health Care. I have been the President for less than a year but have been with Carteret Health Care for 24 years. My roles have included VP of General Services and CIO.

Thank you, members of the SHCC, for arranging this opportunity. I am here to ask you to modify Chapter 15F of the 2024 State Medical Facilities Plan to include a <u>special need for a new shared PET scanner/ CT simulator in Carteret County in HSA VI</u>. This special need involves a rural adjustment that also reduces the expected number of PET only scans from 2,080 to 1,040 by the third operational year.

Background

Carteret Health Care is a 135-bed, not-for-profit, community hospital, with a Community Cancer Center, diagnostic centers, and physician offices. Located in Morehead City, the cancer center also serves residents from Craven and Onslow Counties. Our mission is "to provide Quality Health Care with exceptional compassion and respect." To support that mission, we are constantly looking for ways to offer services locally, so that transportation is not an access barrier for residents. We also look for ways to keep costs down.

Current Situation

Today, Carteret Health Care provides PET scan services through a contracted mobile unit that comes once a week on Sunday. As you know, PET scanning technology involves radiopharmaceuticals with short half-lives. Our mobile contract limits us to one isotope, FDG. However, PET scanning has advanced, and other organ specific isotopes are now available. Without them we cannot perform brain, breast, or prostate cancer scans. That means we are referring almost half of our PET scans out of county.

Even with the limitations, our one-day mobile PET service is busier than three of the fixed full-time PET scanners in the state. This year, we expect to provide about 600 PET scans and we have a two-week backlog. Six hundred is our maximum. The contract limits us to twelve scans a day. We are grateful that the service is available – but it is no longer enough to meet demand. Combined PET/ CT scanner simulators have been around for almost two decades.

The standard Plan methodology will not generate a need for a new fixed PET scanner because the four PET scanners in rural HSA VI operate at 17 to 55 percent and the requirement for a new need is 80 percent. Carteret Health Care has two linear accelerators and offers medical and radiation therapy, but it is not a "major cancer center," so methodology Option 2 is not available. Another mobile does not work. That is just more of the same problem.

Carteret Health Care is in a unique position today. PET/CT simulator technology has advanced, and the price is down. We are midway through plans for major improvements to Carteret Health Care's cancer center. Construction should be complete by mid-2025. Our current radiation therapy CT simulator is a dual work engine already, serving as the backup CT scanner for the ED and the simulator for the linear accelerator. During peak season, it cannot meet demand. The emergency room takes precedence, and we find work arounds or delay the simulations. We need more simulator capacity, but not a full-time simulator.

While deciding how to address the problem, we discovered that two manufacturers have a simulator that has a dual function as a PET scanner. Although the initial investment is more than a standard CT simulator, our CFO found that the savings from not leasing the mobile PET scanner and the income from simulations and additional PET scans would offset the extra capital and operating cost over the equipment's useful life. Economically, it makes sense to our very cost-conscious board. Keeping costs affordable to our community is one of their high priorities. Carteret Health Care rarely borrows money for improvements. We save and pay cash.

This is a unique request for a rural county. However, there is precedent in the Plan's Shared Fixed Cardiac Catheterization Equipment— one piece of equipment does both angiography and cardiac cath. Two physician specialists work together. Carteret Health Care has one and it works well. Qualified hospitals can apply if they show a minimum number of caths done on a mobile unit, 250. Then they must meet a reduced performance standard in their CON applications— about one fourth of the cath capacity standard. We request that you do the same for this proposal. A threshold of 1,040 PET scans would be very reasonable.

The dual function of a shared PET/CT scanner/ simulator would permit us to make available full-time fixed services that we might not otherwise afford a rural community hospital. Today rural hospitals must be cost conscious.

Reasons

This request is consistent with the Basic Principles of the State Medical Facilities Plan.

Access

- Carteret Health Care could:
 - offer PET services in Carteret County seven days per week, if necessary.
 - can meet the patients where and when they are, instead of forcing them to choose
 between a limited schedule and traveling long distances.
 - o offer a full range of isotopes and scan most cancer types.

Value / Cost Efficiency:

• The operating cost of the new dual function scanner will be less than the current mobile contract on a unit scan basis.

Safety and Quality

- Carteret Health Care
 - has expertise and knowledge that normally would not be available in a community hospital.
 - o is a member of the Mayo Clinic Care Network. After an extensive vetting process, Carteret Health Care was the *only North Carolina hospital* granted special access to Mayo's clinical, educational, research and operational knowledge and resources. It helps Carteret Health Care to stay independent, competitive, and innovative. Additionally, and most importantly, it provides patients with the care they need, close to home, at no additional cost to them.
- Our radiologists, Eastern Radiology, are in full support.

Conclusion

I ask that you approve our request for a special need determination for a shared fixed PET scanner/CT simulator in Carteret County, HSA VI and provide for a reduced performance standard of 1,040 combined procedures. I will submit a formal petition later this month. You will hear more about the Community from our Board Member, Julius Taylor. My colleague, Dr. Kyle Rusthoven, will give you more technical information about the equipment and our current patient numbers, but I will be happy to respond to any of your questions.