Petition to the State Health Coordinating Council
Regarding a Special Need Petition for a Linear Accelerator
in Service Area 24
2022 State Medical Facilities Plan

July 28, 2021

Petitioner:		***Contact:***	
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STATEMENT OF REQUESTED ADJUSTMENT

Carteret Health Care ("CHC") requests an adjusted need determination in the 2022 State Medical Facilities Plan (SMFP). for one additional linear accelerator (LINAC) in Service Area 24, to be designated for a licensed acute care hospital in Carteret County. <u>CHC would prefer that the additional linear accelerator be dedicated to a hospital in Carteret County.</u>

Table ##: Fixed Linear Accelerator Need Determination

(Scheduled for Certificate of Need Review Commencing in 2022

It is determined that the service areas in the table below need an additional fixed linear accelerator.

Service Areas	Need Determination	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
24 Carteret County only	1***	TBD	TBD

* *Need determination shown in this document may be increased or decreased during the year pursuant to Policy GEN-1 (see Chapter 4).*

** *Application due dates are absolute deadlines. The filing deadline is 5:00 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).*

REASONS FOR THE PROPOSED ADJUSTMENT

FIRST POINT: UNIQUE CANCER PROGRAM AT CARTERET HEALTH

Carteret County is located in Service Area 24, which contains three LINACs in two different counties. Service Area 24 includes the population base of four counties: Carteret, Craven, Jones, and Pamlico. Only two of these counties have hospitals. Carteret County is unique in its geography, demographics, and health care delivery system. In FY20, the single LINAC at CHC exceeded the Proposed 2022 SMFP Linear Accelerator Methodology definition of "efficient use," 6,750 annual Equivalent Simple Treatment Visits ("ESTVs").

Table 1—Linear Accelerator Utilization, Carteret General Hospital, FY17-20

Notes		FY17	FY18	FY19	FY20	CAGR
a	Total Procedures	5,267	5,853	6,157	6,448	6.98%
b	Total ESTVS	5,481	6,241	6,427	**6,870**	

Source:

a: NC DHSR Hospital License Renewal Applications, 2018-2021

b: Procedures converted to ESTVs using conversion factors by treatment type, as published in the 2021 SMFP (Table 17C-3, p.331)

If Carteret County were its own Linear Accelerator Service Area, these data would justify need for a second LINACs in the Proposed 2022 SMFP. However, the county population is less than 120,000. Hence, the Methodology combines Carteret with Craven, Jones and Pamlico Counties to form the single Service Area 24. Craven County has two LINACs and the average of the three LINACs in Service Area 24 is less than 6,750 ESTVs.

CHC's cancer program has a unique high demand for LINAC services by residents of the communities it serves. In each of the past four years, demand for linear accelerator treatments outstripped population growth. Epidemiologic information indicates that this strong demand for LINAC service will sustain for the foreseeable future. At the recent historic growth rate of 7 percent annually (Table 1), Carteret General Hospital's single linear accelerator will reach 7,865 ESTVs by 2022 and 9,636, three years after that (Table 2).

Table 2—Projected Linear Accelerator Utilization, Carteret General Hospital, FY21-25

Notes		FY21	FY22	FY23	FY24	FY25
a	Projected ESTVs	7,351	7,865	8,416	9,005	9,636

Source:

a: Prior year, starting with Table 1, row b, increased at 7 percent annually

SECOND POINT: SMFP METHODOLOGY WILL NOT GENERATE NEED

The SMFP Methodology will not generate need for another linear accelerator in LINAC Service Area 24 for at least four more years. According to the standard methodology, a need determination occurs when two of three criteria are met.

- Criterion 1 fails because Carteret population of 71,536 will not reach 120,000 for the next five years, according to NCOSBM forecasts. So, Carteret County will not qualify to be treated as its own service area.
- Criterion 2 fails because most Service Area 24 patients originate from within Service Area 24.
- Criterion 3 fails because Service Area 24 average annual use rate for all three linear accelerators is less than 6,750 ESTVs. The slower-growing Cancer Center at CarolinaEast in Craven County, whose two LINACs averaged 4,825 annual ESTVs in 2020, bring down the Service Area 24 LINAC use rate in the Proposed 2022 SMFP. Combined ESTVs at the three LINACs in Service Area 24 increased at a CAGR of 6 percent over the last four years. Even at that sustained rate, Service Area 24 will not show need for an additional LINAC until the 2025 SMFP (Table 3).

Table 3—Projected Linear Accelerator Utilization, Service Area 24, FY2020-2026

Notes		**FY20**	**FY21**	**FY22**	**FY23**	**FY24**
a	ESTVs	16,520	17,511	18,562	19,676	20,856
b	LINACs in Area	3	3	3	3	3
c	ESTVS per LINAC	5,507	5,837	6,187	6,559	6,952

Source and Notes:

a: FY20 ESTVs Per Proposed 2022 SMFP
ESTVs increase 6 percent annually to arrive at projections.

b: Table 17C-4 Proposed 2022 SMFP

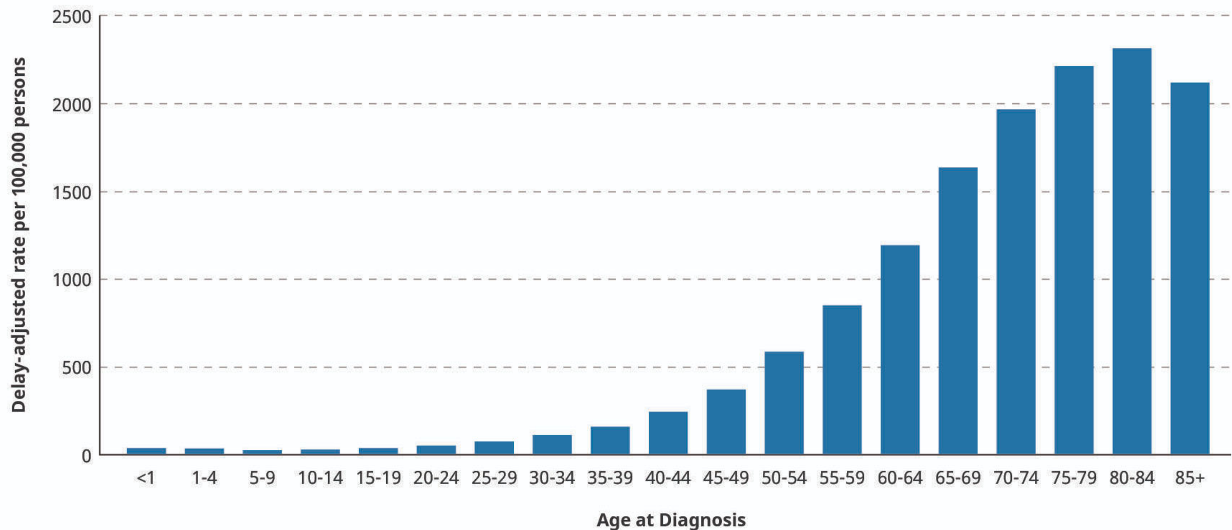
c: a/b

A need in the 2025 SMFP would <u>not result in an operational LINAC until about 2029.</u> It takes a year for CON application and review, about two years to design, build and install a LINAC. It is not reasonable to ask residents of CHC communities to endure access constraints for that long.

THIRD POINT: AN OLDER POPULATION WILL SUSTAIN MORE DEMAND FOR LINAC SERVICES

Advancing age is the most important risk factor for development of cancer[1]; and about half of cancer patients will require LINAC treatment. Cancer incidence rates climb steadily as age increases (Figure 1).

Figure 1—Cancer Incidence Rates by Age at Diagnosis, All Cancer Types, US



Source: National Cancer Institute (NCI). SEER 21 2013-2017, all races, both sexes.

According to the State Demographer (NCOSBM), Carteret County median age is 48.6[2]. Compare this to the NC average of 34.9, and the Craven County average of 36.4. As demonstrated by statistics from the DHSR Medical Facilities Database, older populations have high LINAC use rates. Table 4 compares 2019 Carteret use rates with other counties that have similar median ages. Each county in Table 4 has historical LINAC use rates higher than the state rate.

[1] *Risk Factors: Age*. National Cancer Institute. (2021, March 5). https://www.cancer.gov/about-cancer/causes-prevention/risk/age.

[2] North Carolina Office of State Budget and Management, County Population Projections, Sex and Single Years of Age (2000 – 2050)

Table 4—Median Age and *LINAC Use Rate per 1,000 Residents NC Counties FY2019*

County	LINAC patients/ 1000 residents	Median Age
	a	b
Carteret	**4.3**	**48.4**
Catawba	6.3	41.5
Buncombe	5.2	42.5
Brunswick	4.4 (c)	51.5
NC	3.8	39.0

Notes

a. DHSR Hospital and Equipment Database linear accelerator patient origin divided by NCOSBM population for 2019
b. NCOSBM
c. Brunswick was much higher in 2018 and 2020, indicating a possible reporting error in 2019

Carteret County's aging population is also growing rapidly. By the time a LINAC in the 2022 SMFP could come on line in CY 2025, Carteret County will have 31,356 residents over age 55 and **625 new cancer cases**.

Table 5—Carteret County Cancer At-Risk Population, 2021 & 2025

Notes	Metric	CY21	CY25
a	Carteret Pop 55+	29,819	31,356,
b	Estimated New Carteret County Cancer Patients	589	625

Source:

a. NC Office of State Budget and Management, Population by County by Single Age (NC OSBM); accessed 06.02.21
b. Estimated at the rate of increase in NC Central Cancer Registry 2018-2020

It is important to note that with cancer survival rates increasing, existing cancer cases also represent a significant portion of LINAC patients.

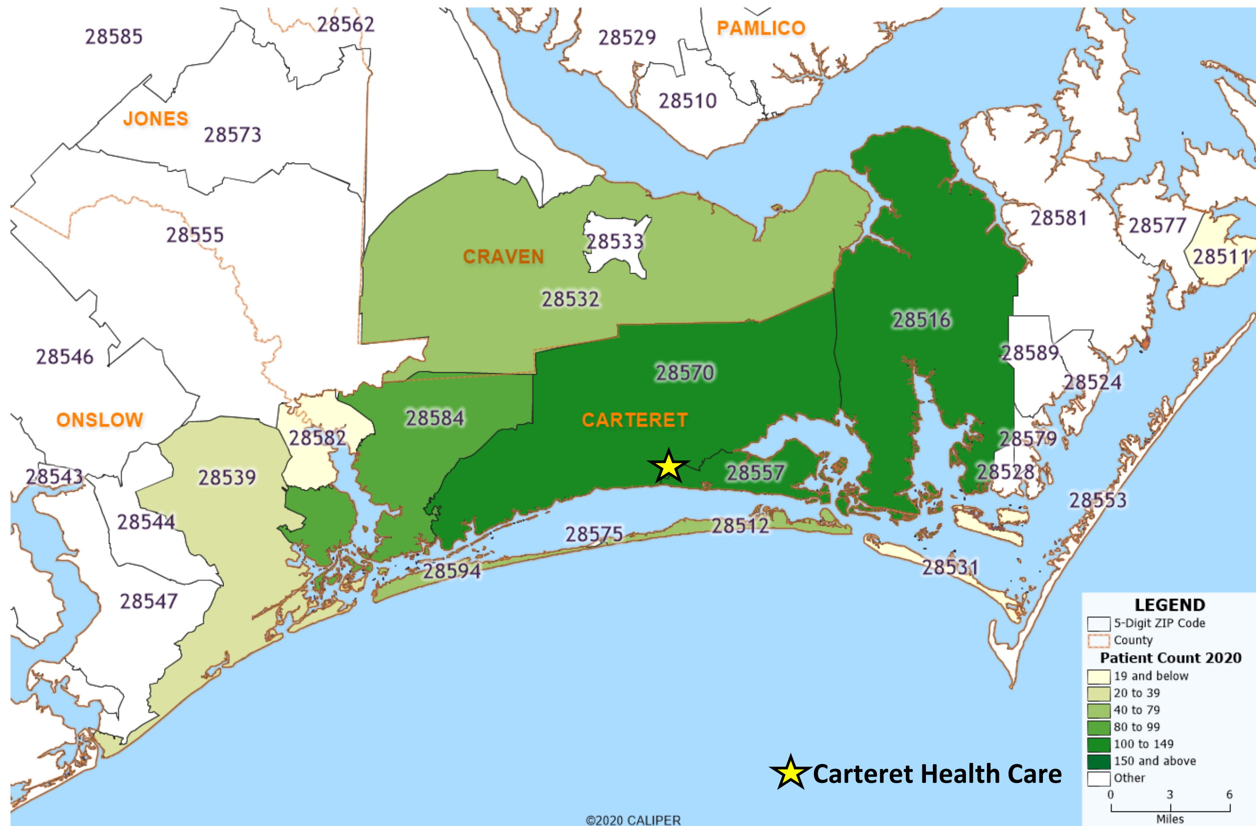
Carteret County is the only coastal county in NC that has been officially designated by the state as a Certified Retirement Community. The designation and supporting services have attracted and will continue to attract an older population. A good school system and expected development of Interstate 42 and the Marine Corps Air Station Cherry Point will sustain overall population growth[3].

[3] Don Kirkman, Retired Carteret County Economic Development Director, July 12, 2021

FOURTH POINT: CARTERET COUNTY HAS A UNIQUE GEOGRAPHY

Table 2 above addresses only Carteret County residents. Because of the coastal geography, parts of Onslow and Craven County are actually closer to and relate more to CHC than to other cancer centers. Figure 2 shows zip codes where CHC patients live. The white areas are rural and have only a few patients from the zip code.

Figure 2—CHC Radiation Oncology Patients by Zip Code, 2020



The coastal location comes with other unique features. Two-lane roads cross waterways at multiple locations. Traffic can slow with a school bus, farm equipment, a cautious driver, or road repair. Cedar Island, the eastern-most town, is itself an hour from CHC under normal travel conditions. Other towns in the eastern peninsula are only slightly closer. Carteret is a tourist county. In low season, the trip from Beaufort to New Bern, the next closest LINAC takes three hours round trip.

LINAC treatments involve care five days a week for extended weeks. Patients depend on support persons for transportation. The longer the distance, the higher the likelihood that patients will miss treatments.

For these reasons, CarolinaEast and CHC serve two different populations.

FIFTH POINT: CARTERET, A RURAL COUNTY WILL NOT LIKELY REACH EFFICIENT USE OF A SECOND LINAC WITHIN THREE YEARS

One LINAC cannot meet the need of residents who depend on CHC. It is also unlikely that the CHC market will generate sufficient demand to reach "efficient operating capacity" on two LINACS within three years.

However, operating two LINACs at an average of 85 percent of the regulatory performance standard for linear accelerators by the third year (10A NCAC 14C.1903), is reasonable and practical. The performance standard requires an average of 5,738 ESTVs or 425 patients by the third operational year. Table 5 above shows CGH will meet the patient standard.

Two LINACs provide critical redundancy during repairs. Practically speaking, if granted the CON, CHC would use new equipment for the heavy workload and put less demand on the existing equipment, thus extending its useful life. CHC agrees that the Performance Standard for the second LINAC should be high enough to justify the capital expenditure. In this rural setting, 85 percent average efficient operating capacity on two linear accelerators would do that. A LINAC will last at least seven years with high use and much longer, with lower demand on its megavoltage.

The CON process itself would supplement this with statutory criteria that require applicants to demonstrate financial feasibility of the entire service line.

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

CONSUMERS

The geographic origin of Carteret Health Cancer Center patients has been consistent from year to year. The one LINAC at Carteret General Hospital ("CGH") in Carteret County reached efficient operating use in 2020, at current cancer rates. Yet, unlike many other counties, Carteret County cancer cases are increasing, Soon, scheduling at Carteret General Hospital's single linear accelerator will be problematic.

Oncology care is multi-disciplinary and treatment protocols involve carefully-timed services that often involve several disciplines on the same day. Asking residents served by the Carteret Health Cancer Center to go elsewhere until the CarolinaEast Cancer Center reaches efficient use of its two LINACs would represent an unreasonable access barrier for the Carteret Health consumers.

People with cancer are already operating under resource constrains; another access barrier is unreasonable. Linear accelerator treatments can involve 20 to 40 visits, some daily; all must occur at the LINAC location. Radiation treatment cannot be done at home. During treatment, cancer patients are too compromised to drive themselves to and from treatment Each patient must be accompanied by a support person. As noted, even CGH is an hour or more away from homes in the Eastern Carteret County Peninsula; CarolinaEast, the nearest provider, is more than two hours away from these residents.

Both Carteret and Craven Counties are tourist destinations with very high related traffic congestion. Route 70 East between the two is peppered with stoplights. When tourism doubles the population between Memorial Day and Labor Day and into the Fall, travel times get longer. Even outside the high season, traffic is heavy and congested. A trip from the town of Beaufort in Carteret County to New Bern in Craven County, can take 1.5 hours in April. This means a 3-hour round trip.

Without the adjustment, Carteret Health Cancer Center will have to turn patients away or send them to other providers; some patients will not make the trip, thus will forego treatment. Foregone treatment generally means unfavorable outcomes.

PROVIDERS

- In North Carolina, a cancer center can plan for growth in most services without considering SMFP limitations. LINACs require a CON; and without the special need adjustment, CGH will face a major care-limiting decision.
- There is a national shortage of physicians. Physician efficiency is a critical element in recruiting and retaining top talent. Radiation oncologists and medical oncologists treat the same patients with continuous protocols. When these specialists must also coordinate care for patients who are getting treatment in multiple locations their efficiency declines. Although solo radiation oncologists are a reality in many locations, it is easier to provide coverage and prevent burnout if the area will support more than one radiation oncologist and more than one radiation oncologist requires capacity of more than one LINAC.
- Patients referred out for one part of their care often arrange to go to those locations for all of

their care. When this happens, the local provider loses continuity and only sees the patient in an emergency. Then, with little time to spare, it is difficult for the local provider to get a complete picture of the patient's full treatment history. This adds extra stress to the local provider.

- Once a LINAC reaches efficient use, scheduling flexibility declines. Providers have more trouble coordinating ideal treatment protocols—and will have trouble accommodating all of the local need on a schedule that works.
- Because cancer care involves integrated treatment, referring patients away to other counties affects the whole local health care delivery system, which in turn can affect availability of services long term. Loss of patients in one department translates to decreased utilization throughout the system.
- CGH can absorb the medical oncology growth. This requires no CON. Without an additional linear accelerator need in the 2022 SMFP, CGH cannot absorb the radiation oncology growth. Hence, the care program would have lopsided growth and could be less comprehensive for some patients.

STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

OVERVIEW

Carteret Health considered several alternatives, limiting its program to one LINAC, extending hours, a mobile part-time LINAC, a new machine with higher capacity, waiting and watching the SMFP need calculations. None solve the problem as well as the proposed petition.

ALTERNATIVES CONSIDERED

Do nothing – eventually means creating an access barrier for the older population. When expected demand is adequate to offset operating costs, this is not an effective alternative.

Extending hours on the existing equipment will not double its capacity. External beam radiation treatment protocols involve several days of sequential treatment, followed by a patient recovery break. Cancer patients need weekend recovery breaks to let their physiology recover. In addition, older rural patients will not, and often cannot travel for services after dark. CGH already accommodates special requests for evening and weekend care. Moreover, extended hours do not address the problem of redundancy on a busy piece of equipment that is down for maintenance and repair. Hence, extended hours are not adequate to solve the problem.

Replacing the one LINAC with a new one will not solve capacity issue. Newer LINAC equipment has more capabilities, and some treatment protocols associated with those capabilities require fewer LINAC treatments, but each treatment takes longer. Otherwise, the new equipment is not faster and does not improve capacity.

Waiting and watching, the present default strategy would put CarolinaEast and Carteret Health in competition with one another when both need capacity for growth. LINAC is fixed equipment that requires a vault specifically designed for it. Planning, designing, and building a linear accelerator that it takes about three to four years from the date a LINAC need appears in the SMFP to the day it is first operational. This equipment needs a long planning lead time.

Although one company makes a mobile linear accelerator (Mobetron), its use is limited to intraoperative surgery in the same surgical suite. That equipment is not designed for daily movement on tractor trailers.

Some would argue that freestanding LINACs have lower unit costs than the hospital-based units. However, CMS determined in a 2015 study that the total treatment costs per patient tend to be higher on freestanding units. Moreover, separating the LINAC into a freestanding setting would require an ambulance transport for each treated inpatient. About 5 percent of patients are inpatient. About one third of cancer patients both medical and radiation oncology. Those patients would face increased logistics issues if a new Carteret County unit is freestanding rather than hospital-based.

EVIDENCE OF NO UNNECESSARY DUPLICATION OF SERVICES

As noted, there is substantial evidence supporting the fact that approving this petition will not lead to unnecessary duplication of services.

- Table 1 shows that CHC reached the Methodology's "efficient use" point in 2020 and all evidence points to increased demand as the already senior age Carteret population gets still older.
- Service Area 24 incorporates two hospital systems that serve different populations, as demonstrated in their patient origin data. Not permitting Carteret Health to add a second linear accelerator will not guarantee that CarolinaEast fills to capacity.
- Limiting the number of LINACS at CHC penalizes patients who live closer to Carteret Health Cancer Center, and the patients' already stressed caregivers, who will face access barriers. A second would represent necessary duplication in Service Area 24.

EVIDENCE OF CONSISTENCY WITH NC 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*."

The proposed special need is consistent with this principle:

- Patient safety is a function of staff, protocols, quality equipment and sufficient volume for the team to maintain proficiency. As proposed, the petition would protect all of these requirements.
- Cancer treatment involves an integrated team. Sending patients to multiple locations for care decreases the level of integration. Coordinated electronic medical records can only go so far in care integration. Pandemic quarantines reinforced the importance of face-to-face interactions to enhanced quality.

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."*

The proposed special need is consistent with this principle:

- Economic barriers to care consist of payor arrangements and patient costs to obtain services. CHC accepts all payors, and has a generous charity care program.
- Carteret County is rural. Access barriers include fewer providers than urban centers and greater distances traveled to get to these providers. Patients in rural areas often lack transportation and support resources needed to get to medical appointments. As a result, people in rural areas are diagnosed with cancer in later stages and are at higher risk of mortality[4]. Cost of transportation and risks of delayed care are also part of economic barriers. Having access to high quality cancer care, such as that offered by CHC, is especially important for rural county residents.
- Provisions in this petition require demonstration that applicants for the proposed need meet reasonable performance standards established by a third-party group of clinical professionals, The International Society Council for Radiation Therapy.

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."*

The proposed special need is consistent with this principle:

According to current charge comparisons available from published websites, CHC is a competitive lower-charge provider. Asking physicians on the CHG medical staff to refer patients to other facilities, which may be outside Service Area 24 can mean higher cost of care associated with the additional travel and housing accommodations and may mean that Service Area 24 residents who have fewer resources do not get care.

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[4] Rural Cancer Disparities in the United States: A Multilevel Framework to Improve Access to Care and Patient Outcomes. K. Robin Yabroff, Xuesong Han, Jingxuan Zhao, Leticia Nogueira, and Ahmedin Jema. *JCO Oncology Practice* 2020 16:7, 409-413

CONCLUSION

In summary, Carteret County needs an additional linear accelerator, specifically dedicated to Carteret County included in the 2022 SMFP.

- The geography of Carteret County is unique in the state. It is bounded on three sides by water. Thus, travel times, even within the county, are longer than the same distances in other counties bordered only by land
- The one linear accelerator in Carteret County operated above 6,750 ESTVs during Fiscal Year 2020 and trends show the number of ESTVs will increase in future years.
- Utilization of the one linear accelerator in Carteret County would have generated a need under the standard methodology were Carteret County treated like other, single county service areas created since the 2006 SMFP.

The proposed changes are timely, would not cause unnecessary duplication of services, are consistent with and support the Basic Principles that govern the *SMFP*. The request is supported by our Cancer Center medical staff, our County-appointed Board of Trustees, and local economic developers.

Carteret Health respectfully requests approval.