Petition to the State Health Coordinating Council Regarding a Change in Methodology for Fixed PET Scanners

2025 State Medical Facilities Plan

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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 CHANGE

Carteret Health, respectfully requests a change in the *2025 State Medical Facilities Plan* methodology for fixed Positron Emission Tomography ("PET") Scanners in Chapter 15 F. The change would provide a path for mid-sized cancer centers in North Carolina to acquire a Positron Emission Therapy ("PET") when the center provides enough external beam radiation therapy to justify two linear accelerators. It changes Part 2 definition of "major cancer center."

The proposed change would also reduce the performance threshold for applications requesting a PET scanner if the proposed fixed PET equipment functions as a linear accelerator simulator. The threshold for the PET simulator / scanner would drop from 2,080 to 1,040 scans in the third year of operation. Suggested in *blue* are the proposed change to Part 2, Step 5, and a new Step 8.

Part 2:

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

Step 6: A service area has a need determination for one additional fixed PET scanner if a major cancer treatment facility, program, or provider identified in Step 5 is hospital-based (i.e., on a hospital's license) and does not own or operate a dedicated fixed PET scanner, except as provided in Step 7 for both parts of the methodology combined.

Step 7: The maximum need determination for a single HSA in any one year will be no more than two additional fixed PET scanners regardless of the numbers generated individually by each part of the methodology (Table 15F-1, Column F).

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 fixed PET scanner. and the number of diagnostic and treatment PET scans proposed is at least 1,040 in the third year of operation..*

REASON FOR THE PROPOSED CHANGE

The standard methodology for PET scanners generates a need in a Health Service Area ("HSA") only when all existing scanners in the HSA reach a performance standard of 2,400 annual procedures. (Translation of Step 3 p 363 2024 SMFP), or when a hospital cancer treatment facility with two linear accelerators reaches 12,500 ESTVs.

The standard methodology provides imperfect access.

Part 2 of the standard methodology effectively 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 yearly. Such centers that do not have a fixed PET scanner can apply for a CON for a fixed PET scanner, regardless of the calculated need for the HSA. This provides for a full complement of diagnostic and treatment services at these centers. However, the standard is too high in today's PET scanner environment. A mid-size cancer center, such as Carteret General Hospital, which the American College of Surgeons ("ACS") certifies as Community Cancer Center and offers medical and radiation oncology services may have two approved linear accelerators but may serve a geography that is too small to reach the 12,500 ESTV threshold. For reference purposes, we note that 12,500 ESTVs almost justify a third linear accelerator, according to the SMFP methodology for linear accelerators in Chapter 15C.

PET scanning is now a standard component of cancer treatment.

PET scanning is now routine in cancer care management. It plays both a diagnostic and a treatment role. With some of the new isotopes< the PET scanner can be part of targeted cancer treatment.

PET scanners produce images of metabolic activity by taking radiographic images of patients who have received a short-lived radioactive isotope. PET scans have the broadest application in care management of cancer patients because most cancers involve rapid development of new cells, which would manifest on the PET scan as an area of unusually high metabolic activity. Until the past few years, only one isotope, FDG, was routinely available, and on the PET scans, it demonstrated only glucose metabolism. Recently, new isotopes have become more widely available, and these show a wider range of metabolic activity. As a result, PET scanners are now more versatile and are routine tools for managing cancer treatment. See Attachment A for more discussion of new isotopes and their role in cancer treatment. At one time, these new, short half-life isotopes were only available in a limited number of places. That, too, has changed. It is now feasible to get the new isotopes to cancer centers that are not in major metro areas.

The 12,500 ESTV threshold definition of a major cancer center is too high. Only exceptionally large cancer centers will provide that many linear accelerator treatments. Today, most patients who get linear accelerator treatment will also require PET scans. Reducing the major cancer center definition threshold will recognize the expanded PET scanner role in cancer care. The capacity of a linear accelerator is 6,750 ESTVs according to the methodology in Chapter 15F of the 2024 SMFP. The 2024 SMFP, as written, does not consider the PET scanner needs of this mid-size cancer center.

Two North Carolina mid-size cancer centers that are like Carteret General, have PET scanners. Nash General Hospital obtained the PET scanner under a different methodology. Southeastern Regional Medical Center obtained the PET scanner in response to a special geographic need petition. Neither provides close to 12,500 annual ESTVs on their linear accelerators or close to 2,400 annual PET scans. However, both PET scanners serve important roles in local cancer treatment.

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

Technology advances make a dual-use PET scanner/simulator feasible.

A "major" cancer center can have enough demand to justify two linear accelerators but not enough patients to reach 2,400 annual PET scans. A dual-function simulator / PET scanner can offset the difference, making the dual-purpose equipment efficient with fewer PET scans.

PET scanning equipment technology has advanced. Several manufacturers make fixed PET scanner equipment that *functions as both a PET scanner and a linear accelerator simulator. The simulator function provides the data needed 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 the patient's position on the linear accelerator platform. Equipment called "simulators" produce these images, exposing the patient to minimal radiation during the planning process. Then, data from the simulators are fed electronically to the linear accelerator to establish the dimensions of the treatment beam. The standard simulator is a CT scanner. That CT scanner may be dedicated to the linear accelerator for simulation only, or it may have secondary use as a diagnostic CT scanner. A cancer center with two linear accelerators can justify a second specialized simulator so that two patients can be in simulation at the same time, especially if that simulator can also have a second function to add operational efficiency. Dual-function fixed PET scanner equipment that can function as either a simulator or fixed PET scanner provides this efficiency.

The PET/CT simulator also has features for radiation therapy planning that are not available on a standard oncology CT simulator. The addition of PET images, obtained in the 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 2024 SMFP Standard Methodology for fixed PET scanners does not anticipate the possibility of dual-function Fixed PET Scanner technology. Yet, a Fixed that can provide both scanner and simulator functions requires fewer PET scan diagnostic or treatment procedures to be financially viable. Reducing the threshold by eliminating the performance standard will open full-time PET scan service for mid-size communities that have developed full-service cancer centers. It only makes sense that the PET scans possible on the dual-purpose equipment will be less than on a dedicated fixed PET scanner. Reducing the threshold in half, from 2080 to 1,040 scans, makes sense.

Chapter 15 A of the SMFP offers precedent for reduced performance standard for dual use equipment. "Shared fixed cardiac catheterization" equipment has a performance standard that is 25 percent of the Fixed Cardiac Catheterization Standard: 225 procedures versus 900. See 10NCAC 14C.1603(a)5 and (b)(3) page 405 of 2024 SMFP.

Mobile PET scanners limit patient access.

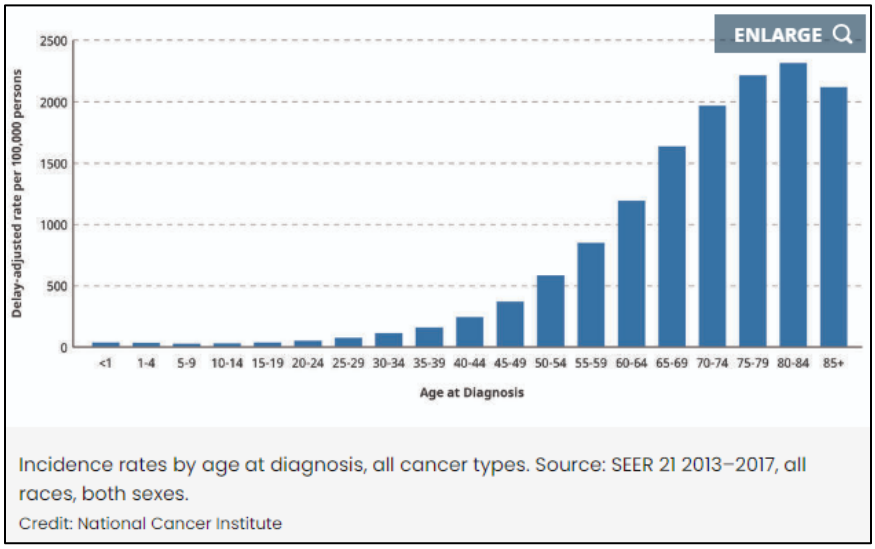
Mobile PET scanners are an imperfect solution – especially for a center with two linear accelerators. Such a center will have more than 250 patients who need regular access to PET scans. Mobile PET scanners are not available every day. They also offer a limited range of isotopes, and they involve the added cost of the mobile management company. Even with the limitations, our one-day mobile PET service is busier than three of the fixed full-time PET scanners in the state.

For example, the Carteret Health mobile PET scanner comes once a week, on Sundays, and provides only the FDG isotope. Last year, we provided 526 PET scans, and we have a two-week waiting list. This itself is an artificial number. The mobile contract limits us to 600 annual scans. 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.

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

The State Demographer forecasts that North Carolina's median age will increase from 39.16 in 2024 to 40.41 in 2030, and the state will add almost three-quarters of a million new residents in that period. In Carteret County, the median age is already over 49.

Geography and Demographics

North Carolina healthcare resources are not evenly distributed across the state. The 34 fixed PET scanners are concentrated in the metro areas. Yet, North Carolina has mid-size cancer centers that serve patients who live in challenging geographies and do not have fixed PET scanners. For example, Carteret County would benefit from this policy. Its population is much older than the state and its two-peninsula geography includes waterways that separate many communities by long distances from even Carteret Health cancer center. It has CON approval for two linear accelerators, and construction of a replacement cancer center is underway. Carteret Health gets mobile PET service from a third-party vendor, but only one day a week, on Sunday. It is in HSA VI, the geographically largest in the state.

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

Without the proposed change, North Carolina will have unbalanced access to a standard element of cancer care. Patients and providers will continue to face costly obstacles to care.

Cancer treatment is taxing for the patient and the patient's family / support group. The person with cancer cannot transport themselves to treatment or 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 cutting barriers to service access.

In a smaller community (county), if the PET scanner is not at the cancer center – and likely there will be only one cancer center – the patient and support person must plan for a whole new set of travel coordination to obtain this essential care element. Staff of the cancer center must also take extra coordination steps – both add to cost and risk communication errors in the transition.

Today, as the result of improvements in cancer treatment, the state has more cancer survivors. Cancer survivors are at risk for re-occurrences that require treatment. This, too, will add to cancer treatment volume. Attachment C provides a summary of selected Cancer Survival rates in North Carolina.

STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

Wait for the Standard Methodology.

Waiting for the SMFP to produce a need without the change 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 VI 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 efficient alternatives are available.

Require fewer Linear Accelerators to define a “major” cancer center.

The requirement for two linear accelerators is consistent with Step 2 of the standard methodology. It also ensures that demand for the linear accelerator simulator function will be sufficient to justify what will be a second, though part-time, simulator.

Some asked why the proposed changes do not apply to cancer centers that offer brachytherapy or chemotherapy. There are two reasons: First, neither service is measured in Equivalent Simple Treatment Visits (“ESTV”). Second, neither requires a simulator, hence could not benefit from the efficiency of the dual-function PET scanner/ simulator equipment. A radiation therapy simulator supports only a linear accelerator. A simulator produces the data needed to set up the radiation configurations on the linear accelerator. Other radiation therapy modalities, such as brachytherapy, do not require a simulator.

There are limitations regarding what can be treated with Brachytherapy. It is specialized, and it takes place in operating rooms, vaults, or bedside with shielding ----depending on what you are treating. If the program offered only Brachytherapy, which is rarely the case, it would be limited. Most Brachytherapy programs are part of much larger systems that have physicians who specialize in that type of treatment. It takes allocated resources for the planning from a physicist role and then "room" time for the insertion. On the other hand, it is entirely possible to have a busy cancer center with two linear accelerators and no brachytherapy program.

PET scans in the cancer world are to see affected areas that may not have symptoms in conjunction with a known area of interest. Most times, the PET scans occur in the initial diagnostic work up phases and then in follow-up during treatment.

Acquire a PET simulator.

Carteret Health formally approached the Agency about acquiring a PET simulator. The NC Certificate of Need statute requires a CON for a PET scanner (GS 131E-176(16) (f1) (8), and a CON would require a need in the SMFP. There is no need in the SMFP, and, particularly in HSA VI, is unlikely to generate a need because, though important, existing PET scanners do too few scans to generate need for more in that HSA, by the standard methodology. They averaged 54 percent utilization in 2022.

File a Summer Petition.

Carteret Health filed a special need petition in Summer 2023. The SHCC suggested that the need could be broader than Carteret, noted that the proposal would require adjustments to the Performance Standards – CON Rules for PET Scanners[1], and recommended that Carteret Health consider a petition for change that would not require an administrative rules change. This petition provides that alternative and reduces the administrative burden on the Agency to implement the change.

The expected scans would be identified in the methodology.

[1] 10A NCAC 14C.3700

EVIDENCE OF NO UNNECESSARY DUPLICATION OF SERVICES

The narrow definition of eligible applicants limits the number of additional PET scanners in the state. A cancer center that has two linear accelerators and is already offering limited PET scanning by means of a mobile unit should have an opportunity to demonstrate that it can provide better and more efficient patient access.

Dual use of the Fixed PET equipment should reduce the capacity threshold requirement. It is impossible to purchase part of a PET scanner or part of a linear accelerator simulator.

With age comes new cancer cases. Official forecasts of "new" cancer cases do not automatically include survivors. These patients currently represent about 25 percent of CHC's cancer patients. Their numbers will increase as systemic therapy becomes 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. Effective care means people live longer, but metastatic cancers do reoccur, and linear accelerators and PET scans can effectively retreat them.

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 planning. Equipment and isotopes have advanced significantly since Massachusetts General introduced this modality in the 1950's. Adopting a policy that permits mid-size cancer centers that have two linear accelerators but fall short of the current definition of "major cancer center" to adopt dual-purpose simulator / scanner technology will provide North Carolina with a natural and systematic progression in access to the methodology while maintaining safety and quality.

Honoring the rest of the wording in the major cancer definition will assure that the PET scanner is in a licensed facility that is subject to oversight by NCDHSR Licensure Section.

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 methodology change that accommodates the cancer center that has two linear accelerators and does not have a fixed PET scanner 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 healthcare 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. This presumes that the equipment has only one purpose. It also fails to acknowledge the travel distances and obstacles in rural areas.

At Carteret Health, mobile PET scanner restrictions on schedule and radiotracers mean 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 worsen when the necessary diagnostic PET/CT imaging is unavailable near their home. 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.

The savings from not leasing a mobile PET scanner and the income from simulations and additional PET scans – even at the reduced 1,040 scan capacity would offset the extra capital and operating cost over the equipment's useful life. Economically, it makes sense to any cost-conscious board. Keeping costs affordable to our community is one of Carteret Health's high priorities.

CONCLUSION

The proposed change would close a substantial gap in the SMFP methodology for Fixed PET Scanners, provide a cost-efficient solution, yet limit the number of new PET scanners in the state.

ATTACHMENTS:

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 the 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 part 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 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.

Simulation 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 is also used for certain cancer simulations. The PET simulator may be involved in cancer treatment.

Attachment C: 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.