



**Petition for a Special Need Adjustment
For One Additional Linear Accelerator in Service Area 23**

Petitioner

Wayne Memorial Hospital, Inc.
2700 Wayne Memorial Drive
Goldsboro, NC 27534

Howard Whitfield, OT/L, MHA
Chief Operating Officer
p (919) 731-6908
Howard.Whitfield@unchealth.unc.edu

STATEMENT OF THE REQUESTED ADJUSTMENT

Wayne Memorial Hospital, Inc., d/b/a UNC Health Wayne,¹ respectfully petitions the State Health Coordinating Council (SHCC) to create a special need adjustment in the *2025 State Medical Facilities Plan (SMFP)* for one additional linear accelerator in Service Area 23, to be designated for Wayne County, and/or with the stipulation that it can only be approved for an existing multimodality provider of cancer care that does not have a linear accelerator.

BACKGROUND

UNC Health Wayne is the sole acute care facility in Wayne County, which, along with Lenoir and Duplin counties, comprises linear accelerator service area (SA) 23. Through its hospital campus, UNC Health Wayne offers a wide range of healthcare services, including cancer care services. These services include the following modalities

- Chemotherapy;
- Immunotherapy;
- Biotherapy; and,
- Oncological surgical services.

¹ Wayne Memorial Hospital, Inc. is managed by UNC Health.

Petition: One Additional Linear Accelerator in SA 23

UNC Health Wayne

Page 2 of 17

UNC Health Wayne also staffs a comprehensive network of care providers not only limited to physicians and surgeons. Its cancer care team includes a “cancer navigator” – a trained professional who specializes in helping patients and their families understand and holistically move through their cancer care journeys – as well as oncology- and chemotherapy-certified nurses, dietitians, pathologists, radiologists, case managers, and social workers. As discussed in detail below, despite this multidisciplinary team of professionals caring for its cancer patients, UNC Health Wayne lacks one of the fundamental components of cancer care: a linear accelerator.

Beyond its high quality provision of cancer care, UNC Health Wayne has been awarded numerous achievements and recognitions for other services, including recognition from the American College of Cardiology as an accredited chest pain center, a Gold Seal of Approval® from The Joint Commission, a Heart-Check mark for Primary Stroke Certification from the American Stroke Association, and a Platinum Performance Achievement Award in Chest Pain from the National Cardiovascular Registry. UNC Health Wayne has also been awarded six consecutive “A” Hospital Safety Grades from The Leapfrog Group, as well as a 4-star rating for quality from the Centers of Medicare and Medicaid Services (CMS). These quality awards demonstrate that UNC Health Wayne is more than capable of meeting the needs of its patients in Wayne County and beyond, and that the approval of the requested adjusted need determination would allow it to seek a CON to expand this quality of care to a radiation oncology program as well.

REASONS FOR THE REQUESTED ADJUSTMENT

Currently, the linear accelerator need methodology in the *SMFP* states that a need determination for an additional linear accelerator exists when two of the following three criteria are met within a service area:

1. The service area population is greater than or equal to 120,000 per linear accelerator,
2. More than 45 percent of the total patients served on linear accelerators in the service area reside outside of the service area, and/or
3. The difference is at least 0.25 when the ratio of the average number of Equivalent Simple Treatment Visit (ESTV) procedures across the total number of linear accelerators in the service area to 6,750 procedures is subtracted from the number of linear accelerators in the service area.²

While SA 23 does not currently meet these criteria, it is near meeting both criterion 1 and criterion 3. As shown in Table 15C-4 in the *Proposed 2025 SMFP*, the population of the three counties of SA 23, which is comprised of Duplin, Lenoir, and Wayne counties, totals 220,332. The inventory of linear accelerators in SA 23 consists of one at UNC Lenoir Main Campus in Kinston, and another at North Carolina Radiation Therapy Management Services-Goldsboro. This, therefore, equates to a population per linear accelerator of 110,116 ($220,332 \div 2 = 110,166$) – less than 10 percent away from meeting criterion 1. Moreover, according to Table 15C-4, the population of Wayne County alone is 117,140, nearly exceeding the 120,000 population threshold on its own. Lastly, Table 15C-5 in the *Proposed 2025 SMFP* notes that the ESTV procedures divided by 6,750 minus the number of linear accelerators in SA 23 is -0.28, which is also relatively near the threshold of 0.25. Of note, no linear accelerator service areas in the entire state meet criterion 3 in the *Proposed 2025 SMFP*; the closest is SA 7 – the largest linear accelerator service area by

² See 2024 *SMFP*, pp. 315-317. Also see “Technology and Equipment Committee Agency Report: Adjusted Need Petition for a Linear Accelerator in Service Area 17 in the 2024 State Medical Facilities Plan,” p. 1, accessed at https://info.ncdhhs.gov/dhsr/mfp/pdf/2023/tec/03_T03%20-%20FirstHealthLINAC_final.pdf.

Petition: One Additional Linear Accelerator in SA 23

UNC Health Wayne

population – with a 0.11 value for criterion 3. In fact, out of all 28 linear accelerator service areas, only five – SA 6, SA 7, SA 14, SA 19, and SA 25 – had a value greater than that of SA 23 and therefore closer to meeting the criterion 3 value of 0.25. This places SA 23 in the top 20 percent of linear accelerator service areas with ESTV procedures relative to procedures and number of linear accelerators. Additionally, four of the five service areas with higher ESTV ratios have five or more linear accelerators. Of note, the SHCC approved a petition for an adjusted need determination for a linear accelerator in SA 20 in the 2023 SMFP, even though that service area showed a surplus of nearly four (3.91) linear accelerators, based on a hospital in that area in a similar situation as UNC Health Wayne that sought the ability to develop a radiation oncology program.

As evidenced by historical SMFPs, need determinations for linear accelerators based on this methodology have become rare. Since 2019, there have been six need determinations for linear accelerators in the SMFP; of those need determinations, four were granted via adjusted need determinations in response to summer petitions. Of the two that were not, one was in SA 7, which includes Mecklenburg County, the second-most populated county in the state; the other was in SA 19, which includes New Hanover County, the twelfth-most populated county in the state and the most populous county east of I-95.

**Linear Accelerator Need Determinations
2019 – 2025**

SMFP Year	Linear Accelerator Need Determinations	Service Area	Via Adjusted Need Determination?
2025	0		
2024	1	SA 17	Yes
2023	1	SA 20	Yes
2022	2	SA 7	No
		SA 24	Yes
2021	1	SA 19	No
2020	0		
2019	1	SA 18	Yes

Source: 2019-2025 SMFPs.

As mentioned above, UNC Health Wayne is a prominent provider of care in linear accelerator SA 23. In fact, it serves the fifth-most populous North Carolina county east of I-95.

**Top Five Most Populous Counties East of I-95
2024**

County	Population
New Hanover	242,708
Onslow	214,782
Pitt	177,440
Brunswick	166,022
Wayne	117,140

Source: North Carolina Office of State Budget and Management (NC OSBM).

However, despite these facts, UNC Health Wayne does not currently operate a linear accelerator. As stated above, of the two linear accelerators in SA 23, one is operated by UNC Health Lenoir, an acute care facility in Lenoir County; the other is operated by North Carolina Radiation Treatment Management Services, a radiation therapy provider with twelve outpatient radiation therapy care locations across the state, including in Goldsboro in Wayne County.

For a North Carolina hospital of UNC Health Wayne’s size and scope of cancer services to not own its own linear accelerator is an anomaly. Indeed, of the 28 acute care hospitals in North Carolina with approximately 200 licensed acute care beds or more, UNC Health Wayne is the only one that has not been approved to develop or does not currently operate a linear accelerator.³ Moreover, as shown in Table 15C-1 in the *Proposed 2025 SMFP*, numerous hospitals with fewer than 200 beds also operate linear accelerators.

³ WakeMed was approved in 2023 to develop a linear accelerator following a petition for an adjusted need determination and an approved application (Project ID #J-012379-23).

Petition: One Additional Linear Accelerator in SA 23

UNC Health Wayne

**Acute Care Hospital with ~200+ Licensed Acute Care Beds
And Corresponding Linear Accelerator Inventory**

<i>Hospital</i>	<i>Total Acute Care Beds</i>	<i>Does Hospital Have a Linear Accelerator?</i>	<i>Total Linear Accelerators</i>
Atrium Health (All Mecklenburg County Facilities)	1,342	Yes	6
Atrium Health Cabarrus	427	Yes	3
Atrium Health Cleveland	280	Yes	1
Atrium Health Wake Forest Baptist	722	Yes	4
Cape Fear Valley Medical Center	500	Yes	5
CarolinaEast Medical Center	307	Yes	2
CaroMont Health	397	Yes	3
Cone Health	709	Yes	4
Duke University Health System	1,279	Yes	9
ECU Medical Center*	776	Yes	4
FirstHealth Moore Regional Hospital	324	Yes	2**
Frye Regional Medical Center	203	Yes	1
High Point Regional Health	301	Yes	2
Iredell Memorial Hospital	199	Yes	2
Margaret R. Pardee Memorial Hospital	201	Yes	1
Mission Hospital	682	Yes	3
Nash General Hospital	250	Yes	2
New Hanover Regional Medical Center	633	Yes	5
Novant Health (Mecklenburg County)	822	Yes	3
Novant Health Forsyth Medical Center	831	Yes	5
Novant Health Rowan Medical Center	198	Yes	1
UNC Health Rex Hospital	468	Yes	4
Southeastern Regional Medical Center	285	Yes	2
UNC Health Blue Ridge	289	Yes	2
UNC Hospitals	785	Yes	6
WakeMed	810	Yes^	1^
Wayne UNC Health Care	251	No	0
Wilson Medical Center^^	267	Yes	1

Source: *Proposed 2025 SMFP*.

* As Vidant Radiation Oncology, partially owned by ECU Health and located at ECU Health Medical Center.

** CON Project ID # H-012513-24 is currently under review and proposes to develop one additional linear accelerator at FirstHealth Moore Regional Hospital, pursuant to an adjusted need determination in the *2024 SMFP* for a total of three linear accelerators at that facility.

^ Includes one linear accelerator pursuant to Project ID # J-012379-23, which is currently under appeal.

^^ As Wilson Radiation Oncology, owned by Wilson Medical Center.

Petition: One Additional Linear Accelerator in SA 23

UNC Health Wayne

Page 6 of 17

Of note, in 2022, WakeMed petitioned the SHCC for a special need determination for one additional linear accelerator in SA 20, which is comprised of Wake and Franklin counties.⁴ The SHCC ultimately approved the adjusted need determination, resulting in a need for one linear accelerator in SA 20 in the *2023 SMFP*.⁵

For reasons elucidated below, UNC Health Wayne believes the circumstances contextualizing WakeMed's 2022 Summer Petition and UNC Health Wayne's current Summer 2024 petition are similar. Given that the SHCC ultimately approved an adjusted need determination for SA 20 in the *2023 SMFP*, UNC Health Wayne believes there is reasonable precedent for it to also approve an adjusted need determination for SA 23 in the *2025 SMFP*. More specifically, UNC Health Wayne believes there is a specific need for additional linear accelerator services in Wayne County; as such, it is preferable that this adjusted need determination be designated for Wayne County, specifically, and/or for an existing provider of cancer services in multiple modalities that does not currently have a linear accelerator.

It should be noted that there is precedent for a determination being allocated to a single county within a multicounty service area. In 2021, Carteret Health Care submitted a petition for an adjusted need determination for one linear accelerator in SA 24 "to be designated for a licensed acute care hospital in Carteret County."⁶ The Agency recommended approval of the petition, and the need determination in the *2022 SMFP* specifically noted that the SA 24 linear accelerator need determination was "designated for Carteret County."⁷ Similarly, in 2019, Southeastern Health petitioned for a PET scanner in Health Service Area V, specifically designated for Robeson County; that petition was approved and the need was so designated.⁸ Given these precedents, UNC Health Wayne believes that the SHCC can approve this petition with its preferred stipulation of one additional linear accelerator in SA 23 being designated for an existing multimodality provider of cancer services in Wayne County that does not currently have a linear accelerator.

The specific reasons supporting this adjusted need determination are as follows:

1. The demographics of Wayne County, including its aging population, racial makeup, and cancer incidence rates relative to North Carolina;
2. The uncertainty of long-term stability with the current sole provider of linear accelerator-based radiation therapy in Wayne County;
3. The need for linear accelerator services at Wayne County's only acute care hospital; and,
4. The Agency-proposed Policy TE-4, and UNC Health Wayne's applicability to that proposal.

⁴ "Petition for an Adjusted Need Determination for One Linear Accelerator in Service Area 20 in the 2023 State Medical Facilities Plan." WakeMed Health & Hospitals. Accessed at https://info.ncdhhs.gov/DHSR/mfp/pets/2022/summer/T04-WakeMed%20Petition_LINAC_SA20.pdf.

⁵ See *2023 SMFP*, p. 323.

⁶ "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," p. 1, accessed at <https://info.ncdhhs.gov/DHSR/mfp/pets/2021/August11/T04-SA24LinAcPetitionFINAL.pdf>.

⁷ See "Technology and Equipment Committee Agency Report: Petition for Adjusted Need Determination for One Linear Accelerator (LINAC) in Service Area 24, 2022 State Medical Facilities Plan," p. 4, accessed at https://info.ncdhhs.gov/dhsr/mfp/pdf/2021/tec/06_Carteret_LINAC_Agency_Report.pdf; also see *2022 SMFP*, p. 333.

⁸ "Petition for Adjusted Need Determination for One Additional Dedicated Fixed PET Scanner in HSA V," accessed at https://info.ncdhhs.gov/dhsr/mfp/pets/2019/tec/0726_pet_hsav_petition.pdf.

Each of these factors will be discussed in turn below.

1. The demographics of Wayne County support the need for additional radiation therapy services.

According to the Centers for Disease Control and Prevention (CDC), the rate of cancer largely increases with age, regardless of race or gender.⁹ This is relevant to Wayne County, as its age 65 and older population is growing significantly faster than its overall population. According to data from the North Carolina Office of State Budget and Management (NC OSBM), while the population of Wayne County decreased slightly from 2014 to 2024, its population age 65 and older *increased* significantly over that same period of time.

Wayne County Population Growth
2014-2024

<i>Population</i>	<i>2014</i>	<i>2024</i>	<i>Numerical Growth</i>	<i>CAGR*</i>
Total Population	122,108	117,140	(4,968)	-0.4%
Age 65 and Older	17,799	20,841	3,042	1.6%

Source: NC OSBM.

* Compound annual growth rate.

Additionally, Wayne County’s age 65 and older population grew at the fastest rate among the three counties in linear accelerator SA 23, increasing at a compound annual growth rate (CAGR) of 1.6 percent from 2014 to 2024. It also added 3,042 residents age 65 and older, nearly double the number of age 65 and older residents added by Lenoir County, which added the second-most residents among SA 23 counties.

Population Growth in Linear Accelerator SA 23
Age 65 and Older Population 2014-2024

<i>County</i>	<i>2014</i>	<i>2024</i>	<i>Numerical Growth</i>	<i>CAGR</i>
Duplin	8,439	7,697	(742)	-0.9%
Lenoir	10,348	11,954	1,606	1.5%
Wayne	17,799	20,841	3,042	1.6%

Source: NC OSBM.

Also relevant to cancer incidence, Wayne County has a relatively high percentage of Black residents; unfortunately, Black individuals are in overall greater need of healthcare services than White individuals. The data indicating this socioeconomic disparity is overwhelming: according to the CDC, racial and ethnic minority groups – including Black individuals – “experience higher rates of illness and death across a wide range of health conditions, including diabetes, hypertension, obesity, asthma, and heart disease, when compared to White counterparts.”¹⁰ This extends to cancer, as well; dashboard data from the CDC shows

⁹ “U.S. Cancer Statistics Visualizations Tool.” U.S. Cancer Statistics Working Group, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Last updated November 2023, accessed at <https://gis.cdc.gov/Cancer/USCS/#/Demographics/>.

¹⁰ “Racism and Health.” Centers for Disease Control and Prevention, September 18, 2023, accessed July 15, 2024, at <https://www.cdc.gov/minorityhealth/racism-disparities/index.html>.

Petition: One Additional Linear Accelerator in SA 23

UNC Health Wayne

Page 8 of 17

that the overall incidence rate for black, non-Hispanic males is the *highest* among all recorded racial and ethnic groups.¹¹ While race is only one social determinant of health that may contribute to the overall health of a group of individuals, it nevertheless stands that Wayne County’s relatively high percentage of Black residents means that it equitably necessitates more accessible oncology care resources, including radiation therapy delivered via linear accelerator.

According to NC OSBM data, 31.2 percent of Wayne County’s population identified as Black, compared to 20.8 percent of the population of North Carolina overall.

Racial Composition of Wayne County and North Carolina

2024

	<i>American Indian and Alaska Native</i>	<i>Asian</i>	<i>Black</i>	<i>Other</i>	<i>White</i>
Wayne County					
Total Population	1,520	36,544	114,813	5,158	71,950
% of Total	1.3%	1.7%	31.2%	4.4%	61.4%
North Carolina					
Total Population	186,957	433,502	2,280,457	471,374	7,611,816
% of Total	1.7%	3.9%	20.8%	4.3%	69.3%

Source: NC OSBM.

These aging and racial factors in Wayne County ultimately contribute to a county-wide cancer incidence rate that is particularly high. According to 2022 data from the North Carolina State Center for Health Statistics (NCSCHS), Wayne County had the ninth-highest cancer incidence rate per 100,000 population among all North Carolina counties. It also had the highest cancer incidence rate among the three counties in linear accelerator SA 23, although Lenoir County had the tenth-highest cancer incidence rate for that year.

¹¹ “U.S. Cancer Statistics Visualizations Tool.” U.S. Cancer Statistics Working Group, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Last updated November 2023, accessed at <https://gis.cdc.gov/Cancer/USCS/#/Demographics/>.

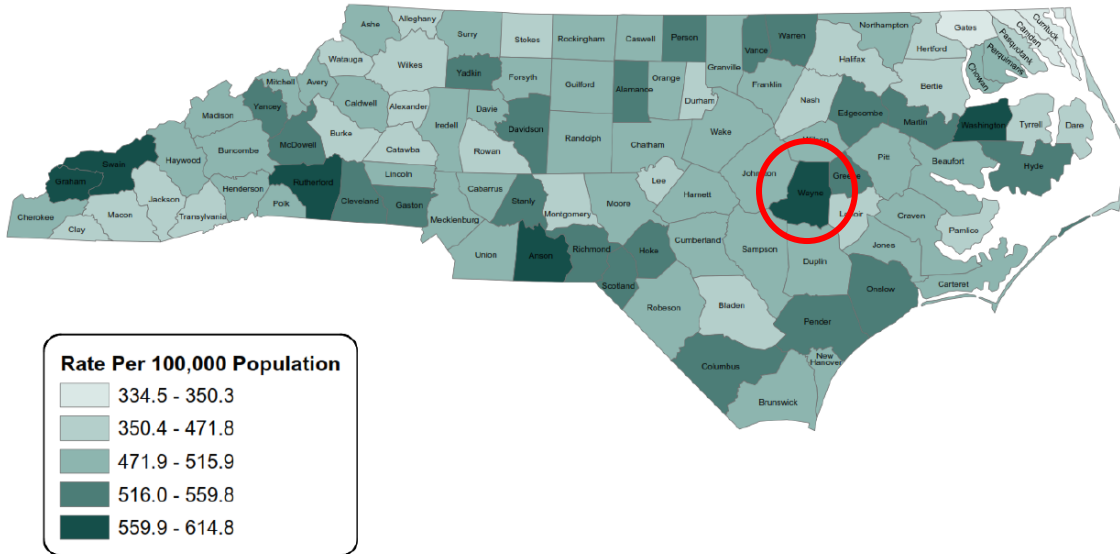
**Top Ten Cancer Incidence Rates per 100,000 Population by North Carolina County
2022**

County	Incidence Rate per 100,000, All Cancers
Swain	574.5
McDowell	550.4
Tyrrell	538.3
Onslow	537.8
Richmond	523.8
Anson	522.0
Martin	520.7
Granville	518.8
Wayne	518.4
Lenoir	515.9
North Carolina	474.6

Source: Source: North Carolina Cancer Incidence Rates, NC State Center for Health Statistics, accessed at https://schs.dph.ncdhhs.gov/data/cancer/incidence_rates.htm.

When visualized, it is evident that Wayne County has a higher cancer incidence rate than any surrounding county, as shown from the map below. Please note that 2021 is the most recent year for which visualized data from the NCSCHS are available.

Map 1: 2021 North Carolina Cancer Incidence Rates by County



Source: North Carolina Cancer Incidence Rates, NC State Center for Health Statistics, accessed at <https://schs.dph.ncdhhs.gov/data/cancer/incidence/2021.htm>.

The cancer mortality rate in Wayne County is also particularly high. NCSCHS data indicate that, in addition to having the ninth-highest cancer incidence rate, Wayne County also had the ninth-highest cancer *mortality* rate among all North Carolina counties. Wayne County's cancer mortality rate of 188.8 per 100,000 population was also the highest among all counties in linear accelerator SA 23.

**Top Ten Cancer Mortality Rates per 100,000 Population by North Carolina County
2022**

County	Mortality Rate per 100,000, All Cancers
Swain	239.7
Richmond	197.4
Halifax	195.9
Scotland	195.4
Onslow	195.4
Tyrrell	193.1
McDowell	192.5
Robeson	191.2
Wayne	188.8
Vance	188.8
North Carolina	153.1

Source: Source: North Carolina Cancer Mortality Rates, NC State Center for Health Statistics, accessed at https://schs.dph.ncdhhs.gov/data/cancer/mortality_rates.htm.

Cancer mortality has also increased historically in Wayne County. From 2018 to 2022, the cancer mortality rate per 100,000 population of Wayne County grew at a CAGR of 1.6 percent. This was the ninth-highest cancer mortality rate CAGR among all North Carolina counties over that period of time, and the highest among counties in linear accelerator SA 23. Of note, only 27 counties in North Carolina have experienced a growth in their cancer mortality rate since 2018; in fact, the overall cancer mortality rate in North Carolina has actually *decreased* at a CAGR of -1.3 percent over that time period.

**Top Ten Cancer Mortality CAGR per 100,000 Population by North Carolina County
 2018-2022**

County	Mortality Rate per 100,000, All Cancers, 2018	Mortality Rate per 100,000, All Cancers, 2022	CAGR
Swain	192.2	239.7	5.7%
Columbus	161.0	186.8	3.8%
Tyrrell	166.5	193.1	3.8%
Camden	139.4	157.2	3.0%
Jones	150.6	167.7	2.7%
Richmond	181.4	197.4	2.1%
Anson	173.7	186.7	1.8%
Hertford	151.1	162.3	1.8%
Wayne	177.2	188.8	1.6%
McDowell	180.8	192.5	1.6%
North Carolina	161.4	153.1	-1.3%

Source: Source: North Carolina Cancer Mortality Rates, NC State Center for Health Statistics, accessed at https://schs.dph.ncdhhs.gov/data/cancer/mortality_rates.htm.

The totality of these demographic factors indicates the need for additional radiation therapy services in Wayne County specifically. Given the status of radiation therapy providers in SA 23 – detailed below – UNC Health Wayne believes that an additional linear accelerator is needed, particularly in Wayne County, and specifically at a facility that already provides multiple types of cancer care, except for radiation therapy.

2. The long-term stability of radiation therapy services in Wayne County is uncertain.

As noted above, the sole provider of linear accelerator services in Wayne County, and one of only two providers of linear accelerator services in SA 23, is North Carolina Radiation Therapy Management Services. North Carolina Radiation Therapy Management Services is owned by GenesisCare, a provider of radiation oncology, medical oncology, urology, and surgical services in North Carolina and Florida; according to its website, GenesisCare operates a total of 12 medical oncology, radiation oncology, or urology centers of care in North Carolina, and 138 total centers of care in Florida.¹²

Of note, GenesisCare is in fact a larger international corporation that is formally headquartered in Australia, and is owned in part by China Resources Group, a conglomerate based in Hong Kong; and Kohlberg Kravis Roberts (KKR), a global investment firm.¹³ Also of note, GenesisCare’s United States operations filed for Chapter 11 bankruptcy in 2023, largely a result of a significant debt load following this

¹² “Our Locations.” GenesisCare. Accessed June 5, 2024, at <https://www.genescareus.com/en/our-locations>.

¹³ “Our Leadership Team.” GenesisCare. Accessed June 5, 2024, at <https://www.genescare.com/uk/our-leadership-global-team#:~:text=GenesisCare%20is%20owned%20by%20doctors,headquarters%20are%20in%20Sydney%2C%20Australia>.

U.S. expansion.¹⁴ While UNC Health Wayne is not suggesting that this ongoing corporate restructuring in any way currently affects or will affect the quality of care that GenesisCare – and therefore North Carolina Radiation Therapy Management Services – is currently able to provide to the residents of Wayne County and SA 23, it nevertheless stands that the sole provider of radiation therapy services in Wayne County is not a part of a not-for-profit, North Carolina-based healthcare system. This lack of a concrete connection to North Carolina, and Wayne County in particular, may create potential risk for Wayne County patients' continuity of care, especially as GenesisCare continues to restructure its businesses and holdings, with a focus on many different areas of the world. Additionally, the absence of provision of radiation oncology care by a non-profit entity could place patients with little or no insurance at greater risk of not receiving care; this would not be the case at a mission-based provider like UNC Health Wayne, where all patients receive needed treatment regardless of their ability to pay.

An additional, perhaps more acute risk is the lack of succession for the current radiation oncology physician in Wayne County. For many years, there has been only one radiation oncologist in Goldsboro who provides radiation therapy care at North Carolina Radiation Therapy Management Services in Goldsboro: Dr. Kevin Kerlin. While UNC Health Wayne has an outstanding relationship with Dr. Kerlin, and therefore has high praise for his competency, ability, and expertise, it should be noted that he is nearing retirement age: Dr. Kerlin is 66 years old.¹⁵ While a second radiation oncologist, Dr. David Cook, provides coverage for Dr. Kerlin when needed, Dr. Cook practices in Clinton, which is in Sampson County – outside of linear accelerator SA 23. Further, like Dr. Kerlin, Dr. Cook is nearing retirement age: he is 65 years old.¹⁶ In other words, the retirement of even *one* of these physicians would effectively cut the capacity of oncology care able to be provided to Wayne County patients in *half*. Without its own linear accelerator and radiation oncology program, UNC Health Wayne has little recourse in recruiting additional radiation oncologists, but is at the mercy of GenesisCare, an international corporation with many other sites that may also be recruiting providers.

UNC Health Wayne believes that, by adding an adjusted need determination for one linear accelerator in SA 23 to be located in Wayne County, this eventual dearth of radiation oncologists can be counteracted. If UNC Health Wayne is able to offer radiation therapy services, it could proactively recruit radiation oncologists to Wayne County, ensuring the ongoing supply of these providers in Wayne County and SA 23. While the linear accelerator need determination methodology does not account for these factors, UNC Health Wayne believes it is vital to consider them given the current status of radiation oncologists in Wayne County, an essential component of providing linear accelerator services.

¹⁴ See Sebastian, David. "KKR-Backed Radiotherapy Group GenesisCare Files for Bankruptcy." *The Wall Street Journal*, June 1 2023, accessed at <https://www.wsj.com/livecoverage/stock-market-today-dow-jones-06-01-2023/card/kkr-backed-radiotherapy-group-genescare-files-for-bankruptcy-LIVUzBoTLS8Z2Z8qPcP9>. Also see LaFrenz, Carrie and Whyte, Jemima. "GenesisCare emerges from bankruptcy, cuts deal with government." *The Australian Financial Review*, February 18 2024, accessed at <https://www.afr.com/companies/healthcare-and-fitness/genescare-emerges-from-bankruptcy-cuts-deal-with-government-20240218-p5f5t5>.

¹⁵ According to Healthgrades; see <https://www.healthgrades.com/physician/dr-kevin-kerlin-2x2kk>.

¹⁶ Ibid; see <https://www.healthgrades.com/physician/dr-david-cook-35qll>.

3. UNC Health Wayne has a need for linear accelerator services for its patients.

As noted above, UNC Health Wayne currently provides a broad scope of oncology services and is proud to offer these high-quality services to patients who choose to seek care at its facilities. UNC Health Wayne has operated an oncology program for over twenty years, starting with outpatient medical oncology and infusion services, eventually expanding its care to inpatient medical and surgical services. However, without the radiation component, which typically 50 percent of cancer patients or more require, it has found itself constrained in the services that it can provide, as well as hampered by the referral wait times that its patients must often face.

According to internal analysis, the current wait times for patients referred to radiation oncology services from UNC Health Wayne is significant. On average, a referral from UNC Health Wayne for radiation oncology services takes 14 days to be processed by the receiving provider; it then takes an additional 10 to 15 days for that referral to be scheduled. Because the scheduling of radiation therapy services can take weeks, this delay adds time between the patient's diagnosis and radiation therapy services being initiated. Overall, the total time from initial UNC Health Wayne referral to actual radiation therapy services first being delivered can be six to eight weeks – in other words, up to two months.

This is a long time for a patient with an incredibly serious, stressful condition to have to wait to receive lifesaving care. Not only do long wait times for services contribute to additional patient mental distress – including anxiety about their disease, depression concerning their physical health, and other negative mental health issues affecting both the patient and their families and caregivers – but it can lead to the patient's cancer continuing to progress; for those in need of urgent services, two months may be a critical period of time in which the cancer can spread to nearby tissue or lymph nodes, or – worse – metastasize to other areas of the patient's body entirely. As noted above, both cancer incidence and mortality rates are high in Wayne County; UNC Health Wayne believes that these delays may contribute to high mortality; at the very least, they do not ameliorate it.

Given this, it is critical that a facility like UNC Health Wayne – which treats a wide variety of cancer patients, and which operates in a geographic location particularly at-risk for cancer, as discussed above – has the ability to apply for its own radiation therapy services on-site. Having a linear accelerator in its hospital itself would drastically reduce the wait time for radiation therapy services for patients, leading to better health outcomes and more satisfied and less stressed oncology patients. While UNC Health Wayne's addition of linear accelerator services is ultimately pending the approval of this petition by the SHCC and the subsequent submission and approval of a CON application by the Agency, it nevertheless believes it can demonstrate the need its patients have for a linear accelerator at UNC Health Wayne.

4. The Agency has acknowledged the need for facilities like UNC Health Wayne to operate a linear accelerator.

Perhaps the most vital argument supporting the need for a linear accelerator at UNC Health Wayne comes from the Agency itself. In Spring 2024, the Agency proposed the creation of a new Policy, Policy TE-4, that would create a plan exemption for linear accelerators. As outlined in that petition, the criteria for this policy would be as follows:

Policy TE-4: Plan Exemption for Linear Accelerators

The applicant proposing to acquire a linear accelerator (LINAC) under this policy shall demonstrate in its certificate of need (CON) application that:

1. it is or proposes to be a cancer center/program as defined in one of the categories used by the American College of Surgeons Commission on Cancer;² and
2. the proposed LINAC will not be located at a site where the inventory in the SMFP reflects that there is an existing or approved LINAC obtained in the five years immediately preceding the filing of the CON application; and
3. it has at least one radiation oncologist affiliated with the center; and
4. it has at least one medical physicist affiliated with the center or available by referral; and
5. if the service area has at least one LINAC, the average ESTVs across all LINACs in the applicant’s service area is at least 3,375.

The performance standards in 10A NCAC 14C .1903 are not applicable.

Source: “Proposed Policy TE-4: Plan Exemption for Linear Accelerators Agency Recommendation.” Spring 2024, accessed at https://info.ncdhhs.gov/DHSR/mfp/pets/2024/spring/T05_PolicyTE-4_LINAC_Agencyproposal.pdf.

Following the June 2024 SHCC meeting, the recommendation was to table the creation of this policy but to continue deliberations on this issue in Spring 2025. However, it is notable that, under the provisions of this policy, UNC Health Wayne would potentially qualify to apply for a linear accelerator without a need determination in the SMFP, as it operates a cancer center, is not a site with an existing or approved linear accelerator, has one radiation oncologist available by referral, would have one medical physicist affiliated with that center, and exists in a service area with at least one linear accelerator and in which, as noted in the *Proposed 2025 SMFP*, the average ESTVs across both service area linear accelerators is far greater than 3,375, as shown in Table 15C-1 from the *Proposed 2025 SMFP*, below.

UNC Lenoir Health Care	23	Lenoir	1	6,015	6,015
North Carolina Radiation Therapy Management Services - Goldsboro	23	Wayne	1	5,595	5,595

Source: *Proposed 2025 SMFP*, p. 318, accessed July 5, 2024.

In other words, UNC Health Wayne’s current petition is supported by the drafting of the policy that the Agency itself has put forth in order to expand much-needed access to radiation therapy care at facilities that have the ability and staffing means to provide such care. While the policy itself has been tabled until next year and may or may not at that time be adopted, UNC Health Wayne believes that, in consideration of the factors discussed above, it must now request the adjusted need for Wayne County. UNC Health Wayne believes that this is in line with the Agency’s current thinking towards linear accelerator-based radiation therapy services in the state and is consistent with the SHCC’s recent approval of similar petitions in recent years; as such, it requests its adoption in the *2025 SMFP*.

ADVERSE EFFECTS ON PATIENTS IF THE PETITION IS NOT APPROVED

If the current petition is not approved, oncology patients at UNC Health Wayne will continue to require referrals to outside radiation therapy providers – either to North Carolina Radiation Therapy Management

Petition: One Additional Linear Accelerator in SA 23

UNC Health Wayne

Page 16 of 17

Services in Goldsboro, to UNC Health Lenoir in Lenoir, or to providers at an even greater distance – thereby leading to a delay in patients receiving this essential and life-saving care and/or additional geographic and temporal barriers to care. As noted above, some Wayne County cancer patients are currently experiencing significant wait times to start linear accelerator-based radiation therapy treatment; for those patients with cancer, already a major medical challenge, this additional time creates yet more unnecessary and avoidable stress. When coupled with the fact that, as stated above, most cancer patients are older and therefore may struggle with transporting themselves to this care – which must be delivered at the site of the linear accelerator daily for multiple weeks – having an additional and accessible provider of linear accelerator-based radiation therapy care in Wayne County will make accessing radiation therapy services much easier for the county’s cancer patients.

ALTERNATIVES CONSIDERED

At this time, UNC Health Wayne believes the only alternative is to maintain the status quo: in other words, wait for the current linear accelerator need determination methodology to show that an additional linear accelerator is needed in SA 23. In absence of the Agency-proposed Policy TE-4 – described above – UNC Health Wayne believes this is unlikely. While UNC Health Wayne recognizes that SA 23 is close to meeting both criterion 1 and criterion 3 of the linear accelerator need determination methodology, population growth in the area is slow, particularly outside of Wayne County. SA 23 is a geographically large service area and is comprised of three rural counties, and there are currently only two linear accelerators in the entire service area; further, only one of these linear accelerators is operated by an acute care facility with the full suite of services of a hospital. Further, given the rural nature of the service area, it is unlikely that it would provide a sufficient percentage of care to residents from outside the area to qualify under criterion 2.

As noted above, the Agency-proposed Policy TE-4 would potentially allow UNC Health Wayne, as an acute care hospital operating an on-site cancer center, to apply for a linear accelerator without a need determination. However, this new policy has not yet been adopted by the SHCC, and, in fact, may never be. As such, it cannot be considered a reasonable alternative by which UNC Health Wayne could potentially apply for and receive a certificate of need for a linear accelerator. As such, UNC Health Wayne believes that the proposed adjusted need determination is the only way to currently ensure that both its patients and the patients of Wayne County have adequate access to linear accelerator-based radiation therapy services, both currently and in the future.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

The proposed special need adjustment would still require any applicant to meet the linear accelerator performance standards, as detailed in 10A NCAC 14C .1903. As such, any need added to the *Proposed 2025 SMFP* would still have to undergo CON review and be approved by the Agency, and as such would not unnecessarily duplicate linear accelerator services in the service area. Additionally, as detailed above, UNC Health Wayne would prefer if the proposed special need adjustment was made specifically for an acute care hospital in Wayne County. Given the demographic factors for Wayne County, and given the risks to the current provision of Wayne County-located radiation oncology care, UNC Health Wayne believes that the proposed special need adjustment would not unnecessarily duplicate linear accelerator services in the service area, and would in fact meet a current need for additional radiation therapy services for the patients of Wayne County and SA 23.

EVIDENCE THAT THE PROPOSED CHANGE IS CONSISTENT WITH THE THREE BASIC PRINCIPLES

UNC Health Wayne believes its petition is consistent with the three basic principles: safety and quality, access, and value.

Safety and Quality

As the only acute care facility in Wayne County, UNC Health Wayne believes that the proposed adjusted need determination would result in additional high quality radiation therapy care in SA 23, particularly in Wayne County. Specifically, the petition requests that the need be limited to an existing provider of cancer services in multiple modalities. As such, the approved applicant would necessarily be expanding its scope of services, providing more comprehensive care with more direct coordination. Moreover, the current uncertainty around the long-term provision of radiation therapy in Wayne County underscores the need for another provider to ensure safe and quality care can continue to be provided well into the future.

Access

The proposed adjusted need determination would also expand access to radiation therapy services in Wayne County and the service area. As noted above, there is only one provider of linear accelerator-based radiation therapy treatment in Wayne County; UNC Health Wayne believes that that provider, owned and operated by GenesisCare, an international corporation that has experienced significant financial turmoil, cannot guarantee long term access to radiation therapy in the service area. This risk, combined with the aging of the local radiation oncologists, brings long-term access for Wayne County patients into question. By allocating a linear accelerator to be developed specifically at another existing cancer care provider in Wayne County, long-term access to radiation therapy services would be more certain for the cancer patients of Wayne County.

Value

The proposed adjusted need determination also promotes the value of care provided to SA 23 and Wayne County patients. As detailed above, UNC Health Wayne must currently refer all cancer patients who require linear accelerator-based radiation therapy to outside providers. This results in a delay in delivered services to the patient, which thereby results in an increase in average expenditures by both the patient and their payor, not only due to the additional travel time, but also due to the possibility of more necessarily aggressive treatments resulting from the delay in patients' radiation therapy care. As such, the cost of care following delays can be more expensive than necessary. The approval of the proposed petition will therefore promote the value and cost-effectiveness of radiation therapy services in Wayne County and SA 23.

UNC Health Wayne appreciates the SHCC's consideration of this petition.