Comments in Opposition to Wilmington Health, PLLC
Certificate of Need Application for one Linear Accelerator in Service Area 19
September 1, 2021 - CON Review Cycle

INTRODUCTION

The 2021 State Medical Facilities Plan ("2021 SMFP") recognized a need for one linear accelerator ("linac") in Service Area – 19 ("SA-19"). Two applicants have filed Certificate of Need ("CON") applications for a linac in response to the identified need including Project I.D. O-12110-21 filed by Novant Health New Hanover Regional Medical Center, LLC ("NHRMC") and Project I.D. O-012120-21 filed by Wilmington Health, PLLC ("Wilmington Health").

The identified areas of non-conformity of Wilmington Health's application along with the comparative analysis set forth below reveal that NHRMC is the only approvable and most effective applicant in this review and as such, should be approved.

OVERVIEW

Wilmington Health is a private, multispecialty medical group practice in southeastern North Carolina. Wilmington Health owns and operates 19 physician practices across eastern North Carolina including the physician practice and infusion center (the proposed location) in Wilmington, North Carolina. Wilmington Health proposes to offer linac services at its practice centrally located in Wilmington, New Hanover County, North Carolina. Wilmington Health has no experience whatsoever providing radiation therapy services. It has never operated a linac, has no radiation oncologist on staff, and has no clear plan for recruiting one. While these facts alone do not disqualify Wilmington Health from applying in this review, they are important facts that the Agency must consider as it evaluates Wilmington Health's proposal. Radiation therapy entails using radioactive materials with a linac to provide external beam radiation therapy and internally with brachytherapy to treat cancer patients.[1] Thus, it is an inherently complex, highly specialized service provided to a seriously ill patient population. Wilmington Health's lack of experience permeates every aspect of its proposal and raises significant concerns about the credibility of its projections, in addition to the overall safety, quality and cost effectiveness of its proposal. Wilmington Health presents concerns such as cost effectiveness, capacity constraints, and outmigration as justification for its proposed project. Wilmington Health's argument regarding outmigration is simply inaccurate. Moreover, Wilmington Health's proposed project will not address any of the mentioned concerns. In fact, Wilmington Health's proposed project will result in the following:

- An underutilized linac and brachytherapy unit that will be limited in access, will not meet the needs of SA-19 patients, and does not meet Performance Standards;
- Increased cost based on lack of experience providing radiation therapy and the cost of contracting for many of the vital positions in order to operate a linac;
- Reduced quality and safety based on lack of experience, unidentified critical clinical resources, underbudgeted staffing, and an absence of continuity and a continuum of cancer services; and

[1] Wilmington Health CON Exhibits, Varian Vendor Quote, PDF pp. 51-53 indicates that equipment will be purchased to provide brachytherapy. Brachytherapy is not, however, discussed anywhere in the CON application.

- Duplication of existing linac services with 3 existing linacs located in downtown Wilmington, 1 mile away from the proposed location.

Given Wilmington Health will likely serve its own patients, and only its own patients, the proposed project will not have any positive impact on existing providers in the service area. The non-conformity with review criteria along with the comparative analysis provided below clearly illustrates that Wilmington Health's CON application for one linac should be denied.

NON-CONFORMITY WITH REVIEW CRITERIA

Criterion (1) Policy GEN-3 – Wilmington Health's Project is not Consistent With the 2021 SMFP

Conformity with the need determination in the SMFP is only one part of Criterion (1). The applicant must also demonstrate that its proposal is consistent with the applicable policies in the SMFP which, in this case, includes Policy GEN-3. Policy GEN-3 asks whether the applicant's proposal promotes safety and quality, equitable access and maximizes healthcare value for resources expended. The applicant's lack of experience in offering radiation oncology services is directly relevant to Policy GEN-3. As discussed throughout these comments, the applicant has presented unreliable utilization projections and questionable financial feasibility. It has no radiation oncologist and no concrete plan for hiring one. The radiation therapist staffing is also unsupported. Understated costs may leave the reader with the impression that this proposal is cost effective when the exact opposite is true. In addition, the applicant proposes to serve mostly (if not entirely) Wilmington Health's own patients. It will not be a resource for the broader community and therefore does not promote equitable access. Additionally, the Financial Assistance Policy the applicant included is unclear, so financial access for medically underserved populations is questionable. As will be discussed in detail below, Wilmington Health's project does not demonstrate that it will be able to implement linac services in a way that promotes quality of care including continuity of care. Fundamentally, then, Wilmington Health's proposal does not maximize healthcare value for resources expended. More detailed discussions of each of these factors can be found, below, in NHRMC's comments concerning Wilmington Health's non-conformity with Criteria (3), (4), (5), (6), (7), (8), (12), (13), and (18a) respectively. Accordingly, the application should be found non-conforming with Criterion (1).

Criterion (3) – Wilmington Health Does not Show a Need for its Project and Projected Utilization is Unrealistic and Unsupported

Wilmington Health fails to demonstrate the need for its proposed project as required by Criterion (3) for several reasons, including unsupported and unrealistic utilization projections and important factors that have been disregarded or misrepresented in its application. These issues are discussed at length below. For the reasons discussed herein, Wilmington Health fails to clearly document the specific need for the proposed project.

<u>There is no Need for Wilmington Health's Radiation Therapy Service</u>

Wilmington Health's need analysis is directly impacted by its lack of experience in providing radiation therapy and its underlying lack of understanding of this service. Wilmington Health directly states it has no experience offering radiation therapy services (see **Wilmington Health CON application, PDF p. 119**). This lack of experience is apparent through the following:

- Lack of actual basis for any of its volume projections;

- Unsupported data analyses;
- Insufficient project costs;
- Defective financial projections; and
- Inclusion of equipment for brachytherapy (see **Wilmington Health CON Exhibits, Varian Vendor Quote, PDF pp. 51-53**) with no supporting projected volume, and insufficient staffing.

Each of these issues with Wilmington Health's projections will be discussed in more detail below.

Wilmington Health clearly lacks proper staffing for its proposed project which is evidenced in its staffing model and costs as presented in its CON application. A linear accelerator service must have a radiation oncologist which Wilmington Health does not currently have on staff. Wilmington Health states in its CON application that it is currently in the process of recruiting a radiation oncologist and that it will have to contract for a physicist as well as a dosimetrist; see **Wilmington Health CON application, p. 36**. Recognizing that it may not be able to successfully recruit a radiation oncologist, Wilmington Health claims that a staffing agency would provide a locum tenens radiation oncologist in the event that one is not hired by the time its proposed project goes live. While Wilmington Health has accounted for one radiation oncologist, either through recruiting or locum tenens, there is no documentation of any other radiation oncologist available to provide backup when the sole radiation oncologist is unavailable such as vacation or sick time. One radiation oncologist with no support cannot cover call 24/7/365.

It is clear that Wilmington Health does not have a well-thought-out staffing plan. It has no radiation oncologist, no real plan for hiring one, and inadequate staffing for the critical position of radiation therapist. Furthermore, the true cost of its project is hidden in its financial pro formas which reveal how costly its proposed project is. Further issues concerning Wilmington Health's staffing and cost will be discussed under Criterion (5) and Criterion (7), respectively.

Wilmington Health's Utilization Projections are Unsupported

Wilmington Health presents unsupported utilization projections that are broken into five steps. Each step is discussed below. By the time Step 5 is reached, it is evident the applicant's projections are unreasonable and unsupported and render the application non-conforming with Criterion (3).

Step 1 – Wilmington Health CON application, PDF p. 119

In the first step of its projected utilization, and several areas of its application, Wilmington Health presents its "Oncology/Hematology" patients seen as its historic utilization and basis for its projected utilization; see **Wilmington Health CON pp. 37, 38, 50 and PDF pp. 119, 120**.

Table 1: Historical Wilmington Health Oncology/Hematology Utilization

	CY19	*CY20*	*CY21**	*CY19-20 Growth*	*CY 19-21 CAGR***
Number of Oncology/Hematology Patients	1,488	1,646	3,403	10.6%	51.2%

Source: Wilmington Health internal data.
*CY 2021 annualized using January to May data. Of note, in just the first five months of CY 2021, Wilmington Health treated 1,418 patients, or nearly as many as it treated in all of CY 2019.
**Compound annual growth rate.

While Wilmington Health providers may indeed have provided care to 1,488 patients in CY19 and 1,646 patients in CY20 with hematologic or oncologic conditions and diagnoses, the relevant statistic in projecting

demand for radiation oncology is new cancer diagnoses ("analytic cases"). Nowhere in Wilmington Health's application or supporting documentation is there evidence of the volume of new cancer diagnoses among its patient population nor is there any attempt to calculate or estimate this key statistic using, for example, unique patients with cancer diagnoses treated by its oncologic specialists.[2]

Moreover, Wilmington Health's "annualization" of the first five months of CY21 (3,403 patients) by dividing by five and multiplying by twelve would seem to confirm that their projections and calculations are based on patient services (perhaps including visits, procedures, and diagnostic services across the entire multispecialty group and regardless of specialty) rather than on unique patients with new cancer diagnoses.

The starting point (1,488 oncology/hematology patients in CY 2019) is overstated in three ways:

- Wilmington Health blended its hematology volume with its oncology volume. It is unreasonable to assume that all hematology patients (patients with cancer of the blood such as leukemia), if any, will receive radiation therapy.[3] To truly project radiation therapy volume for the proposed linac, Wilmington Health should have isolated its *oncology* volume alone.
- This lack of transparency presents other problems. For example, it appears that Wilmington Health included duplicate patients within its data, including:
    - patients seen by the medical oncologist potentially multiple times throughout the year for follow up;
    - the same patient seen by multiple Wilmington Health providers such as primary care physicians, oncologist, and surgeons; and
    - patients treated in prior years and coming in for follow up in multiple successive years.
- It appears that Wilmington Health included all cancer diagnosis includes cancers not relevant to radiation therapy, such as patients with skin cancer (non-malignant) diagnosed by a primary care physician or dermatologist and are not relevant for radiation therapy projections.

Publicly available data contradict the basis for all of Wilmington Health's projections. It can be determined that Wilmington Health overstates its cancer patients seen including duplicate patients/procedures presented in Table 1 based on the following points.

Cancer Incidence Data Contradict Wilmington Health's Data

Cancer incidence data from the North Carolina Office of State Budget and Management ("NCOSBM") does not support Wilmington Health's projections. **Figure 1** below presents the projected new cancer patients for SA-19 based on data from NCOSBM. Wilmington Health projects to "see" 3,403 cancer patients in CY 2021, as shown in Table 1 above. This would mean that, with just one medical oncologist, Wilmington Health would capture 91.7 percent market share (3,403/3,710 x 100 = 91.7%). When NHRMC has 10 medical oncologists unaffiliated with Wilmington Health serving this same market, it is simply unreasonable that Wilmington Health would have over 91 percent market share with just one medical oncologist, as Wilmington Health suggests.

[2] Includes sole medical oncologists and surgeons who provide some specific cancer care that could conceivably need radiation oncology.

[3] According to the Mayo Clinic, leukemia is typically treated through chemotherapy, blood transfusions and stem cell transplant; see https://tinyurl.com/9r2dfhdv

Figure 1
NCOSBM SA-19 Projected New Cancer Incidents

SA-19 Cancer Incidence - New Cases

SA 19 - County	2021 Projected Cancer Patients
Brunswick	1,387
Columbus	375
New Hanover	1,508
Pender	440
Total SA 19	**3,710**

Source: www.osbm.nc.gov/demo/county-projections.

With this unreasonable starting point for its projected utilization, the rest of Wilmington Health's methodology for projected utilization collapses.

NHRMC Analytic Cases Demonstrate the Problems with Wilmington Health's Data

NHRMC's experience directly correlates to the federal and state estimates and projections. In 2019, NHRMC's cancer registry recorded 3,268 analytic cancer cases and another 401 non-analytic cancer cases (meaning it did not have information on original diagnosis or treatment), and it recorded 3,300 analytic cases and 464 non-analytic cases in 2020. This puts total new annual cancer diagnoses (analytic cases) recorded by the NHRMC cancer registry at 3,300-3,800 total cancer cases (3,500 is the approximate mid-point of the range).

Wilmington Health has a single hematologist/medical oncologist, who represents 0.16 percent of total NHRMC medical staff and 8.3 percent of medical oncologists on staff. Extrapolating this to the market analytic cases, with one hematologist/oncologist, it is not possible that Wilmington Health diagnosed and treated 1,646 new and distinct cancer patients in CY 2020, as that would equate to at 45 percent or more (1,646 ÷ 3,500 = 47%) of the entire population of new cancer patients in the area for the year. Likewise, it is not reasonable that in CY2021, still with one hematologist/oncologist, Wilmington Health could double its cancer patients to 3,403 equating to over 90 percent of the entire population of new cancer patients in the area.

Rather, as the Wilmington Health network only includes one (8 percent) of the twelve hematologists/medical oncologists currently practicing in SA-19, it is more likely that Wilmington Health diagnoses and treats a similar percentage of new cancer cases in the service area. Even rounding up to 10 percent would only result in an estimated 350 new and unique cancer cases diagnosed and treated by Wilmington Health's oncology specialist annually in CY 2021. This is much lower than the estimate Wilmington Health provides (3,403 v. 350 in CY 2021).

This estimate is validated by a study of NHRMC's radiation oncology patients, approximately 11-12 percent of whom have some record of care with a Wilmington Health physician during fiscal year 2021 to date, whether referred by a Wilmington Health oncology specialist or simply having a Wilmington Health primary care physician listed in NHRMC's records.

In conclusion, county level cancer incidence and NHRMC cancer registry and referral data confirm that Wilmington Health's "cancer patients seen" is not an appropriate starting point from which to project radiation therapy patients.

Step 2 – Wilmington Health CON application, PDF pp. 119-120

Using the unreasonable starting point from Step 1, Wilmington Health "conservatively" projected its volume forward by taking a third of the compound annual growth rate ("CAGR") from CY 2019 to CY 2020.

Table 2: Projected Wilmington Health Oncology/Hematology Utilization

	CY20	CY21	CY22	CY23	CY24	CY25	CY26	CAGR
Number of Oncology/Hematology Patients	1,646	1,704	1,765	1,827	1,892	1,959	2,028	3.5%

With an unreasonable starting point in Step 2, the growth in utilization is equally unreasonable. Though NHRMC generally agrees with the projected growth rate based on demographic data and other factors, the volume projections are significantly overstated, likely well above five-fold, as discussed above in Step #1. Furthermore, a CAGR based on a trend of only two data points (CY2019 to CY 2020) is unreasonable. A difference in one calendar year does not show a trend that requires smoothing out, which is what a CAGR seeks to do.

Step 3 – Wilmington Health CON application, PDF p. 120

Based on information from the American Cancer Society, Wilmington Health states that approximately two-thirds of cancer patients will receive radiation therapy; see **Wilmington Health CON, PDF p. 120**. Again, to be "conservative", Wilmington Health assumed that it would treat 60 percent of its patients with radiation therapy.

Table 3: Projected Wilmington Health Potential Radiation Therapy Patients

	CY21	CY22	CY23	CY24	CY25	CY26
Number of Oncology/ Hematology Patients	1,704	1,765	1,827	1,892	1,959	2,028
Radiation Therapy Patients as a % of Total Patients	60%	60%	60%	60%	60%	60%
Wilmington Health Potential Radiation Therapy Patients	**1,023**	**1,059**	**1,096**	**1,135**	**1,175**	**1,217**

Though on the surface this ratio appears not to be outside the realm of possibility, it is reasonable only if applied to new cancer cases (analytic cases) and is not appropriate to apply to cancer patient services more broadly, as Wilmington Health has done.

It is again relevant to compare publicly available cancer cases, NHRMC's case data, and the data submitted by Wilmington Health as follows:

- Using the 3,300-3,800 range for new annual cancer cases across the entire market (federal, state, and NHRMC all data agree on this range) and comparing it to NHRMC treating 1,532 patients for annualized 2021, the calculated ratio in this market is between 40 percent and 46 percent.[4] Even when accounting for the limited outmigration from this market for radiation therapy, it is hard to calculate an estimate over 50 percent.

[4] See NHRMC CON application page 78 for annualized 2021 patients treated.

- A 50 percent radiation oncology treatment rate is the general industry and commonly accepted health planning assumption and is used, for example, in projecting radiation therapy patients in Georgia under its CON law[5].

Wilmington Health's 60% assumption lacks a factual basis.

Applying actual parameters experienced in the market would result in Wilmington Health's proposed project falling far short of its projected volume and failing to meet the performance standards.

Step 4 – Wilmington Health CON application, PDF pp. 120 & 121

In Step 4 of its projected utilization, Wilmington Health applies a 10 to 25 percent ramp up of capture rate for potential patients requiring radiation therapy. Wilmington Health provides no basis for this ramp up/capture rate.

Table 4: Projected Wilmington Health Radiation Therapy Patients

	CY21	CY22	CY23*	CY24	CY25	CY26
Wilmington Health Potential Radiation Therapy Patients	1,023	1,059	548	1,135	1,175	1,217
Projected Ramp Up			10%	15%	20%	25%
Projected Wilmington Health Radiation Therapy Patients			**55**	**170**	**235**	**304**

*CY 2023 adjusted to reflect project start date of July 1, 2023.

NHRMC believes it is reasonable that Wilmington Health will capture about 25 percent of its radiation therapy referral volume by Year 3; however, as discussed above, the basis for projected potential radiation therapy patients is overstated in Step #1 and Step #3.

In reality, this factor simply recognizes that there is no possible way the projected figures in Step 3, Table 3 are realistic and that there are not over 1,000 radiation therapy patients coming from Wilmington Health's "total patients seen". As another reality-based data check:

- For the first 6 months of CY2021, 11.5 percent of NHRMC's radiation oncology patients had some type of linkage to Wilmington Health physicians.
- For this same time period, NHRMC treated 576 radiation oncology patients.
- It is reasonable to assume that, at the most, 66 patients were referred by Wilmington Health (and likely far fewer, as some of these patients were associated with Wilmington Health due to their primary care physician on file and were likely referred by other specialists in the community and outside of Wilmington Health).
- Recognizing these 576 patients may have been treated multiple times throughout the year, annualization likely yields a maximum fewer than 100 patients over 12 months – compared to Wilmington Health's projected 304 patients in Year 3.

[5] See GA Rule 111-2-2-.42.(3)(a)(1)(ii) – Standards for Non-Special MRT.

- This is likely a significant overestimate given the liberal methodology used to associate radiation treatment patients with Wilmington Health physicians.

Simply put, Wilmington Health's projections have no basis in reality and cannot be achieved with such a limited referral base of one medical oncologist nor can it be achieved with a limited multi-specialty practice such as Wilmington Health that serves only a fraction of the service area population and that has particularly limited oncology expertise and experience.

Step 5 – Wilmington Health CON application, p. 121

Wilmington Health inappropriately used the experience of 18 existing freestanding radiation therapy providers as the basis for its projected Equivalent Simple Treatment Visits ("ESTVs"); see **Wilmington Health CON application, PDF p. 121**. Wilmington Health averaged the ESTVs per patient for the providers and then applied that average to its projected patient volume.

Table 5: Projected Wilmington Health Radiation Therapy Patient ESTVs

	CY23	*CY24*	*CY25*	*CY26*
Projected Wilmington Health Radiation Therapy Patients	55	170	235	304
Average ESTVs per Patient*	23.26	23.26	23.26	23.26
Projected Wilmington Health ESTVs	**1,275**	**3,960**	**5,467**	**7,076**

*2019 median for 18 North Carolina freestanding linear accelerator providers with one linear accelerator. Please see Exhibit C.5.

The errors in projecting ESTVs in this manner are as follows:

- Wilmington Health picks near the high end of ESTVs range for the sample providers without adjusting for the fact that they admittedly will provide only less complex services; see **Wilmington Health CON application, PDF p. 121 and Exhibit C.5**.
- NHRMC's actual average ESTVs per patient is approximately 21.56 for FY19 and FY20 (compared to the average ESTVs per patient of 23.26 as projected by Wilmington Health). NHRMC's average ESTVs per patient includes the base of patients that Wilmington Health refers to NHRMC and includes patients with more complex procedures.
- It is unreasonable for Wilmington Health to project higher ESTVs than NHRMC, where they refer, when they state they will not have specialized equipment and will likely not provide complex treatments; see **Wilmington Health CON Application, PDF p. 121**.
- Furthermore, if Wilmington Health were to achieve the ESTV-to-patient ratio it proposes in its application, it would by definition mean that they are increasing the cost of care in the community, as the primary driver of total cost of care for provision of radiation treatment is the number of treatments.
    - As noted in NHRMC's application (see **NHRMC CON Application, pp. 33 & 74**), NHRMC Radiation Oncology is materially more efficient than the typical radiation oncology provider. This is validated by NHRMC's participation in the Centers for Medicare and Medicaid Services Radiation Oncology Alternate Payment Model ("APM").

- NHRMC's efficiency is consistently demonstrated by the fact that its average ESTVs/patient are more than 7 percent lower than Wilmington Health's projected ESTVs/patient.
- This impacts the Wilmington Health financial projects in two potential ways:
  - Either Wilmington Health's Medicare reimbursement assumptions are likely too low, and they will be paid exactly the same as NHRMC under the APM, which covers the Wilmington market, or
  - Or if they are paid by Medicare on a per treatment basis, their reimbursement will be approximately 7 percent more than NHRMC based on higher ESTVs.
  - In either scenario, Wilmington Health's Medicare payment is inaccurate which therefore renders Wilmington Health non-conforming to Criterion (5). See the detailed discussion related to Criterion (5) below.

Additional issues with Wilmington Health's projected utilization are as follows:

- Wilmington Health does not provide any letters of support that would provide a reasonable basis to support the projected utilization
  - Wilmington Health's website shows Dr. Michael Marte is the sole medical oncologist at Wilmington Health; however, he is never mentioned by name in the application.
  - Projection Step 2 says the information was reviewed with the Wilmington Health medical oncologist; however, Dr. Marte only provided a form letter with no real insight into the actual volumes experienced at Wilmington Health.
  - Letters of support are all from Wilmington Health employed physicians or staff, regardless of specialty and including unrelated specialties such as orthopedic surgery and cardiology and non-clinical staff such as "manager" that have no relevance to this project.
- Wilmington Health will not provide complex radiation therapy treatments.
  - There is no adjustment in the methodology whatsoever to account for this.

<u>Wilmington Health Will Not Address the Need Generated by NHRMC for Additional Linac</u>

Wilmington Health will not address the published need in the 2021 SMFP for one additional linac in SA-19:

- The need was generated by the high utilization of NHRMC's linacs.
- Wilmington Health will not address NHRMC's capacity constraints because it only generates, at the very most, about 11.5 percent of all NHRMC referrals.
- Wilmington Health will not shift patients from congested downtown Wilmington as its proposed location is one mile from NHRMC's current downtown linear accelerators
- Wilmington Health will not be able to meet required volume based on limited referral volume (11.5 percent).
- Wilmington Health states that it will not provide complex care; see **Wilmington Health CON Application, PDF p. 121**.

<u>Wilmington Health Does not Have the Physician Referral Base to Support the Project</u>

Moreover, Wilmington Health has historically had difficulty recruiting and maintaining a medical oncologist on its staff. Dr. Marte has only been at Wilmington Health since January 2020. According to

Wilmington Biz (local business journal in which Wilmington Health announces physician changes), the following physicians have served as medical oncologist for Wilmington Health since 2015:

- Dr. Fink, who left Wilmington Health and the community in March 2013 and Dr. Markow, who followed suit in December 2014 (note, Dr. Markow returned to Wilmington after his non-compete ended in late 2016 and is now on NHRMC's medical staff).
- After more than a two-year gap in providing oncology services, during which NHRMC oncologists assumed local care and treatment of 100 percent of cancer patients in the region, Wilmington Health announced Dr. McGrath was starting practice in June 2017. Dr. McGrath left Wilmington Health and the community in October 2019.
- After a three-month gap, during which NHRMC oncologists assumed local care and treatment of 100 percent of cancer patients in the region, Wilmington Health announced Dr. Marte was starting practice in January 2020.

Wilmington Health has not had stable staffing at the medical oncologist position, which calls into question its ability to staff the proposed project and the stability of the physician most likely to refer radiation therapy patients.

As set forth in G.S. § 131E-183(a)(3), applicants are required to show the extent to which all residents of the area are likely to have access to the services that are proposed. There is no indication of patient access to the proposed linac unless they are a patient of Wilmington Health. The SMFP projects need for linac services on a regional basis to ensure access to care addresses the overall need of the planning area. It is the applicant's burden to show how it will meet the needs of the region as a whole. Wilmington Health has one medical oncologist. There is no indication that there will be any patients who will be served by the proposed linac other than Wilmington Health's small patient base. The application does not demonstrate the extent to which all residents of the area are likely to have access to the services proposed.

Wilmington Health's Outmigration Analysis is Unsupported

Wilmington Health claims that outmigration of patients is a basis for the need for its project. Wilmington Health erroneously states that outmigration from Service Area 19 doubled from 7 percent to 14 percent between FY2017 and FY2019; see **Wilmington Health CON application p. 48 and Wilmington Health CON application Exhibits, PDF pp. 137 & 138 and Exhibit C4.4**.

The data presented and interpreted by Wilmington Health shows a sharp drop in volume from FY2018 to FY2019, which is clearly incorrect, and ignores data available for FY 2020. Wilmington Health then goes on to conclude the "drop" in volume represents a large base of patients who are out-migrating for treatment. Instead of verifying this data and considering the most recent FY2020 data, Wilmington Health seemingly selectively presented data and then made false conclusions. The patient origin data for NHRMC's linear accelerators in FY 2019 is clearly wrong as shown based on more recent FY2020 as seen in **Figure 2** below:

Figure 2
FY2017 – FY2020 Radiation Therapy Volume in SA-19

	Wilmington Health Ex C4.4			NHRMC LRA
SA 19 - County	**FY 2017**	**FY 2018**	**FY 2019**	**FY2020**
Brunswick	608	990	563	1,107
Columbus	112	152	72	170
New Hanover	1,523	1,248	602	1,356
Pender	364	320	135	347
Total SA 19	**2,607**	**2,710**	**1,372**	**2,980**

Source: Wilmington Health, Exhibit C4.4, NHRMC 2021 LRA

Not only is Wilmington Health's claim of outmigration incorrect, but NHRMC has also experienced a rapid increase in radiation therapy volume even through the pandemic, a fact that Wilmington Health chose not to discuss. Much of Wilmington Health's basis for "need" is its claim of significant outmigration of patients from the service area for radiation therapy, which is objectively false. One only needs to review publicly available data from the LRA to see the inaccuracy of Wilmington Health's premise.

Wilmington Health's Project Will not Meet the Needs of Charity Care or Medicare/Medicaid Patients

Wilmington Health's proposed project will not enhance access to care for charity care patients. Wilmington Health projects charity care but provides not historical basis for such projection. In fact, in Section L, p. 98 of its application, Wilmington Health claims its data does not track charity care as a payor and does not project charity care. It is also unclear what Wilmington Health's basis is for projected Medicare and Medicaid patients is given it is such a low percentage. Considering that cancer incidence rates are significantly higher for seniors aged 65 and older, it is highly unusual that only 25 percent of Wilmington Health's radiation therapy patients are projected to be covered by Medicare. Please see additional discussion under Criterion (13). Wilmington Health's proposal will not enhance access to care for the medically underserved. Without historical data, it is also questionable the extent to which medically underserved population currently use the applicant's existing services.

Wilmington Health's Project Will Not Meet the Need for Linac Services in SA-19

There is no need for the linac proposed by Wilmington Health due to its limited scope of services, limited referral base, lack of continuity of care, and questionable quality. Wilmington Health's proposal cannot meet the identified need based on the following factors:

- Wilmington Health itself states it will not provide a full range of complex treatment; (Form C Assumptions page 3, PDF page 121).
- Wilmington Health has demonstrated that it will only receive referrals from within its own practice and therefore not serving the broader need.
- Since Wilmington Health will only serve its patients, the proposed project will limit access for other patients in SA-19, thus it will adversely impact patients who are not affiliated with Wilmington Health.
- Wilmington Health has not demonstrated how it will provide its patients the same level of quality of care that is available at NHRMC through its comprehensive continuum of cancer services.

Wilmington Health Does Not Document How it Will Ensure Quality

Wilmington Health does not demonstrate that the project will offer quality care based on the following factors:

- Wilmington Health demonstrates no experience in offering radiation therapy services and does not demonstrate any quality-related credentials for such services despite the fact that Wilmington Health claims to treat cancer patients.
- Wilmington Health provides no licenses, accreditations, organizational memberships, or other external evidence of quality of care.
- Wilmington Health identified a potential locum tenens radiation oncologist who is not licensed or located in the State of North Carolina.
- Wilmington Health's proposal demonstrates lack of experience in the following ways:
    - Insufficient staffing projections;
    - Insufficient expense projections for supplies/pharmacy; and
    - Minimal space that is not consistent with planning guidelines.
- Wilmington Health has made no reference to plans for how to care for patients in the event of natural disasters or even just machine down-time, whether brief or extended:
    - Radiation treatment planning is complex and individual plans are designed for specific machines based on their unique capacity and specifications, meaning a patient in the middle of treatment cannot be easily moved to another machine or center if access is interrupted. It would require the planning process to start all over:
    - The nature of radiation treatment requires consistency in treatment and minimization of potential for treatment gaps within a cycle, otherwise patient outcomes can be negatively impacted.
- Wilmington Health included equipment to provide brachytherapy (see **Wilmington Health CON Exhibits, Varian Vendor Quote, PDF pp. 51-53**); however, it did not discuss this service in its CON application, nor did it project volume for brachytherapy.
    - Wilmington Health does not discuss how this service will be provided.
    - Brachytherapy often requires minor surgery, and Wilmington Health did not discuss how this part of the service would be provided.
    - Brachytherapy requires specific radioactive materials licensure and an onsite and physically present medical physicist. Wilmington Health does not discuss how this licensure will be obtained, nor does it provide for an onsite physicist to handle the radioactive materials[6].
    - Brachytherapy also requires a physician to be physically present which means with only one radiation oncologist, there is even less time for supervision of linac treatments.
- Wilmington Health has not identified how it will provide coverage for its one radiation oncologist during vacation or sick time. Patient treatments must continue to be supervised even when the one radiation oncologist is unavailable.
- Wilmington Health has also understated the number of radiation therapists needed to cover both the linear accelerator and CT simulator as well as failed to identify how they will provide treatments if one of their two radiation therapists are sick, take vacation, or leave employment.

[6] Wilmington Health CON Exhibits, Varian Vendor Quote, PDF pp. 51-53. Also see United States Nuclear Regulatory Commission regulations; https://tinyurl.com/cfbn3nv6

- Wilmington Health has not identified how it will provide coverage for 24/7/365 call with only one radiation oncologist and no back up.
    - Cancer patients are often medically fragile and have needs after hours including managing the side effects of treatment.
    - Wilmington Health has not identified how one radiation oncologist would support patients who arrive in NHRMC's emergency department after hours, nor how he/she or the program would participate in utilization of this limited resource in caring for other emergent cases, such as spinal cord compression.

These facts reveal significant issues with Wilmington Health's ability to meet the need in a safe and cost-effective manner.

FAILURE TO MEET PERFORMANCE STANDARDS
10A NCAC 14C .1903(a)(2) states that:

> *(2) each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment;*

As previously discussed, Wilmington Health's unsupported projections will result in a failure to meet the 10A NCAC 14C .1903 Performance Standards that apply to linac services. These issues include:

- Relying on unsupported data showing erroneous outmigration;
- Lack of support for referral volume from non-Wilmington Health-affiliated referral sources;
- An inaccurate starting point of cancer patients from which to base its projected volume, which is not new cancer patients;
- Overstatement of 60 percent of cancer patients needing radiation; and
- Overstatement of ESTVs volume that is higher than the local market experience.

For all the reasons discussed above and any additional reasons the Agency may discern, Wilmington Health should be found non-conforming with Criterion (3) and the Performance Standard for Linear Accelerators.

Criterion (4) – Wilmington Health is not Proposing the Least Costly or Most Effective Alternative

For the same reasons discussed in relation to Criteria (1), (3), (5), (6), (7), (8), (12), (13), and (18a), Wilmington Health should be found non-conforming with Criterion (4):

- Wilmington Health has no experience in offering radiation therapy, so it has no track record of providing quality care in this highly complex field, nor does it provide any evidence of the radiation oncology experience or expertise necessary to deliver quality care – see discussion under Criterion (3)
    - Who will serve as the radiation oncologist? Who are the physicist and dosimetrist?
- Wilmington Health has insufficient resources for the proposed projected linked directly to staffing and funding – see discussion under Criterion (5), Criterion (7), and Criterion (8).
- Wilmington Health has unsupported projections and insufficient base of patients to support the project – see discussion under Criterion (3).

- Wilmington Health's proposed project is not financially feasible – see discussion under Criterion (5).
- Wilmington Health's proposed project will result in a duplication of services – see discussion under Criterion (6).
- Wilmington Health's proposed schematics lack sufficient space for its proposed linac – see discussion under Criterion (12).
- Wilmington Health's proposed project is not accessible to underserved populations – see discussion under Criterion (3) and Criterion (13).
- Wilmington Health's proposed project will not be cost-effective – see discussion under Criterion (18a).

For the reasons noted above and discussed in detail in other parts of this document and any additional reasons the Agency may discern, Wilmington Health should be found non-conforming to Criterion (4).

Criterion (5) – Wilmington Health's Project is not Financially Feasible

As previously discussed in Criterion (3), Wilmington Health's utilization projections are not supported, and the assumptions are not reasonably documented. This calls into question the reasonableness of Wilmington Health's utilization projections which, in turn, undermines Wilmington Health's financial projections. Wilmington Health only projects to make $50,000 in Year 3 – but with reasonable utilization projections and the expected impact of the CMS Radiation Oncology Alternate Payment Model, the program will suffer losses in excess of $100,000/year. As shown in Criterion (3), there is no reasonable basis for projected utilization and projections cannot be supported.

Wilmington Health*'s Project Costs are Incomplete and Understated*

Wilmington Health failed to include the cost of the linac and CT simulator in its total capital cost. See Form F.1a Assumptions, note f. Wilmington Health asserts that if a piece of medical equipment is leased, then it does not need be included as a capital cost. This is false. The lease is only how Wilmington Health funds the acquisition of the linac and CT simulator. The use of a lease to fund the linac and CT simulator would be identified in Section F.2.d. Other Forms of Financing.

For purposes of the CON Law, a lease of linac equipment and a CT simulator is an acquisition and is treated no differently than a purchase. See N.C. Gen. Stat. § 131E-176(16)f1.5a & 9. If Wilmington Health's assumption that the cost of the linac and CT simulator are not required to be identified as a project capital cost, then the Agency will have to agree that there is no dollar threshold for major medical equipment requiring CON approval if the major medical equipment is leased. It is the cost of the major medical equipment, not the means of financing, that generates the need for CON approval. By not identifying the cost of the linac and CT simulator, Wilmington Health underreported the project capital costs and failed to submit the accurate CON filing fee.

The size of the proposed facility and therefore associated costs are also understated. Wilmington Health proposes to offer brachytherapy but does not show sufficient space to accommodate offering the service. Brachytherapy requires special, secure storage of radioactive materials and that space is just not present in Wilmington Health's proposed drawings. It is unclear how the projected patient volume will move through the facility with so little treatment and support space. Moreover, it is unclear how the spaces identified in the area to be renovated will be accommodated. As shown in Exhibit C.1-1, it appears the radiation therapy

service will take the place of the receiving dock, staff break room, laboratory space, and X-ray. How will these functions be covered once the space is utilized for the radiation therapy service? Wilmington Health's application does not answer this important question. These issues result in an understatement of project costs. Please see more detail under Criterion (12).

Wilmington Health Does Not Demonstrate Sufficient Funds for its Capital Costs

Wilmington Health's ability to fund this project as well as its currently pending cardiac cath application (approximately $3.8 million), is questionable. Wilmington Health states that it will fund the project through accumulated reserves, specifically the Line Item "Cash and cash equivalents." There are several problems with this. First, "cash and cash equivalents" is not the same as "accumulated reserves." Accumulated reserves are usually included in the Balance Sheet with Current Assets labeled "Assets limited as to use" because they are not meant to be used to fund ongoing operations or pay expenses. No such line item appears on the Wilmington Health balance sheet, though Wilmington Health's auditors clearly understand this principle because they separated Wilmington Health's investment in SCA-Wilmington, recognizing that investment is not meant to be used to fund ongoing operations. Second, in 2019, Wilmington Health had only $49,125 in "Cash and cash equivalents" but that amount increased to over $21 million in 2020. Superficially, it appears that Wilmington Health has the necessary funds for the project, but the additional $21 million appears to be merely a timing issue at the end of the year because Wilmington Health also experienced a $17.3 million increase in current liabilities as compared to 2019. (34,365,495-17,007,991=17,359.504). Payment of those liabilities would deplete most of the cash and cash equivalents (21,030,821-17,359,504=3,671,317). This makes it impossible for Wilmington Health to fund the linac project ($4.9 million, which amount is understated as discussed previously), not to mention the cardiac cath project ($3.8 million) out of "accumulated reserves". While the ASC project (which is where the cath lab is proposed to be located) is being funded by a loan, see page 56 of the findings for Project I.D. No. O-11441-17, depletion or elimination of Wilmington Health's cash could jeopardize Wilmington Health's loan covenants, as most lenders would require a borrower to maintain a certain cash position. Wilmington Health relies entirely on its so-called "accumulated reserves" as the means by which it will fund the cardiac cath and linear accelerator projects, so it would not be appropriate for the Agency to assume that Wilmington Health might be able to obtain other financing for the cardiac cath lab project or the linear accelerator project.

Wilmington Health's Medicare Reimbursement Assumptions are Inaccurate

As discussed above in Criterion (3), Wilmington Health's Medicare reimbursement assumptions appear to be inaccurate based on set payment rates. If Wilmington Health is paid under the same Alternative Payment Model ("APM") as NHRMC, which applies to the Wilmington Area, then its reimbursement is too low. If Wilmington Health is not covered by the APM, then it should expect even higher reimbursement rates from Medicare, higher than NHRMC, due to Wilmington Health's projections of higher ESTVs (see discussion above under Criterion (3)). However, this higher reimbursement is not reflected in Wilmington Health's Form F.2b. Paired with Wilmington Health's unsupported volume projections, its reimbursement projections are inaccurate.

Wilmington Health's Operating Costs are Too Low

Wilmington Health's expenses are insufficient for its proposed project, further demonstrating its lack of experience with the costs associated with providing radiation oncology.

Wilmington Health's staffing model is insufficient. According to the American College of Radiation Oncology accreditation manual, there are not enough radiation therapists included to cover the proposed service. Wilmington Health needs between 3.0 and 3.4 FTEs at minimum to cover the linear accelerator and the CT simulator. The minimum personnel requirements for clinical radiation therapy indicate 90 patients per radiation therapist with a minimum of 2.0. Two staff members must be present when the linear accelerator is in use based on the American College of Radiology accreditation guidelines. In addition, one is needed to run the CT simulation.

Vacation/sick time would also need to be covered, which Wilmington Health has not addressed. Further, as discussed under Criterion (3), Wilmington Health did not account for the necessary resources and expenses in order to offer brachytherapy, especially an onsite, physically present medical physicist. For this service, the physicist cannot be remote and additional radiation therapist would also likely be required. Moreover, the radiation oncologist must also be physically present during brachytherapy, further limiting the ability of the one radiation oncologist to cover linac treatments.

There are also not enough support staff in the staffing model to provide a full range of support including administrative, clerical support, and patient access support/technicians. Wilmington Health did not include any existing FTEs to cover such functions.

While Wilmington Health provides some expense for one radiation oncologist (whether recruited or locum tenens), there is no cost for coverage when this sole radiation oncologist is out sick or on vacation. The American College of Radiology accreditation guidelines state:

> *Section 6 "Radiation Therapy Personnel" specifically stipulates:*
> *6.1.2. A Radiation Oncologist should be available for patient care and quality review on a daily basis. The Radiation Oncologist, practice, and support staff should be available to initiate urgent treatment within a medically appropriate response time on a 24-hour basis, 365 days per year. When not physically present within the practice, the Radiation Oncologist should be available by cell phone, pager, or other designated means. When unavailable, the Radiation Oncologist is responsible for arranging appropriate coverage.*

Wilmington Health has not accounted for coverage 24/7/365, which cannot be met by 1.0 FTE radiation oncologist. Moreover, the salary included for a radiation oncologist (recruited or locum tenens) is insufficient based on data from the Medical Group Management Association ("MGMA"), which indicates a current salary range of $580,374 to $604,899 with a mean of $589,514. Wilmington Health's salary in CY2026 is more than $140,000 lower than current salary levels.

Additionally, Wilmington Health's medical supply and pharmacy costs, based on NHRMC's actual experience in providing radiation therapy, are too low. As shown below in **Figure 3**, Wilmington Health's medical supply and pharmacy costs are only a quarter of that projected per ESTV than NHRMC, which is based on the actual cost of radiation therapy patients in FY 2021. NHRMC can acquire drugs at a lower cost based on its 340B program participation. As a for-profit physician practice, Wilmington Health is not eligible to participate in the 340B program, so Wilmington Health's expenses should therefore be higher than NHRMC.

Figure 3
Comparative of Supplies Cost per ESTV for NHRMC and Wilmington Health

	NHRMC	Wilmington Health
ESTVs	8,278	7,076
Supplies and Pharmacy Expense	$617,344	$132,962
Cost per ESTV*	$74.58	$18.79

Source: Form C and Form F.3b

Finally, Wilmington Health's vendor quotes and leasing documents for the linac and CT simulator do not tie to the operational cost provided in Form F.3b. The vendor quotes and leasing documents provided in Wilmington Health's Exhibit C.1-2 and Exhibit C.1-3 amount to an annual cost of $1,391,765 for the linac and CT simulator. However, Wilmington Health presents an annual cost of $976,860 in its Form F.3b for the same equipment, a difference of approximately $414,905 as shown in **Figure 4** below:

Figure 4
Wilmington Health Quoted Cost of Linac & CT Simulator Lease

Linear Accelerator	$ 100,154	$ 1,201,853
CT Simulator	$ 15,826	$ 189,912
Total	$ 115,980	$ 1,391,765
Lease payments in Form F.3b		$976,860
Annual Shortfall		**$ (414,905)**

Source: Exhibit C1-3

With just this one correction, Wilmington Health's radiation therapy will be operating at a loss in all of the first three years of operation. In fact, with this correction, all of Wilmington Health combined will operate at a loss through the first two full years of operation as shown in **Figure 5** below. This does not even consider the additional operating costs for staffing, supplies and pharmacy that were understated.

Figure 5
Wilmington Health's Operational Loss

Total Wilmington Health with Radiation Oncology	Partial Year	1st Full Year	2nd Full Year	3rd Full Year
Net Revenue	$ 86,414,668	$ 178,632,573	$ 184,672,102	$ 190,960,546
Expenses	$ 86,868,348	$ 179,005,792	$ 184,442,348	$ 190,052,223
Net Income	$ (453,680)	$ (373,219)	$ 229,754	$ 908,323
Lease shortfall	$ (207,452)	$ (414,905)	$ (414,905)	$ (414,905)
Total Income (Loss)	$ (661,132)	$ (788,124)	$ (185,151)	$ 493,418

Wilmington Health Does Not Demonstrate How it Will Fund *Initial Operating Costs*

In response to Section F.3.a., Wilmington Health indicated that it will not incur any start-up expenses, initial operating costs or working capital. **See Wilmington Health CON pages 74-75.** Wilmington Health states:

"The proposed project involves developing a health service at Wilmington Health on Silver Stream Lane, an existing physician practice and infusion center. As such, there are no startup expenses." – page 74

While Wilmington Health may not be required to show startup cost, it would be required to show it has working capital to cover operational losses (initial operating costs). The CON form on page 11 defines the following:

> **Initial operating costs**: For the purpose of completing this application form, the term "initial operating costs" means the difference between:
>
> 1. total cash outflow (operating costs) during the initial operating period for the entire facility; and
> 2. total cash inflow (revenues) during the initial operating period for the entire facility.
>
> **Initial operating period**: For the purpose of completing this application form, the term "initial operating period" means the number of months, if any, during which cash outflow (operating costs) for the entire facility exceeds cash inflow (revenues) for the entire facility.

Given that Wilmington Health projects the following losses from operation of the proposed linear accelerator, it will clearly need working capital to cover such losses as shown below in **Figure 6**:

Figure 6
Corrected Cash Flow from Operations

	Net Loss	Lease Payment Shortfall	Add Back Depreciation	Cash Loss from Operations
Partial FY	($846,394)	($207,452)	$83,465	($970,381)
1st Full Year	($1,182,210)	($414,905)	$166,930	($1,430,185)
2nd Full Year	($603,506)	($414,905)	$166,930	($851,481)
Cumulative Losses:	($2,632,110)	($414,905)		($3,252,047)

Wilmington Health has not shown how it will cover these significant losses from operations of the radiation oncology program (Section Q, page 7). Not only is the radiation therapy service projected to have significant losses through Year 2, but also the entire Wilmington Health organization is projected to operate at a loss through Year 2 as shown above in **Figure 5**.

It is unclear how Wilmington Health will cover the aforementioned losses, particularly given that it operated at a loss for CY 2020 and had minimal cash in CY 2019. Wilmington Health had a cash balance for CY 2020 as the result of PPP loans and timing of payments (advanced payments); see **Wilmington Health Exhibits, PDF p. 146**.

For the foregoing reasons plus any additional reasons the Agency may discern, Wilmington Health's application should be found non-conforming with Criterion (5).

Criterion (6) – Wilmington Health's Proposal Represents an Unnecessary Duplication of Services

The proposed project will inevitably result in unnecessary duplication of linac services. As discussed above, Wilmington Health will offer lesser services than NHRMC in terms of scope of radiation therapy services and continuity of care. Wilmington Health will result in a duplication of services at a lower quality. Wilmington Health does not have the appropriate staff in place to operate its proposed linac, nor the referral

sources to effectively and efficiently operate its proposed linac. Approval of its project will result in an underutilized, poorly staffed linac unit with questionable quality of care.

For the foregoing reasons plus any additional reasons the Agency may discern, it is clear that Wilmington Health's project is an unnecessary duplication of existing services and should be found non-conforming with Criterion (6).

Criterion (7) – Wilmington Health's Staffing is Inadequate

Wilmington Health presents a highly suspect staffing model with insufficient staff and outsourced critical positions that raise questions concerning operation costs and quality of care. Specifically:

- Wilmington Health claims that all support and administrative staff is already in place but fails to show this staffing in its Form H;
- Wilmington Health has only half the radiation therapists needed to effectively operate a standalone radiation therapy center;
- Wilmington Health will outsource its key staffing positions (physicist and dosimetrist) which will result in higher cost and unclear quality of care;
- Wilmington Health does not account for an onsite medical physicist in order to offer brachytherapy; and
- The locum tenens radiation oncologist lives in Boca Raton, Florida, and it is unclear who will serve as a long-term, stable medical director/radiation oncologist for the project.

For the reason discussed above, paired with concerns raised in Criterion (3) and Criterion (5), and any additional reasons the Agency may discern, Wilmington Health's application should be found non-conforming with Criterion (7).

Criterion (8) – Wilmington Health's Provision for Ancillary and Support Services is Questionable

Based upon the staffing concerns raised under Criterion (7), Wilmington Health does not have the proper ancillary and support services in place and does not provide sufficient information on how these services will be provided. While Wilmington Health provides letters of "willingness" to provide said services, there are no draft agreements in place. Wilmington Health has not documented sufficient staffing for its proposed project or provided the necessary ancillary and support services. No other existing administrative or support positions for Wilmington Health are provided to demonstrate such support is available for the proposed radiation therapy service. No existing positions are shown on Form H.

For these reasons, the reasons discussed in Criteria (3), (5), and (7), and any additional reasons the Agency may discern, Wilmington Health's application should be found non-conforming with Criterion (8).

Criterion (12) – Wilmington Health Cost and Design are Not Reasonable

The size of the proposed facility and therefore associated costs are also understated. Wilmington Health proposes to offer brachytherapy but does not show sufficient space to accommodate offering the service. Brachytherapy requires special, secure storage of radioactive materials and that space is just not present in Wilmington Health's proposed drawings. It is unclear how the projected patient volume will move through the facility with so little treatment and support space. Moreover, it is unclear how the spaces identified in

the area to be renovated will be accommodated. As shown in Exhibit C.1-1, it appears the radiation therapy service will take the place of the receiving dock, staff break room, laboratory space, and X-ray. How will these functions be covered once the space is utilized for the radiation therapy service? Wilmington Health's application does not answer this important question. These issues result in understated project costs.

Furthermore, Wilmington Health's proposed project does not have enough exam rooms in place to accommodate its projected patient volume. Wilmington Health projects approximately 7,000 treatments by Year 3. That equates to 140 treatments per week, assuming Wilmington Health is operational 50 weeks per year with 1 provider. Every treatment patient must be seen at least once per week and is referred to as an on-treatment visit ("OTV"). Most centers do OTVs all in one day to preserve the rest of the week for new patient consults, follow-ups, etc. With its projected volume, Wilmington Health will have just under 30 treatments per day and knowing some patients in a given week are starting or ending treatment, there would need to be 35-40 OTVs per week at the minimum. With this kind of volume, a facility would need at least 2-3 exam rooms to accommodate the patients for efficient throughput. Wilmington Health is only proposing 1 exam room for its projected patient volume. Coupled with its light staffing model, the use of only one exam room will limit capacity and/or lead to delays in patient care.

Criterion (13) – Wilmington Health's Project Will Not Sufficiently Serve Medically Underserved Patients

Wilmington Health fails to show that its proposed project will enhance access to medically underserved groups. Wilmington Health claims that it does not maintain data that includes the number of low-income persons it serves (see **Wilmington Health CON application, p. 59**), and does not provide a charity care percentage in its payor mix (see **Wilmington Health CON application, pp 98 & 99**). This is, however, contradicted by information later presented in its application that seems to indicate that Wilmington Health does in fact track charity care and reduced cost data; see **Wilmington Health CON application, pp. 99 & 100**. Wilmington Health presented projected charity care and reduced cost data for its entire organization and claimed the data is based on historical experience. It is likely that Wilmington Health presented data for its entire organization because it does not provide much charity and reduced care for cancer patients, if at all.

Furthermore, the information presented by Wilmington Health in the medically underserved groups table under **Section C, Question 6b page 59**, is inconsistent. The age group 65 and above is known to be the cohort that has the highest cancer incidence rates. However, Wilmington Health estimates that it will only serve 27.4 percent of individuals that are 65 and older but serve 55 percent Medicare beneficiaries. This does not make sense. Most individuals 65 and older are Medicare beneficiaries; therefore, the estimated percentages of 65 and older individuals served, and Medicare beneficiaries served should be similar. Additionally, information presented by Wilmington Health in Section L confirms it does not serve a large number of individuals 65 and older; see **Wilmington Health CON application, pp. 95 & 96**). Therefore, Wilmington Health's proposal will not enhance access to radiation therapy services for the elderly or Medicare beneficiaries.

Wilmington Health projects to serve just 1.5 percent self-pay patients (no charity care is shown) and only 3 percent Medicaid patients, (see **Wilmington Health CON application, p. 99**). This access for low-income patients is minimal and insufficient to demonstrate access by underserved groups. Based on percent of gross revenue, Wilmington Health projects 2.7 percent charity care and 3.0 percent Medicaid for a total of just 5.7 percent of care for low-income individuals. Moreover, this level of access is not confirmed by

any documented actual historical provision of charity care. Wilmington Health's Financial Statements make no reference to charity care.

Wilmington Health has provided a copy of its "Financial Assistance Policy" as evidence in support of this criterion. This policy is vague and difficult to understand but appears to commit Wilmington Health only to consider applying an unspecified percentage adjustment to a patient's account if that patient meets "charitable guidelines as determined by the U.S. Department of Health & Human Services Annual Poverty Guidelines". We have not seen "charitable guidelines" published by US DHHS, so can only deduce from Wilmington Health's policy that it will *consider* offering an adjustment to patients who are at or below the federal poverty guidelines. This policy fails to support any real attempt to enhance access to the underserved in our community, particularly when compared to the Novant Health policy, which clearly states that uninsured patients below 300% of the federal poverty guideline will qualify for 100% reduction in charges.

For the reasons discussed above as well as any additional reasons the Agency may discern, Wilmington Health should be found non-conforming to Criterion (13).

Criterion (18a) – Wilmington Health's Proposed Project Will not Positively Impact Competition in the Service Area

Wilmington Health's proposed project will not enhance competition in the service area, nor will it have a positive impact upon cost-effectiveness, quality, and access. As discussed, Wilmington Health has unreliable and unreasonable projected utilization. Wilmington Health fails to demonstrate how its proposed project will provide differentiated care from the care that is already available in the service area. Furthermore, Wilmington Health lacks sufficient referral sources in order to produce referral volume for its proposed project, and no other source of external referrals has been identified. Without its proposed project meeting the demand for radiation therapy services, the need will continue to have to be met by the other existing service area provider of radiation therapy services. Therefore, Wilmington Health's project does not propose to increase competition within the service area, and in fact it only results in an underutilized linear accelerator that increases community costs. Wilmington Health proposes an additional linac located within a mile of three existing linacs which is a duplication of available services within the service area.

For the reasons discussed above as well as any additional reasons the Agency may discern, Wilmington Health's application should be found non-conforming with Criterion (18a).

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2021 SMFP, there is a need for one additional linac in SA-19. Thus, although there are two identified applicants, only one can be approved in this review. Wilmington Health's application does not demonstrate conformity with all applicable CON review criteria and rules and is therefore not approvable. Therefore, there should be no need for a comparative review. Nonetheless, NHRMC has provided the following comparative review between the two applicants.

Conformity with Applicable Statutory and Regulatory Review Criteria

As previously stated, the Wilmington Health application is not conforming with all applicable statutory and regulatory review criteria for reasons discussed throughout NHRMC's Comments in Opposition. Therefore,

the application submitted by Wilmington Health is not an effective alternative even standing on its own and is comparatively inferior to the NHRMC application.

NHRMC is conforming with all applicable statutory and regulatory review criteria. Therefore, the application submitted by NHRMC is the most effective alternative with respect to conformity with statutory and regulatory review criteria.

Scope of Services

Wilmington Health admittedly will not have any specialized equipment for its proposed linac and will not provide any specialized radiation therapy services. Furthermore, Wilmington Health lacks the staffing and experience to offer any specialized radiation therapy services. NHRMC, on the other hand, is an experienced provider of a full range of comprehensive cancer care including complex cases within a cancer center and as part of a full continuum of care. NHRMC proposes not only a radiation therapy service with a new linac, but a new cancer center in Scotts Hill in order to expand access to a full continuum of care for patients closer to where they live and work.

As it relates to scope of linac services, NHRMC is the more effective applicant.

Geographic Accessibility

The 2021 SMFP identified a need for one linac in SA-19. The Wilmington and Brunswick areas of SA-19 are already well covered for linac services. Wilmington Health proposes to locate its proposed linac just a mile from three existing linacs operated by NHRMC. NHRMC, on the other hand, proposes to improve geographic access by locating its proposed linac on its Scotts Hill campus in northern New Hanover County. Doing so will reduce travel time for patients residing in northern New Hanover County, Pender, Onslow, and surrounding counties. This is particularly important for radiation therapy services because patients will make multiple trips over the course of many weeks to receive the services.

As it relates to geographic accessibility, NHRMC is the more effective applicant.

Cost of Proposed Project

Wilmington Health severely understated the costs to implement its proposed project and offer radiation therapy services. Wilmington Health did not account for proper staffing, proper space to accommodate the proposed equipment, or proper operating costs. Wilmington Health included equipment for brachytherapy as part of its proposed project but did not account for the necessary staffing for the service or projected volume for the service. Brachytherapy would require special radioactive material licensure and an onsite physicist, which would cost significantly more than the contract physicist proposed by Wilmington Health.[7] Furthermore, such service would require more space to accommodate the equipment, and Wilmington Health did not account for this space in its proposed floorplan. Increased staffing and space for the proposed projected will also lead to increased operating costs and capital costs. Most notably, Wilmington Health incorrectly omitted the cost of acquiring the linac and supporting systems from its capital costs in the application and compounded that error by reporting lower lease costs in its pro formas than were quoted in the equipment lease proposal.

[7] Wilmington Health CON Exhibits, Varian Vendor Quote, PDF pp. 51-53. Also see United States Nuclear Regulatory Commission regulations; https://tinyurl.com/cfbn3nv6

As it relates to project cost, NHRMC is the more effective applicant.

Access by Underserved Groups

Projected Charity Care

Based on its historical experience providing radiation therapy services, NHRMC projects to provide 2.4 percent self-pay as a percent of gross revenue and 2.7 percent charity care as a percent of gross revenue in the 3rd full fiscal year ("FFY"). Wilmington Health, which has no experience providing radiation therapy, projects to provide 1.5 percent self-pay as a percent of gross revenue and 1.0 percent charity care as a percent of gross revenue in the 3rd FFY. Of note, as discussed above under the criterion specific comments, Wilmington Health provided no projected payor mix for charity care but expressed charity care in its Form F.2b. See **Figure 7** below:

Figure 7
Percent of Charity Care Patients - Year 3

Facility	Self-Pay % of Gross Revenue	Charity Care % of Gross Revenue
Wilmington Health - Radiation Oncology	1.5%	1.0%
NHRMC - Scotts Hill	2.4%	2.7%

Source: Form F.2b

As it relates to projected charity care, NHRMC is the more effective applicant.

Projected Access by Medicaid Recipients

Based on its historical experience providing radiation therapy services, NHRMC projects to provide 5.4 percent Medicaid as a percent of gross revenue and 5.7 percent Medicaid as a percent of patients in the 3rd full fiscal year ("FFY"). Wilmington Health, which has no experience providing radiation therapy, projects to provide 3.0 percent Medicaid as a percent of gross revenue and 3.0 percent Medicaid as a percent of patients in the 3rd FFY. Even with its unsupported projected utilization, Wilmington Health still does not propose to offer more care to Medicaid recipients than NHRMC. See **Figure 8** below:

Figure 8
Percent of Medicaid Patients - Year 3

Facility	Medicaid % of Gross Revenue (a)	Medicaid % of Patients (b)
Wilmington Health - Radiation Oncology	3.0%	3.0%
NHRMC - Scotts Hill	5.4%	5.7%

Source: (a) Form F.2b (b) Section L

As it relates to projected access by Medicaid recipients, NHRMC is the more effective applicant.

Projected Access by Medicare Recipients

Based on its historical experience providing radiation therapy services, NHRMC projects to provide 61.3 percent Medicare as a percent of gross revenue and 60.3 percent Medicaid as a percent of patients in the 3rd full fiscal year ("FFY"). Wilmington Health, which has no experience providing radiation therapy, projects to provide 55 percent Medicare as a percent of gross revenue and 55 percent Medicare as a percent of patients in the 3rd FFY. Even with its unsupported projected utilization, Wilmington Health still does not propose to offer more care to Medicare recipients than NHRMC. See **Figure 9** below:

Figure 9
Percent of Medicare Patients - Year 3

Facility	Medicare % of Gross Revenue (a)	Medicare % of Patients (b)
Wilmington Health - Radiation Oncology	55.0%	55.0%
NHRMC - Scotts Hill	61.3%	60.3%

Source: (a) Form F.2b (b) Section L

As it relates to projected access by Medicare recipients, NHRMC is the more effective applicant.

Projected Average Charge per Patient

Charges are not a meaningless comparison because virtually no patients or payor pay charges, nonetheless comparison is provided below. Moreover, a simple comparison of charges neglects consideration of the complexity of services offered or to be offered by each applicant; see **Figure 10** below.

Figure 10
Average Charge per Patient 3rd FY

Facility	Patients	Gross Revenue	Average Charge per Patient
Wilmington Health - Radiation Oncology	304	$6,944,121	$22,842.50
NHRMC - Scotts Hill	414	$23,391,345	$56,500.83

Note: charge per patient must be calculated because Wilmington Health did not provide treatment volume (only ESTVs).

As noted in prior Agency findings, differences in facility types (e.g., hospitals versus freestanding facilities) and the types of services provided by the various facility types may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Projected Average Net Revenue per Procedure

The following table compares net revenue or reimbursement per patient. There is very little difference in the expected reimbursement per patient as shown below. Moreover, Wilmington Health admits that it will only provide standard radiation therapy services, which can easily explain the slight difference in reimbursement rates; see **Figure 11** below.

Figure 11
Average Net Revenue/Reimbursement per Patient 3rd FY

Facility	Patients	Net Revenue	Average Reimbursement per Patient
Wilmington Health - Radiation Oncology	304	$3,291,354	$10,826.82
NHRMC - Scotts Hill	414	$5,255,909	$12,695.43

Note: reimbursement per patient must be calculated because Wilmington Health did not provide treatment volume (only ESTVs).

As described above, Wilmington Health's Medicare reimbursement is understated based on the Alternative Payment Model ("APM") that applies to the Wilmington Area. See discussion in Criterion (5). If Wilmington Health is not covered by the APM, then its reimbursement would be higher consisted with its projections of higher ESTVs as discussed in Criterion (3). Nonetheless, as noted in prior Agency findings, differences in facility types (e.g. hospitals versus freestanding facilities) and the types of services provided by the various facility types may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Projected Average Operating Expense per Patient

As noted above, Wilmington Health fails to include sufficient staffing levels, which would add to the overall operating expense for the proposed service. Wilmington Health's proposal suffers from other issues that make it non-conforming with Criterion (5) including failure to include sufficient staffing, which impacts the projected operating expenses per day. Nonetheless, a comparison of expense per patient is provided below. NHRMC is the more effective alternative on an average expense per patient basis; see **Figure 12** below.

Figure 12
Average Operating Expense per Patient 3rd FY

Facility	Patients	Expenses	Average Expense per Patient
Wilmington Health - Radiation Oncology	304	$3,241,289	$10,662.13
NHRMC - Scotts Hill	414	$4,076,291	$9,846.11

Source: Form F.3b

Summary

The following is a summary of the comparative analysis performed on the proposed projects, ranking the proposals based on effectiveness for each comparative factor provided herein. As discussed at length throughout the written comments in opposition, Wilmington Health's proposal is not conforming with all applicable statutory and regulatory review criteria. Thus, technically, the aforementioned comparative factors do not apply to Wilmington Health and NHRMC is the most effective alternative. Nonetheless, NHRMC has provided the summary of the comparative factors below:

Comparative Factor	NHRMC - SH	Wilmington Health
Conformity with Review Criteria	Yes	No
Scope of Services	More Effective	Less Effective
Geographic Accessibility	More Effective	Less Effective
Access by Underserved Groups: Charity Care	More Effective	Less Effective
Access by Underserved Groups: Medicaid	More Effective	Less Effective
Access by Underserved Groups: Medicare	More Effective	Less Effective
Projected Average Charge per Patient	Inconclusive	Inconclusive
Projected Average Net Revenue per Patient	Inconclusive	Inconclusive
Projected Average Operating Expense per Patient	More Effective	Less Effective

Even if Wilmington Health were conforming with all applicable statutory and regulatory review criteria, NHRMC is still the most effective alternative as shown in the summary table above.

CONCLUSION

Wilmington Health's application is not approvable, as it does not conform to Criteria (1), (3), (4), (5), (6), (7), (8), (12), (13), (18a) and the Performance Standards for linear accelerator services. NHRMC's application meets all applicable criteria and standards for linac services. As shown in the comparative analysis above, NHRMC is the superior applicant. Accordingly, NHRMC's application should be approved, and Wilmington Health's application should be denied.