

Comments in Opposition to Wilmington Health, PLLC
Certificate of Need Application for one Fixed PET unit in Health Service Area V
Project I.D. O-012153-21
November 1, 2021 - CON Review Cycle

INTRODUCTION

The 2021 State Medical Facilities Plan ("2021 SMFP") recognized a need for one fixed PET unit in PET Health Service Area V ("HSA V"). Two applicants have filed Certificate of Need ("CON") applications for a fixed PET scanner in response to the identified need: Project I.D. O-012143-21 filed by Novant Health New Hanover Regional Medical Center, LLC ("NHRMC") and Project I.D. O-012153-21 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 the 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 PET services at its practice centrally located in Wilmington. Wilmington Health has no experience whatsoever providing PET services. Oncology patients are the primary type of PET referral. Yet Wilmington Health has only one medical oncologist and no radiation oncologist on staff. 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.

PET entails using a variety of radiopharmaceuticals to image cancer, neurology, and cardiology patients. Thus, it is an inherently complex, highly specialized service provided to a seriously ill patient population. Wilmington Health's inexperience in this realm 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 and capacity constraints as justification for its proposed project. However, Wilmington Health's proposed project will not address any of its stated concerns, as its project is more costly and will not address NHRMC's capacity constraints. Most importantly, Wilmington Health lacks the supporting referrals to operate a well-utilized PET unit.

Wilmington Health's proposed project will result in the following:

- An underutilized PET scanner that will be limited in access, will not meet the needs of HSA V patients, and does not meet the Performance Standards in 10A NCAC 14C .3703;
- Increased cost, based on lack of experience providing PET services and a cost structure that lacks economies of scale;
- 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, neurology, and cardiology services; and

- Duplication of existing PET services with the existing PET unit located in downtown Wilmington, a half 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 PET unit 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 PET services is directly relevant to Policy GEN-3. As discussed throughout these comments, the applicant has presented unreasonable and unsupported utilization projections and questionable financial forecasts. Despite seemingly lower costs, the Wilmington Health proposal is less cost effective than alternatives such as NHRMC. 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 PET 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), (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 its 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 unreasonable and unsupported 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.

There is no Need for Wilmington Health's PET Service

Wilmington Health's need analysis is directly impacted by its lack of experience in providing PET and its underlying lack of understanding of this service. Wilmington Health explicitly states it has no experience offering PET services; see **Wilmington Health CON Application, p. 75**. This lack of experience is further evidenced through the following:

- Lack of actual basis for any of its volume projections;
- Unsupported data analyses;

- Insufficient project costs;
- Defective financial projections; and
- Insufficient staffing.

Each of these issues with Wilmington Health’s projections will be discussed in more detail below. Furthermore, the actual cost of its project is hidden in its financial pro formas, which reveals how costly its proposed project is, rendering it an unnecessary duplication of expensive resources. 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 steps. By the time the last step is reached, it is evident the applicant’s projections are unreasonable and unsupported and render the application non-conforming with Criterion (3). The steps are flawed for the following reasons:

- Wilmington Health’s historical referrals to the only existing PET provider (NHRMC) in the service area are far below its projected patient volume;
- Wilmington Health assumes 2 PET scans per patient which is an unreasonable assumption (see **Wilmington Health Form C Assumptions, pp. 5-6**);
- Wilmington Health claims it will provide cardiac PET scans (see **Wilmington Health CON Application, p. 39**) but does not provide any projected utilization specific to cardiac PET; and
- Wilmington Health establishes arbitrary, unsupported market share percentages to project its patient volume by county (see **Wilmington Health Form C Assumptions, p. 3-4**).

Projected Scan Volume Compared to Historical Referrals

Wilmington Health uses total historical service area PET patient volume as the starting point for its projected PET scan volume, which is projected forward based on historical CAGR. Wilmington Health then applies projected market share captures ranging from 5% to 30% by county. **See Form C assumptions p. 4.** The most overwhelming flaw in Wilmington Health’s projections is that there is absolutely no basis for such market share capture and that Wilmington Health has not presented any evidence it could capture this market share.

Historically, Wilmington Health providers have ordered fewer than 260 PET procedures per year at NHRMC, which has been the sole provider of PET services in New Hanover, Brunswick, and Pender Counties, see **Figure 1** below. This represents less than 10 percent of the local volume of PET procedures ordered by service area providers.

Figure 1
Historic Wilmington Health PET Referrals vs. NHRMC Actual Volume

	2018	2019	2020
Wilmington Health PET Procedure Referrals	192	230	254
NHRMC Actual PET Procedures	2,163	2,512	2,796
Percent of Procedures at NHRMC Referred by Wilmington Health	8.9%	9.2%	9.1%

Source: Internal Data, 2021

There is no reasonable explanation for how 254 Wilmington Health PET scan referrals will transform into 2,115 PET scans by year 3. Wilmington Health provides form letters, which have little evidence to support an increase in referral volume. **See Exhibit I.2.** Of these form letters, 18 are Wilmington Health employees in various capacities who do not refer PET scans. Approximately 80 letters are completely generic provider letters mysteriously without letterhead, specialty, and some without credentials. A review of the Wilmington Health website provider search easily reveals that all of these letters are from Wilmington Health staff members without exception. Moreover, the letters include numerous Physician Assistants, Family Nurse Practitioners, Podiatrists, and other specialists that would be highly unlikely to refer patients for PET scans. This analysis reveals that Wilmington has documented no other source of referrals other than its own physicians who have historically generated less than 300 PET scans annually. There is absolutely no basis for Wilmington Health’s projected market share capture and projected utilization.

Projecting Two Scans per Patient is Unreasonable

Next, Wilmington Health assumes that each of its projected PET patients will receive at least two scans in a single year. **See Form C Assumptions p. 6.** Though Wilmington Health does not offer any justification for this ratio, it appears inconsistent with both their historical practice and with generally accepted practice and guidelines. In addition, it would likely lead to over utilization of PET imaging. For instance, patients with known coronary artery disease (“CAD”) may receive one cardiac PET scan at the onset of new symptoms per the guidelines of the American College of Cardiology. Cardiac patients who are being assessed for CAD would receive one initial cardiac PET scan and then would *not* receive a follow up scan unless new symptoms presented.

This is also true for all other patients, including cancer patients, who may receive a PET scan for treatment staging. While it is not uncommon that a patient receives more than one scan in a year, it is not reasonable to assume that *every* patient will receive more than one scan in a year. This is evident when analyzing Wilmington Health’s own PET referrals to NHRMC. Between CY 2020 and YTD 2021, Wilmington Health’s referral volume to NHRMC has at most resulted in a ratio of 1.46 PET scans for every one patient, not two scans for every one patient as projected by Wilmington Health; see **Figure 2** below. Wilmington Health will not meet its projected volume as evidenced by its own historical referral volume.

Figure 2

Wilmington Health Historical PET Patient Referrals to PET Procedures Ratio		
	2020	YTD 2021
NHRMC Actual PET Procedures Performed on Wilmington Health Patients	254	222
Unique Wilmington Health PET Patients Referred to NHRMC	174	159
Wilmington Health PET Referral Scans to Patients Ratio	1.46	1.40

Source: Internal Data, January – October 2021

As shown above, Wilmington Health’s 2 to 1 PET scans per patient ratio is unreasonable; however, Wilmington Health claims it will produce 1,121 PET patients and 2,241 PET procedures in the third project year; see **Wilmington Health Form C Assumptions and Methodology, p. 6.** If Wilmington Health’s historical patient to scan ratio of 1.46 is applied to its projected patient volume, this would result in just 1,637 scans in Year 3, which is far short of the Performance Standards. See discussion of 10A NCAC 14C.3703(a)(1) and calculation of corrected scan volume below.

To reach its projected PET patients and volume in the third project year, Wilmington Health providers would have to generate 783 percent more orders for PET procedures on 544 percent more patients than it

did in 2020; see **Figure 3** below. On its face, this is implausible. Wilmington Health presents no justification for this projected volume or how it will achieve such an unreasonable market share shift for its proposed PET scanner. In essence, thousands of PET procedures would have to shift from NHRMC to Wilmington Health, which is not likely to happen, given Wilmington Health’s limited referral base, minimal staffing, and lack of experience in providing PET scans. With no evidence of referrals outside of its own patient base, it is simply not possible for Wilmington Health to approach its projected volumes.

Figure 3
Wilmington Health Referral Volume vs. Projected Volume

	Patients	PET Procedures
Wilmington Health 2020 PET Volume	174	254
Wilmington Health Project Year 3 PET Volume	1,121	2,242
Percent Increase from 2020 Referrals	544%	783%

Source: Internal Data, 2021 and Wilmington Health Form C Assumptions and Methodology, p. 6.

Note: Numbers may not foot due to rounding.

Wilmington Health Does Not Have the Physician Referral Base to Support the Project

Wilmington Health lacks sufficient oncology support to generate the projected PET referrals. In general, cancer patients comprise the large majority of PET scan referrals, and most PET referrals are made by oncologists. Wilmington Health’s oncology program is minimal. It has one medical oncologist, and no radiation oncologist on staff.¹ Wilmington Health has historically had difficulty recruiting and maintaining a medical oncologist on its staff. Dr. Marte, the sole medical oncologist, has only been at Wilmington Health since January 2020. According to Wilmington Biz (the 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 for the medical oncologist position. This calls into question the stability of PET patient referrals from the one Wilmington Health physician most likely to refer cancer patients in need of PET services to Wilmington Health’s proposed unit.

¹ Wilmington Health has applied for a CON to provide linear accelerator services; however, that application does not provide any details of its plans for recruiting a radiation oncologist. If Wilmington Health’s linac project is not approved, Wilmington Health would have no reason to recruit a radiation oncologist.

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 PET scanner unless they are a patient of Wilmington Health. The SMFP projects need for PET services on a regional basis to ensure broad access to care in the planning area. It is the applicant's burden to show how it will meet the needs of the region as a whole. With a very small cancer program, one medical oncologist, and a limited referral 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 Project Will Not Improve Continuity of Care

Wilmington Health claims its proposal will enhance the continuity of care for its patients; see **Wilmington Health CON Application, p. 83**. However, the location of the proposed PET unit as well as Wilmington Health's closed system of care will actually limit continuity of care.

In addition to being important tools for cancer diagnosis and staging, PET/CT images are increasingly valuable as part of the treatment design and planning for radiation treatment. Technology advancements allow modern radiation treatment planning to include "fusing" of various digital images captured in diagnostic studies from multiple modalities (PET, MRI, SPECT, CT) with images captured during treatment simulation, in order to improve both safety and effectiveness of treatment. A combination of complex computing algorithms and highly skilled and knowledgeable physicists and dosimetrists means clearer delineation of tumor volumes versus normal tissues and organs – yielding more reproducible patient set-up for optimal treatment and higher accuracy treatment focused on tumor cells and sparing healthy tissue and organs. This requires significant computing capacity as well as investments in bandwidth and connectivity for image storage and transfer between the diagnostic imaging modality and the radiation treatment planning systems.

Additionally, the majority of Wilmington Health's cancer patients are treated at NHRMC. Wilmington Health's proposed PET scanner would not be compatible with NHRMC's electronic medical records system, meaning that any imaging coming from the proposed scanner would not be automatically shared with NHRMC, the largest provider of cancer treatment including radiation oncology in the service area. While complex and expensive, this interoperability and connectivity has been developed within NHRMC's radiation treatment, PACS, and EHR systems – as it has in many comprehensive cancer programs. Placing an important and limited focus resource, like PET, in a practice-limited setting, like Wilmington Health, would have predictable consequences:

1. Oncologists outside of WHA would be highly unlikely to order PET procedures at WHA knowing the images and results would not be easily integrated into their EHR nor necessarily available for radiation treatment planning;
2. Duplicative PET procedures could be anticipated on some subset of patients scanned at WHA but subsequently treated outside of WHA, simply due to lack of integration of systems;
3. Expensive and time-consuming investments that are not included in the application, by both NHRMC and WHA, would be required to develop the systems necessary for WHA images to be used in radiation treatment planning, assuming WHA would allow such access and integration with its private system.

For these reasons, Wilmington Health's proposed project will not provide continuity of care for its own patients, let alone service area residents in need of PET services served by NHRMC.

Wilmington Health will Not Enhance Geographic Access

Wilmington Health proposes to locate its PET services at its flagship location on Medical Center Drive in central Wilmington, New Hanover County, North Carolina; see **Wilmington Health CON Application, pp. 9 and 31**. Patients in need of PET services who reside in and around central Wilmington are already well served by NHRMC's existing PET scanner. By not considering patients located north of Wilmington in the Scotts Hill area, Wilmington Health has missed the opportunity to enhance geographic access for service area patients who currently must travel into congested central Wilmington for healthcare services. Placing a new PET scanner less than a mile from an existing PET provider in no way enhances geographic access. Wilmington Health's proposed project will result in a costly duplication of services.

Wilmington Health Will Not Address the Need Generated by NHRMC for Additional PET

On page 94 of its Application, Wilmington Health acknowledges that NHRMC drove the need identified in the SMFP. Wilmington Health will not address the published need in the 2021 SMFP for one additional PET in HSA V:

- The need was generated by the high utilization of NHRMC's PET scanner.
- Wilmington Health will not address NHRMC's capacity constraints because it only generates, at the very most, 9 percent of all NHRMC referrals.
- Wilmington Health will not shift patients from congested downtown Wilmington as its proposed location is a half mile from NHRMC's current PET scanner.
- Wilmington Health will not be able to meet the volume required by the PET Performance Standards based on limited referral volume (9 percent).
- Wilmington Health does not demonstrate it has the referrals or experience to offer cardiac PET services.

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 no historical basis for such projections. In fact, in Section L, pages 109 and 110 of its application, Wilmington Health claims its data does not track charity care as a payor. Wilmington Health's basis for projecting Medicare and Medicaid patients is unclear. Wilmington Health projects just 2 percent of its patients as Medicaid recipients, which does not demonstrate financial access for a medically underserved population. 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 populations currently use the applicant's existing services.

Wilmington Health's Project Will Not Meet the Need for PET Services in HSA V

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

- Wilmington Health has demonstrated that it will only receive referrals from within its own practice and therefore is not serving the broader need; see **Wilmington Health CON Application, pp. 57 and 83 and Wilmington Health's Letters of Support**.

- Since Wilmington Health will only serve its own patients, the proposed project will limit access for other patients in HSA V; 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 PET services and does not demonstrate any quality-related credentials for such services, even though Wilmington Health claims to serve cancer patients.
- Wilmington Health provides no licenses, accreditations, organizational memberships, or other external evidence of quality of care.
- 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 also understated the number of PET technologists and other clinical staff needed to cover the PET service and does not explain how it will provide treatments if one of its two PET technologists is sick, takes vacation, or leaves employment.

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 .3703(a)(1) states that:

(1) the proposed dedicated PET scanner, including a proposed mobile dedicated PET scanner, shall be utilized at annual rate of at least 2,080 PET procedures by the end of the third year following completion of the project;

As previously discussed, Wilmington Health’s unsupported projections result in a failure to meet the 10A NCAC 14C .3703 Performance Standards that apply to PET services. These issues include:

- Lack of basis for volume projections;
- Historical referral volume does not support projected volume;
- Unsupported data analyses;
- No projected utilization specific to cardiac PET;
- Lack of support for projected market share of PET procedures;
- Lack of support for referral volume from non-Wilmington Health-affiliated referral sources; and
- Using Wilmington Health’s historic PET scans to patient referral ratio shown in **Figure 2** above, Wilmington Health will fall far short of its projected procedure volume and the Performance Standards of 2,080 annual scans in Year 3 as shown in **Figure 4** below:

**Figure 4
Comparison of Wilmington Health Projected Volume Using the Referral Ratio
vs. the Performance Standard**

Wilmington Health Project Year 3 Patient Volume	1,121
Wilmington Health 2020 PET Referral Scans to Patients Ratio	1.46
<i>Wilmington Health Project Year 3 PET Scans Using Ratio</i>	1,636
PET Performance Standard (Scans)	2,080
Wilmington Health Project Year 3 Volume Shortfall	(444)

Source: Wilmington Health Form C, Internal Data, and 2021 SMFP.

Note: Numbers may not foot due to rounding.

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 Standards for PET Scanners.

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), (13), and (18a), Wilmington Health should be found non-conforming with Criterion (4):

- Wilmington Health has no experience offering PET services, so it has no history of providing quality care in this highly complex modality, nor does it provide any evidence of its plan to address the lack of experience or expertise necessary to deliver high quality PET services – see discussion under Criterion (3)
- Wilmington Health has insufficient resources for the proposed project linked directly to staffing and funding – see discussion under Criterion (5), Criterion (7), and Criterion (8).
- Wilmington Health has unreasonable and unsupported projections and an 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 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 adequately documented. This calls into question the reasonableness of Wilmington Health’s utilization projections which, in turn, undermines Wilmington Health’s financial projections. As shown in Criterion (3), there is no reasonable basis for projected utilization.

Wilmington Health's Project Costs are Incomplete and Understated

Wilmington Health failed to include the cost of the PET scanner in its total capital cost. It appears that Wilmington Health will lease its PET scanner, and therefore, has incorrectly failed to include the cost of such equipment in Form F.1.a. The lease is how Wilmington Health plans to fund the acquisition of the PET scanner. The use of a lease to fund the PET scanner would be identified in Section F.2.d. Other Forms of Financing.

For purposes of the CON Law, a lease of PET scanner equipment is an acquisition and is treated no differently than a purchase. See N.C. Gen. Stat. § 131E-176(16)f1.8 & 9. If Wilmington Health's assumption is that the cost of the PET scanner is not required to be identified as part of the 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, which generates the need for CON approval. By not identifying the cost of the PET scanner, Wilmington Health underreported the project capital costs and failed to submit the accurate CON filing fee.

Wilmington Health's Operating Costs are Understated

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

Staffing Costs are Understated

Wilmington Health may not have accounted for sufficient non-clinical support staff in the staffing model to provide a full range of support including administrative, clerical support, and patient access support/technicians. Given Wilmington Health is not an existing, experienced provider of PET services, it is unclear it has the appropriate existing staff to provide the service. Moreover, Wilmington Health did not include reasonable salaries to recruit qualified Nuclear Medicine Technologists to operate the PET unit. In addition, Wilmington Health did not include an RN in the staffing plan, which is required in order to provide cardiac PET. Please see detailed discussion under Criterion (7).

Supplies and Pharmaceutical Expense is Understated

Wilmington Health's medical supply and pharmacy costs, based on NHRMC's actual experience in providing PET, are too low. Wilmington Health claims it will offer a full range of PET scans including specialty radioisotopes, but it is unclear that sufficient expense has been included for the full range of specialized scans Wilmington Health claims it will offer. As shown below in **Figure 5**, Wilmington Health's projected medical supply and pharmacy costs are 15 percent lower per scan than NHRMC's projected medical supply and pharmacy costs which is based on NHRMC's actual cost for PET patients in FY 2021. Moreover, as a for-profit physician practice, Wilmington Health is not eligible to participate in the 340B program², so Wilmington Health's pharmacy expenses should therefore be higher than NHRMC's.

² The federal 340B program allows covered entities to purchase drugs at discounted prices. See <https://www.hrsa.gov/opa/index.html>. A private, for-profit physician practice is not a covered entity under 340B. See <https://www.340bhealth.org/members/340b-program/overview/>.

**Figure 5
Comparative of Supplies Cost per Scan
for NHRMC and Wilmington Health**

	NHRMC	Wilmington Health
PET Scans	2,214	2,241
Medical Supplies & Pharmacy	\$ 970,977	\$ 857,090
Costs per Scan	\$ 438.48	\$ 382.46

Source: Form C and Form F.3b. Note Wilmington Health's supplies are also noted to include utilities.

Equipment Maintenance

Wilmington Health does not include any cost for equipment maintenance. While the PET unit may be under warranty for the first year, by the second and third year of operation, maintenance costs will be required for the PET unit. Wilmington Health does not allocate any costs for maintenance in Form F.3b or the associated assumptions. There is no mention of maintenance in the lease documents provided by Wilmington Health. This expense is likely well over \$250,000 per year based on NHRMC's experience.

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 PET services. For the same reasons Wilmington Health's proposed project is non-conforming to Criterion (3), it should also be found non-conforming to Criterion (6).

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

Wilmington Health presents a staffing model that raises significant questions concerning operating costs and quality of care. Specifically:

- Wilmington Health does not project enough nuclear medicine ("Nuc Med"), or PET technologist FTEs needed to effectively operate a standalone PET service without additional coverage; and
- Wilmington Health's projected Average Annual Salary per FTE for a Nuc Med technologists in Form H of just \$62,601 in year 3, which is significantly less than the projected industry average of \$89,866 to \$100,136 in CY 2026, assuming a 3 percent annual inflation.

Inufficient FTEs for Nuclear Medicine (PET) Technologists

As previously established, on Form H Staffing, Wilmington Health proposes two FTEs for PET technologists. Two FTEs is insufficient for the hours of operation and projected volumes. Two FTEs to cover a "highly utilized" PET unit is insufficient, considering potential overtime, lunch breaks, vacation, and sick leave, etc. Accordingly, Wilmington Health has not indicated how it will ensure adequate staffing to effectively operate the proposed PET unit. By contrast NHRMC projects 2.1 FTE techs to cover overtime,

breaks, vacations, and such. Moreover, NHRMC's PET will be located in a community hospital with additional staffing coverage.

Insufficient Salary for PET Technologists

By Project Year 3, Wilmington Health only projects an average annual salary per FTE of \$62,601 for the PET Technologist position (or Nuclear Medicine Technologist). This is well below publicly reported industry data for the Wilmington area.

- ZipRecruiter.com identifies a current average for a PET Technologist in Wilmington, North Carolina of \$77,519.³
- Salary.com identifies a median current salary of \$86,378 for a PET Technologist salary in Wilmington, North Carolina.⁴
- Considering inflation at 3 percent annually from 2021 to 2026 (PY 3), the average salary for a PET Technologist would range from \$89,866 to \$100,136 in PY 3, which is far higher than projected by Wilmington Health.⁵

Wilmington Health will not be able to acquire adequate, experienced staffing for the proposed project when it is clearly offering below market salaries. One of two things is likely to happen: Wilmington Health will have to pay market-based compensation to staff its project, meaning the staffing costs stated in the application do not accurately reflect the true staffing costs. Alternatively, Wilmington Health plans to hire entry-level Nuc Med Technologists at a lower salary than the average; however, an entry-level PET Technologist would be inappropriate in the proposed setting with no direct supervision by a manager particularly given that no staff other than the 2.0 FTEs for PET technologists is identified in Form H. Salary.com identified the median salary for a Senior Nuclear Medicine Technologist as \$93,646 and ranging as high as \$124,226 as of October 29, 2021, further confirming the inadequacy of Wilmington Health's salary projection at half this rate five years from now in 2026 (Wilmington Health's Project Year 3).

Insufficient Staff for Cardiac PET

There is a nurse station in Exhibit C.1-1, but no nurse FTEs are projected. A nurse is required to support the provision of cardiac PET services. Wilmington Health fails to include this required staff member and the associated costs. The addition of an RN to the staffing projection would add as much as \$110,000 of expense when benefits are included.

In summary, Wilmington Health has not identified the full staff required to support the proposed project. Moreover, Wilmington Health either: (1) underestimates the average annual salary for Nuc Med Technologists which calls into question the validity of its projected operating expenses and its ability to secure adequate staffing or (2) plans to hire entry-level Nuc Med/PET technologists with no experience and little to no supervision which calls into question the quality of care in the provision of the proposed PET services. Either way, Wilmington Health is not conforming with Criterion (7).

³ As of November 16, 2021. See <https://www.ziprecruiter.com/Salaries/clear-Medicine-Technologist-Salary-in-Wilmington,NC>.

⁴ As November 16, 2021. See <https://www.salary.com/research/salary/benchmark/pet-ct-technology-salary/wilmington-nc>.

⁵ Wilmington Health's Form H Assumptions state that the projected annual salary will be inflated 3 percent annually through the third project year which is 5 years from now (CY 2026).

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 provided. Wilmington Health has not documented sufficient staffing for its proposed project or the necessary ancillary and support services.

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

Wilmington Health fails to show that its proposed project will enhance access for 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. 72**), and does not provide a charity care percentage in its payor mix (see **Wilmington Health CON application, p. 110**). 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, p. 110**. On page 110 of its application, Wilmington Health presented projected charity care and reduced cost data for just its PET service and not its entire organization as requested by this question.

Furthermore, the information presented by Wilmington Health in the medically underserved groups table under **Section C, Question 6b page 72**, is inconsistent. Wilmington Health estimates that it will only serve 27.4 percent of individuals who are 65 and older but serve 65.3 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, Wilmington Health fails to provide any historical information for payor sources on page 106-108 of its application, yet Wilmington Health indicates on Form O that it operates a Diagnostic Center on Medical Center Drive where the proposed service will be located. Wilmington Health should have provided historical payor mix information for this facility/campus. See **Wilmington Health CON application, pp. 106-108**).

Wilmington Health projects to serve just 2 percent Medicaid patients; see **Wilmington Health CON application, p. 110**. Medicaid patients are often designated as indigent patients. This minimal access for low-income patients is insufficient to demonstrate adequate access by underserved groups. Based on percent of gross revenue, Wilmington Health projects only 3.1 percent Medicaid. Moreover, this level of access is not confirmed by any documented actual historical provision of charity care as Wilmington Health failed to provide any historical payor mix. 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.” NHRMC has not seen the “charitable guidelines” published by US DHHS, so it can only be deduced from Wilmington Health’s policy that it will *consider* offering an adjustment to patients who are at or below the federal poverty guidelines. Considering offering an adjustment is not the same as actually offering an adjustment. This policy fails to support any real attempt to enhance access to the underserved in the local 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 unreasonable and unsupported 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 to produce referral volume for its proposed project, and no other source of external referrals has been identified. Because Wilmington Health will not meet the demand for PET services, the need will continue to have to be met by the other existing service area provider of PET services. Therefore, Wilmington Health’s project does not propose to increase competition within the service area; in fact, it only results in an underutilized PET scanner that increases community costs. Wilmington Health proposes an additional PET scanner located within a half mile of the existing PET scanner in the service area 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 PET in HSA V. 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

Both applicants indicate they will provide scans for oncology, neurology, and cardiac patients. While both applicants make this claim, Wilmington Health does not quantify any cardiac patient volume relying entirely on historical oncology and neurology patient scan volume in the service area for its projections. Moreover, it is not clear that Wilmington Health has included sufficient costs for specialized radioisotopes needed to provide certain complex scans based on its comparatively low medical supply/pharmacy cost per scan. See discussion in Criterion (5). For this reason, this factor is inconclusive.

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

Geographic Accessibility

The 2021 SMFP identified a need for one PET scanner in HSA V. The Wilmington and Brunswick areas of HSA V are already well covered for PET services. Wilmington Health proposes to locate its proposed PET scanner just a half mile from the existing PET scanner operated by NHRMC. NHRMC, on the other hand, proposes to improve geographic access by locating its proposed PET scanner on its Scotts Hill campus in northern New Hanover County. Doing so will reduce travel time for patients residing in northern New Hanover County, as well as Pender, Onslow, and surrounding counties. This is particularly important for cancer patients in need of PET services because cancer patients will make multiple trips over the course of many weeks to receive diagnostic and treatment services. Bringing PET services closer to where they live will help to alleviate the travel burden on cancer patients.

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

Effect on Competition

In terms of competition, Wilmington Health may appear to be the more effective applicant as it does not have existing PET services in the service area. However, as a novice provider of PET services, Wilmington Health cannot and will not provide the same quality of PET services nor the same continuity of care as NHRMC. Discussed throughout this document is Wilmington Health's lack of experience providing PET services, lack of understanding of PET services, insufficient staffing plan, and lack of continuity of care for its most vulnerable patients, including cancer and cardiac patients. Wilmington Health proposes to offer its PET services on a completely different campus than its proposed radiation therapy services further detracting from continuity of care. Finally, as Wilmington Health providers diagnose and treat fewer than 10% of cancer cases in the market (generously using Wilmington Health ordered PET procedures as a proxy) and because of the importance of efficient transfer of images and results to ensure timely, safe, and effective cancer treatment, a Wilmington Health PET scanner will effectively be inaccessible to 90% of service area patients. While the proposed project may appear to introduce competition in the service area, it actually will not do so. Patients of the proposed project will not be afforded the level of quality care or continuity of care they would receive if scanned at NHRMC.

Historical Utilization

NHRMC currently operates one PET unit, which is highly utilized and generated the need identified in the SMFP. Wilmington Health does not currently provide PET services, and thus has no historical utilization to report. Thus, the result of this analysis is inconclusive.

Access by Underserved Groups

Projected Charity Care

Based on its historical experience providing PET services, NHRMC projects to provide 2.8 percent charity care as a percent of gross revenue in the third full fiscal year (“FFY”). Wilmington Health, which has no experience providing PET, projects to provide 2.2 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 documented charity care dollars in its Form F.2b. See **Figure 6** below:

Figure 6
Percent of Charity Care Patients - Year 3

Facility	Charity Care % of Gross Revenue
Wilmington Health - MCD	2.2%
NHRMC - Scotts Hill	2.8%

Source: Form F.2b

Regardless of the discrepancies in Wilmington Health’s projected payor mix, NHRMC is still the more effective applicant as it relates to projected charity care.

Projected Access by Medicaid Recipients

Based on its historical experience providing PET services, NHRMC projects to provide 3.1 percent Medicaid as a percent of gross revenue and 3.8 percent Medicaid as a percent of procedures in the third full fiscal year (“FFY”). Wilmington Health, which has no experience providing PET, projects to provide 2.0 percent Medicaid as a percent of gross revenue and 2.0 percent Medicaid as a percent of procedures in the 3rd FFY. Even with its unsupported projected utilization and payor mix projections, Wilmington Health still does not propose to offer more care to Medicaid recipients than NHRMC proposes. See **Figure 7** below:

Figure 7
Percent of Medicaid Patients - Year 3

Facility	Medicaid % of Gross Revenue (a)	Medicaid % of Procedures (b)
Wilmington Health - MCD	2.0%	2.0%
NHRMC - Scotts Hill	3.1%	3.8%

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 PET services, NHRMC projects to provide 66.1 percent Medicare as a percent of gross revenue and 70.0 percent Medicaid as a percent of procedures in the third full fiscal year (“FFY”). Wilmington Health, which has no experience providing PET, projects to provide 65.3 percent Medicare as a percent of gross revenue and 65.3 percent Medicare as a percent of procedures in the 3rd FFY. Even with its unsupported projected utilization and payor mix projections, Wilmington Health still does not propose to offer more care to Medicare recipients than NHRMC proposes. See **Figure 8** below:

Figure 8
Percent of Medicare Patients - Year 3

Facility	Medicare % of Gross Revenue (a)	Medicare % of Procedures (b)
Wilmington Health - MCD	65.3%	65.3%
NHRMC - Scotts Hill	66.1%	70.0%

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 Net Revenue per Procedure

The following table compares net revenue or reimbursement per procedure. There is very little difference in the expected reimbursement per procedure as shown in **Figure 9** below.

Figure 9
Average Net Revenue/Reimbursement per Procedure 3rd FY

Facility	Procedures	Net Revenue	Average Reimbursement per Procedure
Wilmington Health - MCD	2,241	\$3,999,603	\$1,784.74
NHRMC - Scotts Hill	2,214	\$5,159,169	\$2,330.25

NHRMC provides very complex and therefore costly PET studies. The complexity and costs associated with these advance studies means higher reimbursement. The mix of types of scans/radioisotopes also changes from time to time. 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.

Comparative Staffing

As discussed under Criterion (7), Wilmington Health does not project sufficient FTEs to operate its proposed PET scanner. Of note, Wilmington Health does not project any registered nurses for its proposed PET scanner which is necessary to provide cardiac PET scans; see **Figure 10** below. Furthermore, Wilmington Health understated the salaries for the PET/Nuc Med Technologist necessary for the proposed project which means the operating costs for its proposed project are unreliable. As an existing and experienced provider of PET services, NHRMC appropriately and accurately accounted for all necessary FTEs and salaries required to operate its proposed PET scanner. NHRMC is clearly the more effective applicant.

Figure 10
Staffing Comparative of NHRMC and Wilmington Health in the 3rd FFY

Positions	NHRMC FTEs	Wilmington Health FTEs
Registered Nurses	1.0	0.0
PET/Nuc Med Technologist	2.1	2.0
Total	3.1	2.0
Year 3 PET/Nuc Med Tech Salary per FTE	\$104,618	\$62,601
Year 3 RN Salary per FTE	\$85,449	\$0

Source: Form H

Projected Average Operating Expense per Procedure

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 Criteria (5) and (7), including failure to include sufficient staffing, which impacts the projected operating expenses per scan or procedure. Nonetheless, a comparison of expense per procedure is provided below. NHRMC is the more effective alternative on an average expense per procedure basis; see **Figure 11** below.

Figure 11
Average Projected Operating Expense per Procedure 3rd FY

Facility	Procedures	Expenses	Average Expense per Procedure
Wilmington Health - MCD	2,241	\$ 2,790,868.82	\$1,245.37
NHRMC-Scotts Hill	2,214	\$ 2,079,610.62	\$939.30

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 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
Competition	Less Effective	More Effective
Scope of Services	Equally Effective	Equally Effective
Historical Utilization	Inconclusive	Inconclusive
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 Net Revenue per Procedure	Inconclusive	Inconclusive
Proposed Staffing	More Effective	Less Effective
Projected Average Operating Expense per Procedure	More Effective	Less Effective
Number of More Effective Comparisons (One point per “more effective” comparison)	6	1

Even if Wilmington Health were conforming with all applicable statutory and regulatory review criteria, which it is not, 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), (13), (18a), and the Performance Standards for PET services. NHRMC’s application meets all applicable criteria and standards for PET 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.