2025 HSA IV PET SCANNER CON REVIEW
PUBLIC COMMENTS
SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

March 31, 2025

Seven applications were filed in response to the need identified in the 2025 SMFP for two additional fixed PET scanners in HSA IV, including two submitted by Duke University Health System, Inc. ("DUHS"). These comments are submitted by DUHS in accordance with N.C. Gen. Stat. § 131E-185(a1) regarding the other applications, including comparative factors and a discussion of the most significant issues regarding those applications' conformity with the statutory and regulatory review criteria ("the Criteria") in N.C. Gen. Stat. §131E-183(a) and (b). Other non-conformities in the competing applications may exist and DUHS reserves the right to develop additional opinions, as appropriate upon further review and analysis.

Comparative Analysis

PET scanning is unusual in that its planning methodology reflects the entire health service area, not just a single or adjacent counties. This reflects that PET scanning is historically a highly specialized service for which patients will travel great distances to obtain care from the provider of their choice. The patient origin for the existing scanners in HSA IV reflects this statewide draw. The Agency should consider this context in comparing the applications.

Conformity with Criteria

As set forth below, all of the competing applications have serious issues that render their utilization and resulting financial projections unreliable. Only DUHS's applications, which are directly based to historical growth trends, provide reasonable and adequately supported assumptions.

Scope of Services

- All applications except for the one filed by Associated Urologists of North Carolina (AUNC) propose to offer cardiology, neurology, and oncology PET scans. While AUNC states it will provide this scope of services, its projections make clear that the vast majority of its projected volume is for PSMA scans for urology patients referred by its own providers. It has the narrowest scope of service.
- Only DUHS's two applications and UNC Hospitals' application propose to offer PET services in a hospital setting that will allow treatment of inpatients as well as outpatients. It is notable that in HSA IV, the hospital-based PET scanners experience significantly higher volume per machine than the freestanding machine that does not serve hospital patients, indicating that a hospital setting better meets the need for these services.

Geographic Accessibility (Location within HSA IV)

- All scanners are proposed in counties which already provide PET scanning services.
- Duke Cary Hospital and Wake Radiology propose to develop scanners in western Cary and Garner, respectively, which are areas with relatively lower local access than Raleigh, Durham, and Chapel Hill. However, Wake Radiology's application is not conforming with all applicable criteria.

Service to the HSA IV Counties (Access by Service Area Residents)

- The need for additional capacity was driven by utilization at the major academic medical centers in the service area, which serve patients from across the state. Accordingly, this need is not limited to patients residing with the service area and an applicant's percentage of patients from the service area does not accurately reflect how well that applicant would serve that need.

Access by Underserved Groups (Charity Care, Medicare, and Medicaid), Projected Net Revenue, and Projected Operating Expenses:

- The applicants are offering to add PET scanners to a variety type of facilities. In addition, each applicant's specific procedure mix, including the tracers used, reflects different patient populations entails different costs and reimbursement Larger, high-acuity facilities like Duke University Hospital and UNC incur higher costs due to the complexity of patient scans.
- This variable scope and procedure mix directly affects average net revenue, average operating cost, and payor mix. It is not possible to create an apples-to-apples comparison for each procedure type (cancer, PSMA, cardiac, etc.) based on the varying amount of detail about procedure type provided in each application.
- Facilities that bill separately for technical and professional fees cannot readily be compared to facilities that bill a global fee. Note also that AUNC, while it states it will bill a global fee, also states that the contracted radiology service that will provide professional interpretations will separately bill for Medicare scans. AUNC application, p. 94.

Competition

- HSA IV already has three providers of PET scanning services across multiple locations, reflecting robust patient choice and multiple options across several locations. These locations include nationally recognized academic medical centers and their systems. The introduction of a new provider will not have any effect on the quality, cost, or access to services at the existing providers.

WR Imaging, LLC/ Wake Radiology Diagnostic Imaging, Inc.
Renovation of Existing Space to add a Fixed PET/CT Scanner at
Wake Radiology UNC Rex Healthcare - Garner
Project ID J-012602-25

Introductory Comments regarding UNC Hospitals and Wake Radiology

UNC Hospitals and Wake Radiology have each filed applications for an additional fixed PET scanner. Although these applicants have a legal relationship and are closely linked, their applications are not consistent with each other.

UNC Hospitals in Chapel Hill and UNC Rex are both existing providers of fixed PET services in HSA IV. UNC Health wholly owns UNC REX Healthcare.[1] In 2017, UNC REX Healthcare and Wake Radiology formed a joint venture (Wake Radiology UNC REX Healthcare) to combine their outpatient imaging services. That partnership became official on February 23, 2019.[2] Thus, consistent with the definition of related entity set forth in 10A NCAC 14C .0202(10) – as well as the clear marketing of the parties that Wake Radiology is part of the UNC system and network, Wake Radiology, UNC Rex, and UNC Healthcare will all be related entities for the provision of PET services if Wake Radiology's application is approved.

While UNC Hospitals, as an academic medical center, may not need to specifically address specific regulatory performance thresholds for other facilities, it must nonetheless address how its proposed project meets the need of the identified patient population for the proposed services, is the most effective alternative available to meet the need, and does not unnecessarily duplicate services in the service area – all statutory criteria that apply equally to academic medical centers.

Wake Radiology, meanwhile, must demonstrate that all equipment owned or approved to be operated by a related entity will be appropriately utilized under the applicable performance standards and must also demonstrate conformity with all statutory criteria.

Each of these applicants tries to ignore the relationship with the other. Neither offers no explanation for the differing projections of utilization at UNC Rex. This calls into question the assumptions for the volume projections in both applications.

Specific Comments regarding Wake Radiology Application

This application was submitted by WR Imaging, LLC and Wake Radiology Diagnostic Imaging, Inc. (collectively "WR"). WR Imaging, LLC, is a joint venture which includes Wake Radiology and UNC Rex Healthcare ("UNC Rex") as owners. WR Imaging, LLC currently operates fourteen diagnostic facilities, including Wake Radiology UNC Rex Healthcare – Garner ("WRUNC Rex –

[1] UNC Rex Healthcare is part of UNC Health Care. UNC Health Care comprises UNC Hospitals and its provider network, the clinical programs of the UNC School of Medicine, and nine hospitals across the State including UNC REX. https://www.UNC Rexhealth.com/rh/about/collaboration-within-unc-health-UNC Rex/#:~:text=Collaboration%20within%20UNC%20Health%20UNC Rex,-Community%20Involvement&text=UNC%20Health%20Care%20is%20a,and%20based%20in%20Chapel%20Hill.

[2] https://www.wakerad.com/feature-stories/partnership/.

Garner"), where the Applicant proposes to add a fixed PET unit. The CON application acknowledges, but downplays, the role of UNC Rex Healthcare ("UNC Rex") in the partnership for this project and denies that it is a related entity for the purposes of addressing the performance standards and other parts of the application including Form O.

The application's projected PET volumes are based on arbitrary and aggressive assumptions and are likely overstated. The omission of its impact on the UNC Rex unit(s) in addition to its own PET volume overestimations result in questionable conformity with the performance standard, both individually and combined. Further, there are omissions and questions related to operating expenses that in combination with lower volumes could result in questionable financial feasibility. For these reasons, the project should not be approved.

Criterion (1)

- WR appears to want to blur the requirements related to its affiliation with UNC Rex in its ownership discussion. Moreover, the status of the PET units at UNC Rex is unclear. According to the application, UNC Rex was awarded a CON in 2019 for a second PET unit. According to the 2025 SMFP, UNC Rex has two operational/approved units and all volume shown for FY 2023 was performed on its original unit.
- Based on information provided in the application, it is unclear if the second unit was ever installed and if it is currently operational.
    - At best, UNC Rex took four years to implement its 2019 PET approval.
    - At worst, UNC Rex has been holding on to an approval for six years and hindering real PET capacity in HSA IV this entire time.
- This joint venture including UNC Rex is now requesting approval for another PET unit, when UNC Rex has not timely implemented its last CON approval for PET.

Criterion (3)

Scope of the Project (pages 34-37)

- The application states that WR Imaging will relinquish its 2023 CON (Project ID #J-12402-23) that approved the transfer and replacement of one of two existing UNC Rex hospital-based PET units to an off-campus joint venture location. UNC Rex will either develop or continue to operate 2 scanners on its campus and apparently intends to replace this unit in the hospital via exemption, although it is unclear whether this unit was ever put into service. The application does not state whether the relinquishment is contingent on approval of the application under review. WR spends almost three pages (34-36) describing the history of the UNC Rex PET scanners, detailing its delay in implementation due to Covid-19 epidemic, but does not identify at any point that the second approved unit has ever installed. The application does not address why the original project will not adequately meet the needs of patients.

Patient Origin

- Historical patient origin for WRUNC Rex – Garner shows a primary service area limited to five counties (Wake, Johnston, Harnett, Sampson, Wayne) and 4.0% originating elsewhere. (page 38). In contrast, projected patient origin for PET includes the eleven service area counties and no additional patients from outside HSA IV (page 39).
- There is a disconnect with the historical utilization of WRUNC Rex – Garner. (pages 39 and 40). While PET is a more complex and limited service than other diagnostic modalities, the application provides no explanation for why the patient origin patterns would be so dramatically different than for its existing diagnostic services already located in the same location. Most notably:
    - WRUNC Rex – Garner serves patients from Harnett, Sampson, and Wayne Counties. However, the PET is not expected to serve two of the facility's five primary service area counties <u>at all</u> as shown below.

	2024	**YE 9/30/2027**	**YE 9/30/2027**
	All Dx Services	**PET**	**All Dx Services incl. PET**
Wake	14,189	564	15,860
Johnston	7,929	119	8,655
Harnett	1,323	-	1,427
Sampson	738	-	796
Wayne	282	-	302
Other	1,021	199	1,300
Total	**25,482**	**882**	**28,340**

Source: CON application pages 38-40.

    - Given the location of Garner in the southeast quadrant of the service area and its patient origin for other services, it is unreasonable that its patient origin will only reflect counties within HSA IV and exclude counties like immediately adjacent Harnett County.
    - WRUNC Rex – Garner's projected PET patient origin is unreasonable and unsupported. Therefore, the Applicant has not reasonably defined the population to be served. Please see additional discussion under "utilization projections."

Demonstration of Need (Pages 42-64)

- WR Imaging presents an outline of the 2025 SMFP methodology and explains that UNC Rex Hospital is only using 1 of the 2 PET units identified in the inventory. On page 35, the Applicant provides a long history of PET services at UNC Rex Hospital and Wake Radiology; however, it is never adequately explained why UNC Rex Hospital has never implemented its second PET units approved through Project ID #J-11659-19).
    - Approved Project ID #J-12402-23, now proposed to be relinquished, would have relocated UNC Rex Hospital's **<u>original</u>** PET unit. This still does not explain why the 2019 PET unit is not implemented.
    - On page 126, it is noted that "UNC Rex **<u>now</u>** plans to develop the second UNC Rex PET scanner within UNC Rex Hospital," <u>six years past its CON approval</u>.
- Capacity constraints are discussed as a basis for need on pages 47 and 49.

  - Any capacity constraints at UNC Rex appear to be of its own making by failing to implement its 2019 PET approval. Moreover, if UNC Rex "now plans to develop" that equipment, such capacity constraints will presumably be addressed.
- Pages 51-52 discuss the merits of a radiologist owned and operated PET unit.
  - WR Imaging discusses lack of referral bias in relation to other specialty owner/operators like urology or cardiology. This provides no greater benefit than a hospital-operated scanner.
  - WR Imaging claims that the project's Garner location will enhance geographic access, as it is located southeast of the two existing clusters of PET providers. (pages 52-54). The geographic location, standing alone, does not create any need for the proposed project. The application projects very limited patient origin, primarily in Wake County which already has existing providers, whereas PET scanning services typically reflect a broad and multi-county service area.

10A NCAC 14C .3703 PERFORMANCE STANDARDS (pages 69-70)

- As mentioned above, WR inaccurately argues that UNC Rex is not a related entity to WR Imaging, LLC. However, based on the definition in 10A NCAC 14C .0202(10). UNC Rex very clearly meets part (c) of the definition:
  - *…participates with the applicant in a joint venture that provides the same type of health services proposed in the application."*
  - UNC Rex provides PET services and is **a partial owner** of the Applicant in a joint venture proposing to offer PET. As a result, these are related entities.
  - The Applicant suggests that UNC Rex is unrelated because it does not - *as of today* - participate with WR Imaging LLC or Wake Radiology in proving PET services. This suggestion ignores the obvious:
    - UNC Rex is an owner of WR Imaging, LLC (the Applicant) and is approved to provide PET services using one of UNC Rex's existing PET units. (Project ID #J-12402-23).
    - With this project, WR Imaging, LLC, which is co-owned by UNC Rex, <u>proposes</u> to provide fixed PET services as part of this project. By year three of the project, both entities would be PET providers.
  - To ignore UNC Rex under the performance standards would totally circumvent the meaningful definition of a related entity. If the project is approved, WR Imaging, LLC and UNC Rex <u>will</u> be related entities providing PET scanning services.
- See additional comments below under *Utilization Projections – Methodology and Assumptions.*

Utilization Projections - Methodology and Assumptions (pages 119-126)

The utilization projections are not reasonably supported.

- Step 1 – WR Imaging uses NC-OSB&M data to project population by HSA IV-county through 2029[3].
- Step 2 – The applicant calculates a state PET use rate for 2025-2029. (pages 120-121)
- Step 3 – The Applicant applies its calculated state use rates from Step 2 to the Step 1 population projections to calculate projected PET demand by HSA IV-county and overall, for 2025-2029.
    - As shown below, WR Imaging projections for 2025 are completely unreasonable when compared to actual historical utilization from the Agency's patient origin reports. The Applicant's projections imply that:
        - 3 counties would have declines in PET utilization when they have grown historically (Lee, Orange, and Warren).
        - 3 counties would have PET growth much lower than the historical growth experienced (Chatham, Franklin, and Vance).
        - 1 county would have growth that was more than double its historical growth (Johnston). This is notable given the significant percentage of patients projected to come from Johnston County; if this volume is overstated, it has a material impact on the resulting utilization projections.

Comparison of Historical HSA IV PET Utilization to the Applicant's Projection

	Actual PET Utilization by County				Applicant's Projection		
Report:	**2022**	**2023**	**2024**	**Change from**		**Change from**	**2023-2025**
Data:	**2021**	**2022**	**2023**	**2021-2023**	**2025**	**2023 to 2025**	**CAGR %**
Chatham	333	430	614	281	666	52	4.1%
Durham	1,080	1,536	1,910	830	2,725	815	19.4%
Franklin	296	332	534	238	657	123	10.9%
Granville	271	290	382	111	497	115	14.1%
Johnston	809	879	1,160	351	2,027	867	32.2%
Lee	220	549	639	419	554	**(85)**	-6.9%
Orange	854	1,049	1,508	654	1,217	**(291)**	-10.2%
Person	168	285	318	150	316	(2)	-0.3%
Vance	138	202	321	183	326	5	0.8%
Wake	4,831	5,401	7,578	2,747	9,803	2,225	13.7%
Warren	67	82	238	171	148	**(90)**	-21.1%
Total	**9,067**	**11,035**	**15,202**		**18,936**		11.6%

Source: 2024-2022 PET Procedures - Patient County of Residence Reports
Application page 122.

- Step 4 – For each of the first three project years, the Applicant determines estimated market share by county. By year 3, these range from 2.0% to 15.0%. (pages 122-124)
    - The Applicant projects a 15% market share in Year 3 for Franklin, Wake, and Johnston Counties due to its geographic location and referral network. 15% is extremely aggressive, particularly given UNC Rex's 2 PET units and current utilization patterns.

[3] The Applicant uses a combination of unlabeled years, calendar years, and fiscal years throughout its analysis. This outline references them in the same manner as referenced by the Applicant.

  - Market share assumptions for other counties are similarly aggressive, given their geographies. All other HSA counties except Durham are expected to reach a 5% market share in Year 3; however, many of these areas are located more than an hour from the proposed location. Patients from these counties would drive past multiple other providers to reach this location, even though there would be no other services co-located at this facility for oncology, neurology, or cardiology patients as exist at hospital locations.
  - These market share assumptions do not consider UNC Rex and fail to consider the impact on UNC Rex's PET units.
    - It is unclear whether any of the projected market shares will be shifted from UNC Rex to alleviate the capacity constraints discussed in the application.
    - It is unclear how much, if any, market share will be new incremental market share.
    - Despite the availability of data, no discussion is provided of UNC Rex's historical market share.
    - It is unclear how the implementation of UNC Rex's second PET scanner would affect market share expectations.
- Step 5 – Step 4 market shares are applied to Step 3 volumes to calculate the projected utilization by HSA IV-county and overall, for each of the first three project years. (Page 124)
- WR Imaging's assumptions are both arbitrary and aggressive. They also fail to consider the relationship to UNC Rex, which is discussed throughout the application and whose high utilization is relied upon as a basis for need for the project.
- The Applicant does address utilization of UNC Rex in its response to the performance standard (124-126). However, these projections are unreasonable.
  - This time it provides two methods to demonstrate that it conforms with the standard if it includes UNC Rex's PET unit(s). Neither method considers the impact of the proposed WR Imaging PET on the PET service at UNC Rex.
  - The UNC Rex Health projections differ from the projections generated by UNC Rex's parent UNC Health in the UNC Hospitals application.

Criterion 4

WR does not adequately address the obvious options of increasing capacity in the UNC Rex-Wake Radiology System by implementing the approved UNC Rex scanner, either at the hospital or as previously proposed at a WR Imaging joint venture location.

Criterion (5) Financial Feasibility

See discussion related to Criterion 3. The utilization projections are not reasonable and are based on aggressive and arbitrary assumptions. As a result, revenues are likely overstated, and financial feasibility is questionable. Further, both capital costs and ongoing operating expenses appear understated:

- WR did not include fees for the management agreement with Wake Radiology Services, LLC in the operating costs (Pages 94 and 129).
- WR Imaging will only hire 1.0 FTE PET Technologist for its first year of operation Form H (page 130). This raises questions as to whether it intends to offer PET services full-time in the first year. One technologist cannot cover 5 days a week, 8 hours per day when vacation and sick time are considered.

Criterion (6) Unnecessary Duplication

- WR Imaging does not adequately respond to this item (pages 90-91). It simply references the need identified in the 2025 SMFP and refers to its discussion of need in Section C.4.
- It fails to consider and address whether the project unnecessarily duplicates the second PET unit already approved and/or in use at UNC Rex Health or the PET scanners in use at UNC Hospitals, or any other provider in the area.

Criterion (7) Staffing

- The Applicant only identifies a 1.0 FTE PET Technologist on Form H for PY1. This increases to 2.0 FTEs (still limited to PET Technologist) for Years 2 and 3.
    - This would indicate that WR Imaging does not intend to operate the proposed PET unit full time in Year 1.

Criterion (8) Support Services

- Except for image interpretation, WR Imaging will contract all support services through Wake Radiology Services, LLC. The operating costs do not include this contract. (Pages 94 and 129)

Criterion (13) Medically Underserved Population

- Payor mix projections are based in part on the FY2024 payor sources of outpatient PET services at UNC Rex Hospital (page 105)
    - This suggests that some UNC Rex outpatients are anticipated to seek PET from the proposed unit and indicates that this project will have an impact on UNC Rex's PET units.
    - As noted above, the Applicant does not present any consideration of a shift of patients from UNC Rex to the proposed new PET unit.

Criterion (20)

- UNC Rex is not listed on Form O (page 136). As a related entity, UNC Rex should be listed and the various question in Section O answered to include this entity. UNC Hospitals should also be listed and addressed.

University of North Carolina Hospitals at Chapel Hill (UNC Hospitals)
Certificate of Need Application for a fixed PET Scanner in HSA IV
Project ID J-012595-25

UNC Hospitals at Chapel Hill (UNCH) has applied for an incremental PET scanner. As discussed above, its application obscures its relationship with UNC Rex and Wake Radiology as well as obscuring its ability to accommodate any patient demand on its existing PET-CT and PET-MR scanners acquired via Policy AC-3. These efforts are necessary to demonstrate a need that does not exist when the full context is available.

UNCH currently operates three PET scanners, including one traditional PET-CT scanner acquired pursuant to Policy AC-3 and one PET-MR machine as well as one PET-CT acquired pursuant to a need determination. One of these AC-3 units is co-located at the NC Cancer Center with the existing need-determined unit. The PET-MR unit is reported with no volume on recent LRAs. This is in addition to one existing and one approved PET scanner at UNC Rex in Wake County. This project proposes the renovation of existing space at the NC Cancer Hospital on the campus of UNCH for the addition of a fixed PET unit for a total of 2 need-determined units and four PET scanners in total (including the PET-MR).

UNCH uses internal PET data that appears inconsistent with its publicly reported LRA data. While it tries to draw a firm distinction between the need-determined and AC-3 PET-CT equipment, it cannot provide the actual utilization on each, instead relying on "estimated" utilization. UNCH fails to explain why its SMFP need-determined PET unit is so highly utilized, while its AC-3 unit operated at the same location is only operating at 40% of capacity (2024 LRA). It similarly offers insufficient explanation why the PET-MR machine is not able to accommodate PET procedures. While AC-3 allows eligible applicants to pursue projects without a need determination, and the resulting equipment and utilization are not included in the need methodology, nothing in the statutory or regulatory criteria relieves that provider from addressing the utilization of equipment acquired under that Policy.

These fundamental flaws and inconsistent data call into question data and projections throughout the application. As a result, UNCH's application should be disapproved.

Criterion (3)

Demonstration of Need

<u>SMFP Need Determination (pages 54-55)</u>

- The 2025 SMFP shows need for 2 additional fixed PET units om HSA IV generated by UNC Hospitals (1) and DUHS (1). UNCH claims that the 2025 SMFP should show a need for three additional PET units in HSA IV because the SMFP erroneously included its AC-3 PET unit in its inventory. If removed from the inventory, UNCH claims it would generate a need for two units. However, this does not address whether UNCH actually needs that equipment, given the available capacity on the equipment acquired through Policy AC-3.

- On page 54, UNCH claims that its one need-determined PET unit operated at 179 percent of capacity based on one PET unit and a 2022-2023 volume of 5,375.

> * NOTE: The *2025 SMFP* planning inventory for HSA IV incorrectly includes one AC-3 PET scanner at UNCH. UNCH has one licensed PET scanner that was acquired through a *SMFP* need determination. The utilization rate for this PET unit, which is based upon only the procedures performed on the need determination-acquired PET unit, was 179 percent in FFY 2023. The correspondence with the Healthcare Planning and CON Section clarifying the correct inventory figures is included in Exhibit A.5.

  However, the 5,375 scans used in this analysis appears to also include the volume from the AC-3 approved unit based on the historical utilization provided in the Assumptions and Methodology on pages 128-130. The 179 percent capacity measure is used by UNCH throughout the application to justify its need for a second need-determined PET unit but is both inaccurate and mischaracterized. If the AC-3 unit is unable to serve a comparable volume of patients for any reason, UNCH could simply replace the equipment. ***See analysis below under "Projection Methodologies and Assumptions."***
- Each SMFP since at least 2018 shows UNCH to have an inventory of two PET units. At any time during this period, UNCH could have brought its SMFP issues regarding the AC-3 unit to the attention of the SHCC. Moreover, UNCH could have petitioned the SHCC if it believed the inventory or need calculation was in error. Based on publicly available information, it does not appear that UNCH has ever requested this amendment or correction.

Population Growth and Aging

- Population growth is demonstrated by county for all HSA IV counties (page 56). However, this analysis measures growth for a different group of counties than those included in its projected patient origin (page 51), which only includes several HSA IV counties.
- Franklin County, located in HSA IV, is projected to have an overall CAGR of 13.8% from 2025-2030 and a 4.8% CAGR for the 65+ cohort – the highest growth rate for all HSA IV counties. However, UNCH does not include Franklin County in its projected patient origin.

Need (page 64)

- There is no discussion or quantification of wait times for PET scans for UNCH patients on any of its units. If there is an issue with capacity constraints for patients waiting for PET scans, it is not discussed.
- On page 64, UNCH states *"Of note, while both UNC Hospitals and Duke University Hospital show a facility deficit in Table 15F-1 in the 2025 SMFP, as explained previously, the deficit for UNC Hospitals should be two, not just one, since the inventory incorrectly includes one of the AC-3-acquired PET scanners. As such, UNC Hospitals has an even higher facility utilization rate and has an even greater need for additional capacity to serve its patients than is reflected in the 2025 SMFP."* DUHS similarly has one PET scanner acquired through Policy AC-3 that is currently included in the need reflected in the need methodology. Whether or not these scanners are included in the need determination is unrelated to whether or not they are available to meet the need identified by UNCH. Ignoring the AC-3 PET-CT (even excluding the PET-MR equipment) also overstates the

need; there is no identified difference in the equipment itself and both machines should provide capacity for clinical procedures. UNCH does not explain why there is such differential utilization in the equipment.

- Throughout the application UNCH references that its dedicated fixed PET is operating at 179.2% of capacity. See Table 1, page 54 which is also copied below.

Table 1: Utilization of Existing Dedicated Fixed PET Scanners in HSA IV

Facility	*Planning Inventory*	*2022-2023 Procedures*	*Facility Utilization Rate*	*Facility Deficit*	*Need Determination*
Duke Raleigh Hospital	1	2,002	66.73%	0	
Duke University Hospital	3	7,442	82.69%	1	
Rex Hospital	2	4,772	79.53%	0	
University of North Carolina Hospitals	1*	5,375	179.2%	1	
Wake PET Services	1	1,660	55.33%	0	
HSA IV Total	**8**	**21,251**	**0**	**2**	**2**

Source: *2025 SMFP,* Table 15-1.

* NOTE: The *2025 SMFP* planning inventory for HSA IV incorrectly includes one AC-3 PET scanner at UNCH. UNCH has one licensed PET scanner that was acquired through a *SMFP* need determination. The utilization rate for this PET unit, which is based upon only the procedures performed on the need determination-acquired PET unit, was 179 percent in FFY 2023. The correspondence with the Healthcare Planning and CON Section clarifying the correct inventory figures is included in Exhibit A.5.

Application page 54

- <u>The calculated utilization rate for one scanner of 179.2% using 5,375 procedures for 2022-2023 appears greatly overstated</u>. The notation at the bottom of the table states that the total procedures only represent those performed on the need determination-acquired PET. This does not align with the historical utilization figures presented in the methodology and assumptions for volume projections on pages 129 and 130 of the application. ***See analysis for Utilization Projections, Methodology, and Assumptions below for additional details***.
- UNC's LRA data appears highly inconsistent with the internal data UNCH uses throughout the application. The need-determined PET scans reported in the 2024 LRA totaling 5,375 – if correctly reported as performed on the need-determined unit – for the year ending 10/23 are 29% higher than the internal volume of 4,142 used in the CON application for the previous year ending June 30, 2023. Two annual periods of utilization data for the same PET unit that are only separated by a single quarter would not typically **result in a variance of more than 1,000 PET scans**. This discrepancy raises questions related to the reliability and accuracy of the PET data reported on the LRA.

Comparison of CON Application and LRA PET Utilization Data

UNC Fiscal Year:	**July 2022 - June 2023**	**Oct 2022 - Sept 2023**	**% Variance**
Need PET	4,142	5,375	29.8%
AC-5 PET	1,381	1,198	-13.3%

Total	5,523	6,573	19.0%
Average Quarterly Utilization	1,381	1,643	

Source: 2024 LRA, CON pages 190-130

- An almost 30% variance in PET scans performed on the need determined unit and a 19% variance in total PET volume is highly suspect with only a quarter-year (three month) difference in reported time period.
- To show the magnitude of this discrepancy, it is helpful to look at it on a quarterly basis. Based on internal data provided in the CON application, for YE June 30, 2023, UNCH performed 1,381 scans per quarter (5,523/4). To achieve the 6,572 total scans reported in its LRA for YE September 30, 2023, UNCH would have performed 2,430 scans in the last three months of this reporting year after averaging 1,381 scans in each of the previous three quarters.

Avg Quarterly Utilization for YE June 30th				
Q End Dec 31	Q End Mar 31	Q End Jun 30	Q End Sept 30	YE Sept 30
1,381	1,381	1,381	2,430	6,572

- UNCH makes no attempt to reconcile or explain this vast variance between the LRA data and the internal data used in its application. This calls into question the validity of both data sets and undermines UNCH's entire application.

- UNCH's most recent 2025 LRA data further calls its utilization data into question. The 2025 LRA data shows a significant drop in PET volume from 6,573 total scans to 5,841 total scans representing an 11% decline in just one year. There was a 28.7% decline in scan volume on the need determined unit and a 67.7% increase in utilization of the AC-3 Unit. While total volume may have decreased, this suggests that UNCH has figured out how to use its AC-3 PET scanner more appropriately and that in the future, it could make use of existing capacity more effectively.

LRA Reporting Year:	Oct 2019 - Sept 2020	Oct 2020 - Sept 2021	Oct 2021 - Sept 2022	Oct 2020 - Sept 2023	Oct 2023 - Sept 2024	% Change 2023-2024
Need PET	3712	3,952	4,320	5,375	3,832	-28.7%
AC-3 PET	982	887	745	1,198	2,009	67.7%
Total	**4,694**	**4,839**	**5,065**	**6,573**	**5,841**	**-11.1%**

- UNCH states that the proposed PET unit will also support patient care and research at Lineberger Comprehensive Cancer Center. According to pages 129 and 130, the estimated 2025 utilization of the existing AC-3 PET unit at NC Cancer Hospital/Lineberger CCC is only 1,471 scans (5,885-4,414). This existing nit has abundant capacity for additional scans, operating at 46% of SMFP defined capacity (1,373/3,000), which capacity appears sufficient to accommodate any additional volume projected in the application.

  - UNCH also ignores or omits that it has a PET/MR that is dedicated to research identified on its LRA which has little to no reported volume with 0 scans reported on its 2024 and 2025 LRAs and just 54 total scans reported on its 2023 LRA. UNCH provides no explanation why this unit is not available to accommodate any identified patient demand.
- UNCH states that expected growth in cardiac and neurology referrals for PET as well as physician recruitment in these areas and in oncology and urology are expected to drive future PET growth. Neither referral growth nor physician recruitment is estimated or quantified in the application.

Utilization Projections, Methodology, and Assumptions (beginning on page 129)

Historical Utilization

- Table 1 (Assumptions and Methodology, page 129) shows 4,620 and 5,523 PET procedures for FYs 2022 and 2023, respectively, to represent the **combined total** performed on the need-determined and AC-3 approved PET scanners at NC Cancer Hospital. See Table below.

Table 1: UNC Hospitals Historical Clinical and Clinical Research PET Procedures

	FY21	FY22	FY23	FY24	FY25*
PET Procedures	4,410	4,620	5,523	5,493	5,885

Source: UNCH internal data.
*FY 2025 acute care days are based on actual July through November utilization annualized.

- Although UNCH should have actual data on the utilization of its need determined and AC-3 units, it estimates this split of utilization.
- Table 2 (page 130) estimates an annual total of scans performed on the need-determined PET scanner by applying 75% to the totals in Table 1 above. UNCH provides no explanation for its failure to have or to present the documented historical utilization for this unit by year if the utilization is, as represented, not consistent across both machines - particularly when actual data by unit is provided each year on its LRA. Similarly, it provides no persuasive explanation why it cannot use the two scanners more equitably to increase effective capacity. See Table 2 below.

Table 2: UNC Hospitals Historical PET Procedures (Need Determination-Acquired PET Scanner Only)

	FY21	FY22	FY23	FY24	FY25*	FY21-FY25 CAGR^
PET Procedures	3,308	3,465	4,142	4,120	4,414	7.5%

Source: UNCH internal data. Table 1 x 75%.
*Annualized based on partial year FY25 data (July – November).
^ Compound Annual Growth Rate

- There is no basis for the 75/25 split between the two units; further, the split is inconsistent with data reported on UNCH's previous LRAs as shown below. The allocation to the AC-3 PET has recently increased.

LRA Reporting Year:	Oct 2019 - Sept 2020	Oct 2020 - Sept 2021	Oct 2021 - Sept 2022	Oct 2022 - Sept 2023	Oct 2023 - Sept 2024
Need PET	3,712	3,952	4,320	5,374	3,832
AC-3 PET	982	887	745	1,198	2,009
Total	4,694	4,839	5,065	6,572	5,841
% on Need Determined Unit	***79.1%***	***81.7%***	***85.3%***	***81.8%***	***65.6%***

Source: 2021-2025 LRA data

- Table 2 (page 130) estimates that 3,465 procedures were performed on the need determined-unit in FY22 and 4,142 procedures in FY 2023 – both are far less than the 5,375 procedures used by UNCH in Table 1, page 54 to recalculate the 2025 SMFP facility utilization rate. An average of the FY22 and FY23 totals (3,804) would result in a 126.8% utilization rate, far lower than the 5,375 procedures and 179.2% utilization rate claimed by the applicant.
- The utilization figures used by UNCH are not reliable. The total PET procedures used in Table 1 (page 54) do not reconcile with utilization figures provided in either Table 1 or Table 2 presented on pages 129 and 130.
- Further, the figures used in Table 2 (page 130) above are not reliable as they represent an estimated allocation of procedures to the need-determined PET unit rather than documented volumes for the need-determined PET unit.

Utilization Methodology and Performance Standard (pages 130-132)

- UNCH uses an annual growth rate of 7.5% based on its CAGR calculated in Table 2 above and applied to the "estimated" 2025 utilization for its need-determined unit. The estimated 2025 utilization is calculated based on just 4 months of FY2025.
    - To the extent that UNCH relies on utilization just of its need-determined equipment, its historical utilization belies any need for additional capacity. Using publicly reported LRA data for the need-determined PET unit that breaks out its dedicated utilization, the result is a declining volume of scans and a -1.0% CAGR.
    -

Oct 2020 - Sept 2021	Oct 2021 - Sept 2022	Oct 2022 - Sept 2023	Oct 2022 - Sept 2023	Oct 2023 - Sept 2024
3,952	4,320	5,374	3,832	-1.0%

Source: 2022-2025 LRA data

- Total PET utilization on both machines also demonstrates a significant <u>decrease</u> between 2023 and 2024, calling into question any projections for future growth.

- UNCH's utilization projections are flawed by their significant discrepancies from publicly reported LRA data upon which the need in the SMFP is based. Moreover, UNCH cannot produce actual historical volumes for its need-determined unit but instead estimates this utilization based on a percent of total scans. These inconsistencies lead to unreliable and flawed utilization projections.
- UNCH's utilizes its affiliation with UNC Rex Hospital inconsistently throughout the application.
    - UNC Rex is included in Form O (page 144).
    - In response to the Performance Standard in Section C, the two PET units at UNC Rex are listed in Item a.1 as owned or operated by a related entity. However, in response to Item a.7, UNCH claims that UNC Rex does not have to be considered because UNCH is an academic medical center (pages 74 and 75).
    - In response to the Performance Standard in Section Q, UNCH claims that its relationship with UNC Rex is not applicable but goes on to provide projected utilization for UNC Rex (page 133). These projections are inconsistent with the projections provided for UNC Rex in the WR Imaging application (J-012602-25) pages 125-126 as shown below.

UNC Rex Historical and Projected PET Procedures

	FY 21	FY 22	FY 23	FY 24	FY 25	FY 26	FY 27	FY 28	FY 29
UNCH CON	3,846	4,158	4,606	4,982	5,273	5,363	5,454	5,546	5,641
WR Imaging CON Ver. 1			4,772	4,772	4,772	4,772	4,772	4,772	4,772
WR Imaging CON Ver. 2			4,772		4,707	4,802	4,899	4,998	

Sources: UNCH CON page 133, WR Imaging CON pages 125-126.

        - These inconsistent data, including differing volume for actual FY 2023, call into question the validity of UNCH's projections.
    - UNCH projects a total of 5890 on its two need determined-fixed scanners. To the extent that UNCH states that the need determination reflects only the existing need-determined scanner, this would reflect only an increase of 5 scans over all project years.
    - While UNCH claims that the agency stated it should not include AC-3 units "in the inventory," it is unclear what this means (application, p 132). Policy AC-3 calls for such equipment to be excluded from the SMFP planning inventory, but does not direct that it be ignored for the applicable regulatory performance standards for additional equipment.

Summary for Criterion (3)

UNCH uses unverified and inconsistent historical volumes for its need-determined PET unit. Moreover, UNCH mischaracterizes its current capacity constraints providing an inadequate explanation of the use of its AC-3 unit in combination with its existing need-determined unit and proposed unit. As a result, the proposal does not reliably reflect need or projected utilization for a second need-determined unit.

Criterion (4)

Status Quo

- UNCH eliminates the status quo as an alternative stating "UNCH is seriously constrained in its ability to keep pace with the increasing patient demand for PET services and will certainly not be able to keep pace with population growth and aging in the service area, as discussed in Section C.4."
    - This is not documented quantitatively or with any documentation (letters, stories, etc.).
    - The utilization of the AC-3 unit is clearly well below capacity and UNCH treats both its need-determined and AC-3 units as interchangeable based on its estimate of scans on each unit.
- UNCH does not address the proposal by Wake Radiology, which is the joint venture partner of its wholly-controlled subsidiary.

Criterion (6)

UNCH's response to Criterion 6 only describes the erroneous need determination in the 2025 SMFP (which purportedly understates the need driven by UNCH) and describes how an additional PET unit will help UNCH. Its response does not address existing capacity at UNCH or at other providers. UNCH fails to consider and demonstrate the impact of the proposed project on UNC Rex, a controlled entity, under this criterion.

Criterion (9)

- UNCH's response to Criterion 9 is inaccurate and/or not supported by data that correlates with previous patient origin projections in the application. Its patient origin is previously reported in Criterion (3) to show 50% of projected patients originating from outside of HSA IV.

Criterion (13)

- UNCH fails to complete the payor mix table for the PET service for the year prior to application on page 108. Therefore, it is not possible to determine if the service in question has been financially accessible.
- UNCH states that it projects a shift of patients Self-Pay to Medicaid based on Medicaid expansion (referenced on page 110). This cannot be verified because historical payor mix for the service was not provided. (See also comments to Form F.2b assumptions).

Criterion (18a)

- UNC has not documented that it does not have sufficient capacity on its existing equipment; the fact that one was acquired pursuant to Policy AC-3 rather than a need determination does not obviate the fact that the capacity it provides exists to create access

for patients. Failure to adequately address its existing capacity undermines any claim that the additional project will enhance competition.

Durham Diagnostic Imaging
Certificate of Need Application for a fixed PET/CT Unit in HSA IV
Project ID J-12593-25

Durham Diagnostic Imaging ("DDI") is a freestanding imaging center operating under the organizational umbrella of Novant Health. It currently operates a standard array of diagnostic modalities and proposes adding a PET/CT unit. The application lacks logical supporting data to demonstrate the need for a highly specialized diagnostic modality at the proposed location.

DDI's application fails to conform with multiple review criteria, particularly (3) and (5). DDI uses arbitrary methodology and statistics to calculate its proposed utilization while failing to identify any meaningful referral sources for PET services. DDI relies on an affiliation with Samaritan Health Center as a referral source for the project; however, this partnership does not provide the volumes or the revenue to sustain a PET/CT program at the imaging center. Without meaningful or reliable projected volumes, the project will also not be financially feasible.

Criterion (3)

- DDI's application is based on generic projections of need for PET procedures for the service area, without reasonable assumptions as to why patients would be referred to its facility specifically. The application refers to "1,400 referral sources" for its standard array of diagnostic modalities including MRI, CT, ultrasound, x-ray, bone density, R/F, and mammography units (pages 34-35). However, PET is significantly more specialized in nature than its existing modalities and would primarily be needed only for specific subsets of cardiology, oncology, and neurology patients.
- DDI also provides very limited documentation of support for its services. It provides letters from one community health clinic (Samaritan Health Center), 15 primary care/internal medicine physicians, and 4 urologists.
    - Notably, none of the individual physicians state that they personally refer patients for PET scanning procedures.
    - Similarly, Samaritan Health Center offers primary care plus, endocrinology, gastroenterology, nutrition, optometry, orthopedics, and physical therapy. No oncology, cardiology, or neurology services are listed on its website. As such, there is unlikely to be significant physician referrals related to PET services from this group practice. The total volume of all diagnostic imaging procedures (composed of lung cancer screenings, prostate MRI, and breast MRI) DDI provided in 2024 to patients referred by SHC totaled 1,014. The same physician referral and patient base would generate a much smaller percentage of PET/CT referrals than any of these procedures such as x-ray, mammography, ultrasound, bone density, fluoroscopy, CT, all of which can be referred by primary care physicians.

  - Novant Health has a limited number of affiliated providers in the service area. According to the Novant Health website:
    - The nearest oncologists is in the Novant Physician network is 54 miles away in Greensboro – Novant Health Cancer Institute – Greensboro.
    - The nearest cardiology within the Novant Physician network is 54 miles away from Durham in Greensboro – Novant Health Cardiology - Greensboro.
    - The nearest neurologist in the Novant Physician network is 54 miles away in Greensboro – Novant Health Neurology & Sleep – Greensboro.
    - None of these provides indicated they would refer patients to Durham for PET imaging.
  - The identified potential referring providers would not generate the volume DDI needs to meet performance standards for PET/CT.

- DDI's methodology relies on an assumed capture consistent with its projected capacity, with no discussion of why patients would choose DDI over any other provider. This is inconsistent with its projected patient origin and its discussion of need. On page 44, DDI states:

> Health Service Area IV is nationally recognized for offering the highest quality of healthcare services. Patients from across North Carolina routinely travel to Health Service Area IV for the advanced expertise of healthcare providers in this service area. More than 1,400 referring physicians rely on DDI's ability to provide exceptional imaging services in a comfortable environment at a low overall cost to the patient in a culturally competent manner.

  However, these patients are traveling to HSA IV for care at tertiary and quaternary academic medical centers and acute care providers, and not simply to seek out freestanding imaging. Perhaps recognizing that DDI would not serve this identified need, DDI's historical patient origin shows that 93% of its patients originate from HSA IV counties and it projects identical patient origin for the proposed PET/CT. Based on these assumptions, DDI does not anticipate that its patients will be drawn from a statewide catchment area.

- This methodology projects the volume that DDI could accommodate, not the volume of patients who would actually seek out care at this facility. This calculation/projection is not based on projected referrals or any historical utilization of DDI or its Novant affiliates. DDI inaccurately and illogically utilizes Novant Health's existing PET scanners' capacity (exceeding 9,000 procedures annually) to demonstrate reasonability. While capacity can limit volumes (i.e., when units cannot perform more procedures due to time constraints), it does not in and of itself drive demand. Moreover, DDI's assumptions about capacity are unreasonable. It claims that existing providers will not have excess capacity because they will be averaging 2998 scans in DDI's third project year. However, DDI claims that the capacity of its PET scanner will be 4000 procedures. Based on a capacity argument alone, DDI has not demonstrated that there is a need for its project.

- The aggressive and unsupported nature of DDI's projections is demonstrated by comparing the resulting PET utilization to DDI's actual experience in providing MRI services. In 2023, statewide MRI utilization totaled 1,104,821 (SMFP Table 15E-1), of which DDI provided 2330 at the Independence Park location and 3317 across its fixed and mobile service locations. Total state PET utilization was 77,351 (SMFP Table 15F-1 and 15F-2),

or 7% of the MRI volume. DDI . With an Its presumed capture of PET volumes is higher by an order of magnitude. With the same referral network, DDI now projects that it will serve 2875 PET scanners in year 3, in a year that it also projects 3183 MRI scans with the identical patient origin and referral base. It is not credible that this patient population would generate such a high PET volume.

- For the same reasons that its volume projections are unreasonable, DDI's identification of geographic origin of patients to be served is unreasonable. While it points to the statewide utilization of PET equipment in the service area, DDI utilizes the same patient origin for its proposed project as its existing combined modalities in the last full FY (page 47). It provides no analysis of patient origin of its anticipated referring providers for PET or other source of its projected volume.
- To demonstrate a purported need for a freestanding PET provider, DDI presents a general discussion about the rising cost of healthcare in the U.S. (unrelated to the provision of PET/CT). It also cites the CIGNA website, which encourages its members to shop around for services. No relevant data is provided that indicates a specific need in HSA IV for a freestanding provider over a campus-based provider, especially given the current respective utilization of the hospital-based and freestanding imaging providers. (page 59)

Criterion (4)

- DDI fails to sufficiently explain or demonstrate how mobile PET availability is limited, especially given the low volume anticipated from its existing referral network.

Criterion (5)

- DDI provides no start-up or working capital. While DDI is an existing facility, the proposed project represents a new service line that will require additional staffing, recruitment, training, etc. and includes the renovation of 1100sf as well as the addition of a modular building.
- This project is not financially feasible, as its utilization projections are not based on reliable, measurable data or referral sources. The most significant referral source mentioned in the application (Samaritan Health) cares solely for charity care and other financially underserved patients. The other revenue assumptions are not based on known referral sources or volumes.
- Revenues and Net Income **(Forms F.2a and b)**
    - Revenues related to Self-Pay are not included
    - DDI total charity care for the 2nd Interim Full FY (FY26) is projected to be $57,662. DDI total charity care for 3rd Full FY (FY29) is projected to be $419,509, **a 627% increase in three years.** Assumptions state that charity care is based on historical experience; this statement is inaccurate.
    - DDI total Medicaid revenues for the 2nd Interim Full FY (FY26) are projected to be $467,701. DDI total Medicaid revenues for 3rd Full FY (FY29) are projected to be $918,725, **a 96.4% increase in three years** inconsistent with the projected growth in procedures of the same time period**.** This level of growth (which does not begin until FY27) cannot be reasonably attributed to NC Medicaid expansion as

referenced in the assumptions. NC Medicaid expansion would not align with the timing or volume of growth.

Criterion (13) Medically Underserved Population

- DDI projects a dramatic increase in charity care and Medicaid patients at the entire facility compared to its actual historical experience, although the historical payor mix is cited as the basis at page 105.

Payor Source	Entire Facility Percentage of Total Patients Served - FY 2024 page 102	PET Only Percentage of Total Patients Served - FY 2029 page 105	Entire Facility Percentage of Total Patients Served - FY 2029 page 105	Percentage Increase/Decrease 2025-2029
Self-Pay	1.60%	1.60%	1.60%	0.0%
Charity Care	0.27%	1.00%	1.00%	**270.4%**
Medicare	42.92%	42.92%	42.92%	0.0%
Medicaid	2.19%	5.50%	5.50%	**151.1%**
Insurance	48.10%	44.10%	44.10%	**-8.3%**
Workers Compensation	2.62%	2.62%	2.62%	0.0%
TRICARE	0.55%	0.55%	0.55%	0.0%
Other	1.76%	1.76%	1.76%	0.0%
Total	**100.01%**	**100.05%**	**100.05%**	**0.0%**

- DDI estimates charity care for the PET project *"based on its historical experience as well as its arrangements with charitable providers, like Samaritan Health Center (105)."* Even if the PET project operated with a 1% charity payor mix, this would not bring the charity mix for the entire facility to 1%. There is also no support for the assumption that the facility would provide charity care of PET patients at such a higher rate than it does for other services.
- DDI projects an increase in its composition of Medicaid patients with the approval of the PET unit due to the *"economic factors that impact the residents in Health Service Area IV (page 106)."* Given that DDI's projected patient origin for PET is the same as its historical patient origin for FY 2024 – 93% originating from HSA IV counties – this statement is illogical and does not accurately apply to the estimates presented.
- Immediately following these statements, the Applicant claims (page 106):

> DDI has projected increased service to the medically underserved populations in the service area based on the full-time availability of the proposed PET/CT scanner, Novant's Charity Policies, and the increasing number of Medicaid recipients due to Medicaid expansion in North Carolina. Medicaid expansion will cover people ages 19 through 64

  - This statement does not provide support for the magnitude of the shift from Commercial Insurance to Medicaid and Charity Care. If much of this shift was due to Medicaid availability, one would expect to see some of the self-pay percentage shift to Medicaid rather than all from commercial insurance.
  - Novant's Charity Care Policies are presumably the policies in place supporting the current payor mix for DDI.
  - DDI's historical provision of care to underserved populations reflects the Applicant's true level of effort related to financial accessibility. DDI unrealistically inflates its charity care and Medicaid projections to enhance its CON application. The factors listed by the Applicant could not possibly result

in the specific shifts in patient/payor mix for PET and for the overall facility that is projected by DDI.

Criterion (18a)

- DDI repeatedly touts its use of global billing, stating that it means that the patient only receives one bill, rather than one for imaging and one for review of the images by a radiologist. While this is true, it does not mean that the patient is not getting charged for both components. It just means that they receive one combined bill, rather than two.

- DDI claims lower charges but does not state whether this is in relation to hospitals and/or to other imaging centers. It does not quantify this comparison at all in the application.

Raleigh PET, LLC
CON Application for the Development of a Diagnostic Facility with Fixed PET
Project ID J-012598-25

Introduction:

WakeMed (the sole owner) is applying to develop Raleigh PET, LLC ("Raleigh PET"), a diagnostic facility with fixed PET to "replicate" its existing affiliated 210 PET Imaging ("210 PET") in nearby Cary. In many parts of the application, Raleigh PET is characterized as an open-referral freestanding diagnostic center. In other parts, it is characterized to meet the need of WakeMed Raleigh, a tertiary medical center which cannot adequately support its patients without a PET scanner on its campus. The latter characterization is completely speculative; the application includes no data to support this claim.

WakeMed presents unsupported patient origin data and an unsupported utilization methodology. Based on its projections and the historical 210 PET data on which it relies, it is not likely to meet the required performance standards. As a result, it is not financially feasible and cannot be approved.

Criterion (3)

Need for the Project

- WakeMed references being "absent" from the PET providers in HSA IV, particularly as "the only level one trauma center in Wake County." (page 42). This does not demonstrate a need for its project for several reasons:
    - PET scanning is not a service strongly associated with trauma care. It is typically a scheduled outpatient service used to assist in the diagnosis and evaluation of medical conditions including cancer, cardiac, and neurological conditions. WakeMed provides no significant discussion of any volume of trauma patients who require this service.
    - Even if WakeMed needed an in-house PET unit to serve its level one Trauma Center, its application for a diagnostic facility in a separate medical park across the street will not meet this need. Its stated plan to "replicate" the outpatient imaging center it already participates in undermines any claim that this service would support trauma care.
    - Finally, WakeMed is <u>not</u> absent from area PET providers, given its majority ownership in 210 PET. WakeMed wants it both ways. It relies on the experience of 210 PET as the basis for its application while claiming it does not have PET service.

- WakeMed similarly states that "210 PET Imaging temporarily filled a gap for WakeMed, but alone, 210 PET Imaging cannot meet the long-term needs of all WakeMed cancer patients. WakeMed is also the leader in cardiac, vascular, and thoracic care, with stroke

and cardiac intervention teams available 24/7, an Advanced Heart Failure Program, and Accredited Chest Pain and Primary Stroke Centers. PET scanning is one of the few emerging standards of care that WakeMed cannot offer cardiac patients, because it does not have this technology. The development of Raleigh PET will help to alleviate this care deficit." (page 45)

  - WakeMed previously states on page 42 that 210 PET does offer "cardiac, neurology, urology and oncology procedures".
  - The historical utilization presented by WakeMed and the LRA data (publicly reported) indicate that 210 PET was highly underutilized for at least its first four years of operation. This application claims that it is now operating above 80% capacity in FY25 YTD, but its utilization lags well behind other providers in the service area (see pages 42 and 126.). For FY24 (ending just four months ago 9/30/24), 210 PET was operated at 75.5% of capacity. See page 42. This equipment has available capacity to support additional patients.
  - 210 PET is 51% owned by WakeMed. WakeMed does not explain why WakeMed are impeded from accessing PET care. For example, the application does not explain why WakeMed cannot refer its cardiac patients to 210 PET, which offers cardiac PET scanning. PET scanning is typically an outpatient scheduled procedure. This appears to be an issue of its own making.
  - On page 42, the Applicant states "Raleigh PET proposes replicating the 210 PET service program in east Raleigh." If 210 PET does not meet the needs of WakeMed, it is unclear why the new facility will better meet those purported needs.

- On page 44, WakeMed claims that its patients get sent to the back of line and wait longer than other patients for PET but provides no documentation or explanation for this. According to the application, patients may even have a longer wait at 210 PET, of which WakeMed is a co-owner. See the excerpt below. If WakeMed is the 51% owner with controlling interest, it can control the schedule for patients.

> With virtually all PET scanners in HSA IV operating in the 80 percent capacity range, including the one in which WakeMed is a part owner, patients of WakeMed physicians risk placement at the end of the schedule queue for PET scans. Wait time to schedule a PET scan at 210 PET Imaging is currently seven days. Together, the high utilization and wait times mean that WakeMed patients may wait longer for the diagnostic tool most appropriate for their conditions.

- In summary, WakeMed does not demonstrate how any need for patients for PET services cannot be appropriately met with capacity at 210 PET.

Utilization Projections – Assumptions and Methodology (pages 113-128)

The methodology used to project Raleigh PET's future volumes uses a series of arbitrary assumptions compounded on each other throughout the projection steps. It results in volume projections that are not reliable to reasonably demonstrate performance standards or financial feasibility. Examples include:

- Step 4 – (page 117-118) The Applicant estimates the rate of PET scans per 1,000 population for the primary service area. This estimate projects a rate (9.5 per 1,000 population) by multiplying the FY2023 NC average PET use rate (7.41) by 1.33 (a 33% increase) for application to all PSA counties for all years of the projection period. This rate is also inexplicably 48% higher than the HSA IV rate of 6.40 shown on page 44. There is therefore inadequate support for the assumed increase in use rate necessary to support WakeMed's projections.
- Step 6 – (page 120) The Applicant separately determines a new set of use rates per 1,000 population for each service area county that is more conservative.
    - Raleigh PET again arbitrarily assumes that the HSA IV use rate will be 25% higher than the NC FY23 use rate (7.41), and higher still than the current HSA IV use rate of 6.4.
        - There is no basis for the 25% increase from the statewide rate.
        - The statewide rate is already higher than the HSA rate of 6.4.
        - WakeMed ignores the actual county-level PET use rates it identifies on page 44, which vary by county. The use of a consistent 8.93 rate across all counties will overstate demand in certain counties such as Johnston with a 4.66 rate. See page 44.
    - As a result, from FY 2024-FY 2027, WakeMed assumes that the use rate in HSA IV will ramp up from 6.4 (actual) to 8.93 and is then held constant through the first three project years (FY28-30). It is unclear why the use rate would ramp up so dramatically between 2024 and 2026.
- Step 8 – The Applicant determines estimated market share by county for each of the project years by arbitrarily assigning market shares for each PSA county and applying a 60% and 80% ramp up factor for Project Years 1 and 2.
    - There is absolutely no basis for the projected market share. WakeMed has access to 210 PET's historical market share data, as well as its market share data for other services but opted instead to use unsupported percentages. There is also no explanation for the variability in market share projections by county.
    - WakeMed fails to acknowledge the impact the projected market shares for the new PET unit will have on 210 PET, which it controls.
- Step 9 – (page 125) Raleigh PET estimates In-Migration for patients originating outside the PSA.
    - Notably, Raleigh PET relies on 210 PET for the in-migration factor after ignoring 210 PET for its market share projections.
- This project is intended to "replicate" 210 PET and uses many assumptions based on 210 PET internal data. According to the 210 PET data (page 126), it served only 594 PSA patients in FY20 (assumed to be first full FY), and only 1,534 PSA patients in FY 23 (fourth full fiscal year). The starting volumes and ramp up for Raleigh PET are much more aggressive than PET 210's actual performance in its first three project years

Steps 10-12 Relate to the Performance Standards for 210 PET

Step 10 – (page 126) Because WakeMed is the controlling owner of 210 PET, it also necessarily estimates projected 210 PET patients for FY2025 – FY 2030. However, this projections are also flawed.

- Historical (internal) utilization data for 210 PET Imaging is used to calculate a FY20 - FY24 CAGR for each county of patient origin and for the PSA (35.9%).
- 210 PET uses a 7.2% CAGR (based on an arbitrary 20% of 35.9%) to project FY25-FY30 volumes by PSA county and for the total PSA.
- The 8.2% in-migration percentage referenced in Step 9 is applied to calculate in-migration and total patients.
- Step 11 – (page 128) The projected volumes for Raleigh PET and 210 PET are used to determine average scans per unit (2 total units) for the first three project years (FY28-FY30).
- While the combined facilities meet the Year 3 performance standard, it is heavily reliant on the projected volumes of 210 PET scans.
    - 210 PET's CAGR for FY20 - FY24 is artificially high because the volume of scans was so low (626) in FY20, and because the project has been in a ramp-up phase.
- In addition to numerous arbitrary and unsupported assumptions, WakeMed's projections are flawed by the fact that the projections for 210 PET and Raleigh PET are performed independent of the others, disregarding that they will likely be serving, at least in part, the same patient base. WakeMed apparently assumes that Raleigh PET will capture incremental market share while 210 PET is <u>also</u> gaining market share. This reflects "double-dipping" of patient volume and is unsupported and unreasonable.

	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2030
Step 5: Projected PSATotal Utilization	19,658	21,192	22,758	24,352	24,751	25,133	25,524
Step 8: Raleigh PET PSA Utilization					1,178	1,504	2,039
Step 10: 210 PET PSA Utilization	2,026	2,171	2,327	2,494	2,673	2,865	3,071
Total WakeMed Affiliated Utilization	**2,026**	**2,171**	**2,327**	**2,494**	**3,851**	**4,369**	**5,110**
Raleigh PET Market Share	0.0%	0.0%	0.0%	0.0%	4.8%	6.0%	8.0%
210 PET Market Share	10.3%	10.2%	10.2%	10.2%	10.8%	11.4%	12.0%
Total WakeMed Affiliated Market Share	**10.3%**	**10.2%**	**10.2%**	**10.2%**	**15.6%**	**17.4%**	**20.0%**

Source: WakeMed's projection methodology pages 121, 123, 127.

- There is nothing to support that Raleigh PET and 210 PET will collectively capture 20% market share of the PSA by FY 2030. This represents a doubling of the market share for WakeMed's affiliates between FY2027 and FY2030 in a highly competitive service area with other PET scanners operated by nationally renowned academic medical centers. This is unreasonable.

Criterion (5)

- The financial feasibility of the project is questionable due to flaws in the assumptions which would result in overstated utilization projections.
- Assumptions to Form F.2.b (page 132) states that payor mix is based on a blend of Raleigh Oncology and Raleigh Cardiology patients. There is no discussion of these (assumed)

referral sources in the application and no documentation of the payor mixes on which it is based.
    - Assumes oncology and cardiology PET utilization which is not otherwise documented in the application in terms of volume or percentage of volume for either specialty.
- Gross and Net Revenue are based on 210 PET FY24 gross and net revenue per case by payor without any recognition that the mix of PET scan types may be different.
- WakeMed has understated its staffing expense. It only identified PET Technologists and a PET supervisor. There is no information in this application indicating that the PET unit will be anything but a stand-alone operation. There is no identification of any staff to manage scheduling, patient registration, or nursing support.
- Radiopharmaceutical expense is based on 210 PET, though Section C states that 210 PET does not meet the needs of all WakeMed PET patients, particularly cardiovascular patients
    - Expenses related to radiopharmaceuticals would vary based on use by differing types of scans. For example, cardiac PET and PSMA PET radiopharmaceuticals are typically significantly more expensive than other types of scans.

Criterion (6)

- WakeMed repeatedly states that the proposed project will replicate 210 PET, while also claiming that 210 PET is not meeting its needs. As a result, this project represents unnecessary duplication of existing services.
- WakeMed's response to G-2.a related to unnecessary duplication simply points to the need for 2 PET scanners identified by the 2025 SMFP. It provides no reason(s) why its proposed project, located near other existing PET scanners, does not duplicate other units in the HSA. (page 73)

Criterion (18a)

- Competition – The Applicant states that Raleigh PET will represent a new provider of PET and a new competitive option, while simultaneously claiming to replicate its existing 210 PET diagnostic facility in HSA IV. See excerpt from page 100 below. Raleigh PET does not represent a new provider of PET.

> **Response:** Two health systems, Duke Health and UNC Health, own all but one of the PET scanners in HSA IV. WakeMed is a joint venture partner in the only freestanding PET scanner in the HSA, 210 PET Imaging, LLC. Raleigh PET will represent a new provider of this service and a new competitive option for residents of the HSA, and surrounding counties, and the state as well.

Application Page 100

Associated Urologists North Carolina, PA ("AUNC")
Certificate of Need Application for the development of Raleigh PET Imaging, a diagnostic facility with a fixed PET/CT Scanner
Project ID J-012598-25

The application by Associated Urologists of North Carolina ("AUNC") for the acquisition of a fixed PET/CT unit is unclear and internally inconsistent, but generally appears to propose a project for the benefit of AUNC physicians, not for patients needing services in the service area. The utilization projections and financial projections indicate that the proposed PET unit will be utilized almost entirely by AUNC patient referrals and that its project payor mix will not enhance access to any underserved patients and communities. This application fails to meet many review criteria and should not be approved.

Criterion (3)

Though the Applicant addresses the specifications of the proposed PET/CT unit and the space where it will be installed and supported, many details regarding the project's organization as a diagnostic facility are omitted and the project appears to involve renovation of space within the existing AUNC physician practice for an in-house PET unit. However, the application states that this is a new facility without any historical information. There is no discussion of how patients would access the space for the PET/CT unit (to include a check-in, waiting area, etc.) for diagnostic patients who arrive to the AUNC office for scanning at Raleigh PET Imaging. There seems to be no separation, physical or operational, in the operation of the two entities.

- On page 34, AUNC states that the Siemens Biograph mCT-S(64) PET/CT scanner will be located in renovated space "within the existing medical practice of AUNC (page 34)."
    - However, the application lists the name of the proposed facility on Item A-4(a) as "Raleigh PET Imaging" (page 16). The Applicant states/checks that it is developing a new health service facility on page 19.
    - The space which will house Raleigh PET Imaging is currently a CT suite within the AUNC medical office. The applicant does not mention the construction of any separate entrance or any operational changes to the space to create a diagnostic facility operated separately from the AUNC practice office.
    - The does not specifically address what will happen with the CT unit/service but mentions trade-in as a possibility during discussion of the financial projections.
    - The application provides no historical information about volumes or patient origin on any of its other equipment, as required by the application form.
- The Applicant discusses applications of PET diagnostics within the specialties of Oncology, Cardiology, and Neurology. (Pages 43-52). However, only two applications for PET with significant volume in the utilization projections are limited to Urological Oncology: PSMA PET and Renal Specific PET. While AUNC states that it will serve patients referred by neurologists or cardiologists outside the practice, it is not reasonable to expect that a neurology or cardiology patient would elect to go to a urology practice for PET scanning services given the other options available in the service area.

Population to be Served (page 56-57)

- Patient origin methodology and assumptions are entirely omitted in response to Item C-3.a and are not included in Section Q. No discussion of patients already served at the facility is included.

Need (Pages 60-65)

- As almost all projected PET volume will come from AUNC internal referrals, AUNC does not provide any discussion of where they refer their patients now nor any evidence that their patients are unable to receive needed PET scans on a timely basis at existing providers. By redirecting their own referrals to an inhouse PET unit, AUNC will gain a significant new stream of revenue without documenting that the needs of its patients are not met today. That is, the project appears designed to meet AUNC's business goals rather than the needs of patients in the service area.
- AUNC presents the historical utilization of HSA IV fixed PET scanner utilization (by unit and overall) as well as the historical utilization of the total PET scanners in each health services area for FY 2019-FY2023. The CAGR calculations are inaccurately calculated on both tables (page 68).

Utilization Projections - Methodology and Assumptions (pages 66-70, pdf pages 139-154)

AUNC projects 2,123, 2,434, and 2,646 total PET scans in Project Years 1-3 respectively. The projected volumes are based almost entirely on the purported historical referrals of AUNC practitioners for PET scans or other related diagnostics which will be replaced or substituted with PET scanning in the immediate future. 95% of projected volume is estimated to come from AUNC practice physicians. Analysis of the projected volumes and its related methodology and assumptions indicates that it is **primarily the patients of AUNC** providers who will benefit from approval of this project.

- Total PET projections are composed of three components:
    - Projected PMSA PET scans
    - Projected Renal PET scans
    - Projected PET scans referred from outside cardiologists and neurologists
    - Of these, PSMA PET scans appear to be by far the highest percentage.

PSMA PET Scans Assumptions and Methodology (pdf pages 141-143)

Step 1 – AUNC presents a total AUNC physician count of 14 for FY 2024 and projects to have 18 physicians from FY 2025 forward. It is unclear if these additional physicians have been recruited.

Step 2 – Calculate PSMA PET referrals per AUNC physician and in total. This first step assumes that 94.3% PET referrals from AUNC physicians will be referred in-house. This does not sufficiently allow for patient choice or other clinical factors. Essentially all patients are treated as

captive to the practice. Given the available options for patients to seek specialized cancer care in the service area, this is not reasonable.

- AUNC calculates the average PET referrals per AUNC physician in FY 2024 to be 59.1 (828/14). The Applicant also calculates the average referrals for bone scans per physician for FY24 to be 23.1 (324/14 page 141).
    - The volume attributable to PSMA procedures as a percentage of total PET volumes is unreasonable. The Duke Cancer Institute, which hosts a National Cancer Institute-designated comprehensive cancer center and participates in cutting edge research into PSMA and other new PET scanning applications, provides a relevant point of comparison. In FY 2024, DUHS provided 1076 PSMA procedures, which constituted approximately 10% of total PET scanning services, across three PET scanners. AUNC projects that it will provide double that volume at a freestanding urology practice in only a few years.

Renal PET Scans Assumptions and Methodology (pdf pages 143-145)

Step 3 – AUNC intends to begin converting certain Renal MRI/CT referrals to PET scans as of FY 2026 due to the anticipated FDA approval of an associated radiotracer by 3rd Quarter 2025. Step 3 calculates the projected referrals appropriate to PET that will be referred to RPI.

Step 3 uses a similar methodology to Step 2 with several noteworthy differences (See table below):

- AUNC chooses a 25% conversion rate of Renal MRI/CT diagnostics to be performed with PET after FDA approval of the radiotracer. There is no justification for the use of this rate; it is only attributed to the projections from the AUNC physicians. However, the physicians provide no documentation or explanation within the application for this assumption. Since this radiotracer is not yet FDA approved, it is not clear what percentage of MR/CT scans will shift and how quickly that shift will occur.
- While AUNC projects between 772 and 859 Renal PET scan referrals for PYs 1-3, it only projects that RPI will accept 50% of them due to capacity constraints. It does not explain why more than 90% of PSMA PET referrals will be kept in house while 50% of renal scan referrals will be to other providers.

PET Volume Originating Outside of AUNC (pdf page 145)

Step 4 – AUNC provides seven letters of support from physicians who support the project and will refer patients to the proposed PET unit if approved. These letters purport to document a total of 490-510 annual PET referrals from these physicians. These are form letters with physician signatures only, many of which are illegible. Only one letter designates the practice the physician is affiliated with. It is unclear where these physician practice, what their specialties are, and what type of scans would be referred. An average of 70 referrals annual per individual physician in the identified specialties is very high. This volume is also inconsistent with the actual utilization projections, undercutting AUNC's claim that it will provide a new option for an "open-referral" diagnostic facility (see page 97). As shown in the table below, outside PET referrals are projected to compose only 5.77% of PET scans performed in year one of operation and decrease as a

percentage of the total each year from that point on. See the table below. Use of the corrected/modified projections above would result in even smaller percentages.

	FY2027	FY2028	FY2029
Outside Referrals	123	123	123
Total Projected PET Volume	2,123	2,433	2,645
% of Outside Referrals	5.79%	5.06%	4.65%

See application Section Q assumptions pages 1 - 6.

AUNC's financial projections confirm that little if any PET volume will be provided for outside referrals. Almost all radiotracer expense is attributed to PSMA scans or Renal Scans, which confirms that outside scans for other specialties are limited. As shown below, only 0.29% of expenses for radiotracers are associated with some type of scan other than PSMA and Renal scans in Year 3. This also confirms that in addition to accepting limited patients outside of AUNC, there are few if any scans for cancer types other than prostate and renal. This highly limited use does not meet the needs of the broader HSA for PET capacity.

PSMA / Renal Radiotracer	$	12,413,508
Non-PSMA/Renal Radiotracer	$	35,530
Total Expense for Radiotracers	$	12,449,038
% non-PSMA/Renal		0.29%
Source: Form F.3b and assumptions.		

Criterion (5)

- No financing costs are listed on Form F.1.a (pdf page 154) even though the entire project, including start up and initial operating costs, is financed.
- No financials included for the Applicants to demonstrate that they can realistically undertake the debt (as the entire project will be financed).

Form F.2b (Income Statement) pdf pages 157-163
Charges and Reimbursement

- Payor Mix - 65% of gross patient services revenue comes from commercially insured patients.
  - Given that 95% or more of the projected scans are PSMA PET or Renal PET, a higher patient population composed of primarily 65+ would be expected. However, Medicare revenues account for only 29% of gross revenue. This composition is contradictory to the patient demographic for PET described by the Applicant in Sections A and C.
  - Medicaid is projected to be just 2.1%, which is minimal and undermines the claims regarding accessibility described in Sections A and C of the application.

Operational Expenses

- A significant expense item ($230,000 in year 1) is listed for "Facility Assessment." The assumptions state that "it will be charged to Raleigh PET Imaging to assure the expenses

incurred by the property owners are covered after the payment rent" without any additional explanation. It is not clear what possible expenses would be incurred by the property owners that are not included in the lease rate. Utilities are separately budgeted. Moreover, the property owner is Associated Urologists of NC Properties I, LLC, the second Applicant for this project. See pages 19 and 110. The facility assessment accordingly appears to be additional fees paid directly to one of the co-applicants.

Staffing and Related Expenses

- AUNC only includes 2 nuclear medicine technologists and 2 medical assistants in its projections of FTEs. It is not clear how the staff will provide all other aspects of the care process from scheduling, reception, to billing will be handled. There is no indication that these services are included in the "management services" line item. Moreover, these staff positions are clearly not included in the list of services to be provided by Solaris on page 24. Only higher-level management/administrative functions are listed – not direct staffing of a local office.
    - It is unclear who will employ staff needed to complete the full process of an RPI PET patient from scheduling, to entering the facility and registering, to billing.

Criterion (6)

Page 101 – AUNC makes the following two statements:

> *"Raleigh PET Imaging will focus on outpatient PET imaging, catering to individuals referred by independent physicians and those seeking alternatives to hospital-based care."*
>
> *"Existing hospital-based PET facilities primarily serve patients within their own healthcare systems, including inpatients and emergency cases, those referred by affiliated physicians, as well as patients with in-network specific hospital insurance plans. Raleigh PET Imaging will serve all physicians and patients including those outside these networks, reducing strain on hospital facilities while ensuring that all segments of the population have access to PET imaging services."*

It claims to "cater" to individuals referred by independent physicians and serve all physicians and patients; however, it projects only 5% or less of its PET procedures in the first three years will originate from provider referrals outside of AUNC. Moreover, providers such as Duke University Health System routinely accept referrals from unaffiliated providers. AUNC does not document any barriers to access for existing patients.

AUNC represents a direct duplication of PET services provided by existing HSA IV providers and is clear that most, if not all, of its volume will be achieved through the redirection of AUNC PET referrals from other PET providers to its own practice.

Criterion (7)

As noted under Criterion (5), AUNC only proposes 2 nuclear medicine technologists and 2 medical assistants in its projections of FTEs. It is not clear how the staff that will provide the ancillary aspects of the project - from scheduling, reception, to billing - will be handled. There is no indication that these services are included in the "management services" line item. Moreover, these staff positions are clearly not included in the list of services to be provided by Solaris on page 24.

- The employer of these staff positions is unclear/unidentified.

Criterion (13)

- Payor mix shows no enhanced access to financially underserved patients and communities and far more limited access to PET for these patients than the current providers of PET in HSA IV.
- RPI projects approximately 5% of its patients will be charity care/reduced cost, but its projected payor mix for Self-pay, Medicaid, and Other patients totals less than five percent of its projected payor mix.