

March 31, 2025

Ms. Micheala Mitchell, Chief
Ms. Tanya Saporito, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation

Via electronic mail to: Tanya.saporito@dhhs.nc.gov and DHSR.CON.Comments@dhhs.nc.gov

Re: Comments by Raleigh PET, LLC on Competing Certificate of Need Applications for Two New Fixed PET Scanners in HSA IV, 2025 SMFP

<u>Project ID</u>	<u>Applicant(s)</u>
J-012593-25	Novant Health, Inc.; Novant Health-Norfolk, LLC; Durham Diagnostic Imaging (“DDI”)
J-012595-25	University of North Carolina Hospitals at Chapel Hill (“UNCCH”)
J-012598-25	Associated Urologists of North Carolina, PA; Associated Urologists NC Properties I, LLC (“AUNC”)
J-012602-25	WR Imaging, LLC; Wake Radiology Diagnostic Imaging, Inc. (“WR Imaging”)
J-012607-25	Duke University Health System, Inc. (“Duke Cary”)
J-012610-25	Duke University Health System, Inc. (“DUHS”)
J-012611-25	Raleigh PET, LLC (“Raleigh PET”)

Dear Ms. Mitchell and Ms. Saporito:

On behalf of Raleigh PET, LLC (Project ID J-012611-25), we appreciate the opportunity to comment on the certificate of need applications filed in the March 1, 2025 review cycle for two new fixed Positron Emission Tomography (“PET”) scanners in Health Service Area IV in response to the need determination in Chapter 15 of the 2025 SMFP. These comments focus on we identified as the most critical issues in this review.

We believe that the applications submitted confirm and support the proposal from **Raleigh PET, LLC as the best to address the identified need.**

Each of the seven applications in this review offers a unique approach to fulfilling the identified need. We understand that the Certificate of Need (“CON”) award for the proposed PET scanners must be based upon finding conformity with the statutory review criteria in G.S. 131E-183. We also understand that the Agency has discretion in choice of comparative factors when all applicants conform to the statutory review criteria. In attachments to this letter, we provide comments specific to each application in the context of the statutory review criteria. There are conformity issues with six of the applications, ranging from insufficient filing fees (DUHS) to unreasonable population use rates (DDI) to failure to justify the non-competitive nature of the proposed project (UNCCH and WR Imaging).

Knowing that the Agency has discretion regarding measures used to compare competing applications, we ask that the Agency consider exceptional circumstances regarding PET equipment in HSA IV.

Geographic Access to PET Services is Important

Relative to the major health center counties in HSA IV, **Wake County is significantly underserved** by PET scanners. Other counties have at least four times' greater access.

County	PET Scanners	2025 Population	Population/Scanner
Durham	4	344,479	86,120
Wake	3	1,238,170	412,723
Orange	2	153,098	76,549

Source: PET scanners Table 15F, 2025 SMFP, population, NCOSBM

Clearly, Wake County is the best location for the next PET scanner. The **Raleigh PET**, WR Imaging, and Duke Cary applications meet this test.

Within Wake County, access to PET technology is uneven. The map provided in Attachment G demonstrates that all existing PET scanners are concentrated in the western part of the county, which is also close to PET scanners in Durham and Orange Counties. Eastern Wake County is the best location for the next fixed PET scanner. **Raleigh PET** and WR Imaging meet this test.

Financial Access is Critical to Removing Barriers to Care

PET scanners that organize as freestanding providers are more financially accessible for patients and can generally offer care at lower cost than PET scanners that are hospital-based (HOPD). Only three applicants in Wake County propose freestanding PET scanners: **Raleigh PET**, WR Imaging and AUNC. Given that payers are increasingly incentivizing patients to utilize non-hospital settings for their care, and that health care providers are moving more services to value-based settings, it makes sense to give favorable consideration to proposals involving non-HOPD reimbursement.

Medicaid and Charity patients pay nothing or receive discounts for health services. People who have commercial coverage or Medicare outpatient coverage face deductible and copayment challenges. Patients have fewer bills and fewer copayments when they get PET scans from providers who send only one bill that includes both physician and technical fees, otherwise known as Global billing. Three Wake County applicants propose Global billing: **Raleigh PET**, WR Imaging and AUNC.

Coordination Of Care Increases Quality, Reduces Errors, and Encourages Patients to Follow Through with Treatment

PET scans are standard diagnostic elements for detecting and managing care plans for people who have cancer, cardiovascular conditions or diseases, and nervous system issues or diseases. These care plans involve specialized services and people who have these diseases more than PET scans to complete their care. The next fixed scanner should be located where patients can obtain other services associated with their care.

Because even two new fixed PET scanners in Wake County will not reduce the access disparity, the next PET scanner should be located close to where patients receive other related specialized services and where results can be easily incorporated in and easily accessed by patients and providers in electronic medical record systems. Among the applicants proposing new services in Wake County, the **Raleigh PET** and WR Imaging proposals meet this test. Today, the Duke Cary campus has limited specialties, and therefore does not meet the test.

WakeMed Raleigh is the only tertiary care hospital in Wake County and in HSA IV that does not have a PET scanner associated with its main campus. **Raleigh PET** would satisfy this requirement.

The primary beneficiary of PET scans is still cancer patients. WakeMed Raleigh is the only hospital cancer center in Wake County and HSA IV without a wholly owned PET scanner. **Raleigh PET** would satisfy this requirement.

Competition Challenges All Providers to Respond to Customer Needs

With two exceptions, every applicant already has a PET scanner or proposes locating a new fixed scanner in another county. Only two applicants are new providers in Wake County, **Raleigh PET** and AUNC. Comparing the number of scanners owned by system favors **Raleigh PET** and AUNC.

Impossible to Compare Costs and Charges in This Review

Each applicant proposes a different mix of scan types and/or billing approaches and billing rates differ with the type of scan, regardless of how it bills. Therefore, direct comparisons of costs and charges are not possible.

Isotope/Pharmacy Costs Vary by Type of Scan

Global charges and costs include physician costs, freestanding and HOPD billing do not. Moreover, the WR Imaging application has a very low formula for calculating professional fees. In this case, the professionals earn both the professional fee and the net revenue because the Applicant is an LLC in which the professionals have an interest.

Comparing costs would require adjusting for professional fees and pharmacy isotopes and applications do not contain enough standardized information to make the comparison.

Summary

We realize that the Agency will prepare its own comparative analysis. For summary purposes, we organized our observations in the form of a comparative matrix, which is included in Attachment H. Attachments A through F provide comments on conformity of other applications to relevant statutory criteria. Attachment G provides a map showing the locations of all existing and proposed PET scanners in HSA IV. We note that one application, DUHS (J-012610-25), failed to pay a sufficient filing fee to cover the true capital cost of the project. That application proposes to convert a capital investment, the cost of which received an Exemption from CON under N.C.G.S. §131E-179 -- for "research only"; the application proposes a nominal cost to convert it to clinical service and the applicant paid an application fee sufficient to cover only the nominal cost.

Thank you for your careful consideration of these comments. Please do not hesitate to contact me should you have any questions or require additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Rick Shrum", with a long horizontal flourish extending to the right.

Rick Shrum
Vice President & Chief Strategy Officer
WakeMed Health and Hospitals / Raleigh PET, LLC

cc: Robbie Roberts, Director, Market Planning

Attachments

ATTACHMENTS

Competitive Review of J-012593-25, Novant Health, Inc.; Novant Health-Norfolk, LLC;
Durham Diagnostic Imaging.....A

Competitive Review of J-012595-25, University of North Carolina Hospitals at Chapel HillB

Competitive Review of J-012598-25, Associated Urologists of North Carolina, PA;
Associated Urologists NC Properties I, LLCC

Competitive Review of J-012602-25, WR Imaging, LLC; Wake Radiology Diagnostic Imaging, Inc..... D

Competitive Review of J-012607-25, Duke University Health System, Inc. (Duke Cary) E

Competitive Review of J-012610-25, Duke University Health System, Inc. F

Map of Existing and Proposed PET Scanners Relative to HSA IV Residents..... G

Comparative Matrix H

ATTACHMENT A

Competitive Review of J-012593-25: Novant Health, Inc.; Novant Health-Norfolk, LLC; & Durham Diagnostic Imaging

Overview

Three applicants, Novant Health, Inc., Novant Health-Norfolk, LLC, and Durham Diagnostic Imaging, LLC, (“DDI” or “Applicant”) propose to locate a new freestanding Siemens Trinion Fixed PET/CT scanner in a mobile unit that will be parked adjacent to an existing freestanding Durham Diagnostic Imaging location in north Durham County. The applicant is proposing a global bill.

The DDI application should be found non-conforming to statutory Criteria 1, 3, 4, 6, 7, 8, 12, and 18a for the following reasons.

Criterion 1

The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, ambulatory surgery operating rooms, or home health offices that may be approved.

The need in the 2025 SMFP is for a new fixed PET scanner. The vendor quote in Exhibit F.1 clearly identifies the proposed purchase as a mobile PET scanner with trailer. This project is not responsive to the need determination. Therefore, the DDI application does not conform with Review Criterion 1.

Criterion 3

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

DDI fails to project a need for PET scans by the population that it proposes to serve. DDI’s need methodology in Section Q describes historic growth in PET scanner volume in HSA IV and statewide for the period 2020-2023, citing CAGRs of 19.9 percent and 15.2 percent, respectively. DDI describes the merits of projecting PET volumes using both CAGRs, as well as applying one-half the statewide CAGR ($15.2\% * 0.5 = 7.6\%$). Missing from its methodology was discussion of historic county-specific use rates within HSA IV. As a service area with a wide variation of urban and non-urban counties, PET use rates may vary significantly based on a number of factors, including population, incidence of diseases and conditions that contribute to PET utilization, and proximity to existing PET resources. PET utilization in Warren County, a rural county located on the eastern edge of HSA IV, is likely to be very different than that of Durham County, which has 3 existing PET scanners and is located near the center of the service area. DDI does not offer any discussion to address these disparities, and assumes that projected growth in PET utilization will be uniform throughout the HSA.

Ultimately, DDI opted to estimate its Project Year 1 PET volume based on one-half of its purported equipment capacity of 4,000 procedures, justifying this volume on the supposition that “DDI...has access to market and service expertise that was used in the development of the

estimated number of procedures for a new PET program (Section Q, page 3), citing parent company Novant Health's approved PET scanners in Mecklenburg, Forsyth and New Hanover Counties. No mathematical calculation was provided to support this claim, nor was any historical experience offered to show that DDI's project could be considered reasonable.

PET volumes for Project Years 2 and 3 were derived by multiplying the previous year's projection by HSA IV CAGR of 19.9 percent, not the statewide CAGR of 15.2 percent or one-half rate of 7.6 percent. DDI's conformity with the PET Performance Standard found in 10A NCAC 14C .3703(5) is dependent on applying the high historic CAGR percentage.

DDI's conformity with 10A NCAC 14C .3703(5) is completely dependent on its ability to perform 2,000 PET procedures in Project Year 1. This utilization is provided without any justification, as well as the assumption that PET utilization in HSA IV will continue to grow at 19.9 percent per year through Project Year 3. Therefore, DDI's projections are not reasonable.

DDI's assumptions regarding projected patient origin for PET in Question C.3 is based on patient origin for imaging modalities at its existing facility. DDI provides no evidence that approval of a fourth PET scanner in Durham County would enhance competition in HSA IV.

PET is still a specialty service, unlike MRI or x-ray, which the applicant used to generate its patient origin. PET use rates calculated from information DDI presented in its application are not reasonable. The applicant proposes that more than half of its PET scans (55.4 percent) will be provided to Durham County residents (page 47).

All forecasts in the methodology in Section Q are based on procedures completed at PET scanners located in HSA IV. No forecasts are based on the population to be served.

The critical flaw occurs on page 51, where the application has forecast future PET scans performed in scanners located in HSA IV on the basis of historical scans provided by HSA IV PET scanners. It fails to address the origin of patients associated with those scans. This leads to a fatal error in the patient origin projections. A review of patient origin for the existing nine (9) scanners shows the historical use rates for HSA IV were generated by people from counties across the state and out of state.

Throughout, the application provides many generalized statistics, but the statistics do not tie back to quantitative need described in the patient origin.

Furthermore, the application revenue and expense are associated with an entire diagnostic center. The application contains no methodology for forecasting use of other modalities at the diagnostic center. This is important because the revenue and expenses presented in Forms F.2b and F.3b depend on efficiencies associated with performance of those modalities.

Criterion 4

Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

In Section E, DDI states that a mobile scanner is not an effective alternative. Yet, it proposes to develop a mobile PET scanner. Exhibit F.1 provides an equipment quote for a Siemens Biograph Trinion EP PET scanner, as well as a quote from AMST a Kentucky Trailer company for a “New build Siemens Trinion PETCT Mobile Unit [emphasis added] (Exhibits, page 117). Given that the new scanner appears to be located outside the existing building envelope, it is not clear whether DDI is proposing a fixed or mobile PET scanner.

Criterion 6

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

On page 89, the application indicates that global billing is unique to DDI’s proposal. It ignores the global billing program at 210 PET Imaging, Inc., an existing provider located in HSA IV.

Approval of the DDI proposal would add a fourth PET scanner in Durham County. DDI provided no evidence that its project will not be duplicative of existing PET providers.

Criterion 7

The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

On page 86, the applicant indicates that it intends to bill globally. This means that the physician fee is included in the bill. However, the application provides no information in Section H or I to demonstrate who will provide the physician services. Cardiac PET requires the presence of a cardiologist. No cardiologists are mentioned in the application.

Radiologist costs are not tied to volume of services. See Section Q assumptions for Form F.3 (pages 5, (Exhibits, page 171). The application does not describe how these are calculated.

Criterion 8

The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

Isotopes with short half-lives are essential components of PET scans. The application contains no information in sections C, H, or I regarding who DDI would contract with for the source of isotopes for the proposed scanner, nor did it provide correspondence from an existing local provider of radioisotopes expressing willingness to work with DDI should its application be approved.

The application provides no mention of physicist resources for calibration. The PET Equipment quote is based on a mobile unit, see Exhibit F.1.

The equipment quote from AMST a Kentucky Trailer Company contained in Exhibit F.1 (page 119) is addressed to Medquest Associates, Inc, not the applicants. The DDI application does not explain the relationship of Medquest to any of the applicants.

Criterion 12

Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

Section K provides no information to indicate that power at the site is adequate to support the proposed PET scanner. It does not describe how power will be provided to the site – see page 100.

Floor plans provided in Exhibit K.2 (page 220) show DDI’s proposed PET scanner will be located in a mobile trailer outside the DDI facility. Patients must go outside to access the PET scanner. DDI did not describe how non-ambulatory patients will access the scanner.

Criterion 18a

The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.

Although DDI would be a new provider of PET services in Health Service Area IV, the DDI application provided scant evidence that its project would enhance competition for PET services within HSA IV. DDI proposes what would be the fourth PET scanner in Durham County and only add to the maldistribution of scanners in the western portion of the service area.

ATTACHMENT B

Competitive Review of J-012595-25: University of North Carolina Hospitals at Chapel Hill

Overview

University of North Carolina Hospitals at Chapel Hill (“UNCCH” or “Applicant”) proposes to add one Siemens Biograph Vision X PET scanner in the basement of its Cancer Center, adjacent to an existing PET scanner at UNC Medical Center in Chapel Hill, for a total of 3 scanners at project completion. The project will be organized as a hospital-based scanner.

The UNCCH project should be found non-conforming to Criteria 3, 5, 8, 9, and 18a, based on the following discussion.

Criterion 3

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

The UNCCH application does not demonstrate the need that 53 percent of its proposed patients have for the services proposed. There is a mismatch between the project and the identified need.

The project proposes to increase the number of patients served by the applicant from 4,120 in 2023 to 5,890 in 2029, an increase of 1,770 patients. However, only 48.6 percent of patients served will originate from HSA IV (pages 49 and 51). This actually represents a reduction in the percentage of patients served from HSA IV. Application page 50 indicates that 50 percent of UNCCH’s PET patients in 2024 were from HSA IV.

In response to Policy GEN-5, pages 35 and 36, the UNCCH notes that transportation access to existing facilities and affordability of care are two major barriers to services for residents of Orange and Wake Counties, the two counties the applicant identifies as the central sources of its projected PET patient origin (page 51).

On page 55, UNCCH clearly notes its intent that fully one-half of proposed patients will originate from outside HSA IV. Yet on pages 56 and 57, the application notes the growing needs of residents of HSA IV. The application does not propose to serve all HSA IV counties. As shown on page 51, **the Applicant only identifies six of the 11 HSA IV counties in its proposed PET patient origin**. The Analyst is left to assume that patients from the remaining five counties – Franklin, Granville, Person, Vance and Warren – are grouped into the “Other” category. Without that breakout, there is no way to determine if or how many patients UNCCH intends to serve from those counties.

UNCCH also notes that much of its identified need is research-based, which indicates that the project could qualify for an exemption from review per N.C.G.S. §131E-179.

Criterion 5

Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs, as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

The applicant proposes a PET scanner that will bill hospital outpatient department (HOPD) technical fees. However, professional fees are not included in the proformas. The application mentions the importance of ACO arrangements for third party payors and the related need for providers to offer value-based payments. Form F.3 assumptions indicate that UNCCH will continue to bill academic medical center charges inflated 3 percent annually (page 140). The assumptions provide no change in contractual adjustments to account for value-based payments. As such, it is impossible to evaluate the long-term viability of the project.

Criterion 8

The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

The application mentions that UNCCH has a rubidium generator to make the cardiac radioisotopes. It does not explain the source of other isotopes, nor does the application provide correspondence from a local provider of radioisotopes.

Criterion 9

An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

In Section G, the applicant makes a blanket statement that only 2.7 percent of patients served will be from outside HSA IV and contiguous health service areas. However, the application provides no supporting documentation. On page 51, the projected patient origin table projects that 35.6 percent of PET patients will originate from unspecified "Other" counties and out of state. The application does not document the "special needs and circumstances that warrant services to these individuals." It simply increases the number of patients in each county at 0.9 percent annually.

Criterion 18a

The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.

UNCCH proposes services by an existing provider at an existing location on the western edge of Health Service Area IV. The application is not clear how the proposed project will enhance competition – on page 55, UNCCH suggests that the proposed service area is statewide. However, in Section C.4, the application suggests that the service area is HSA IV. With this uncertainty, it is difficult to evaluate the true meaning of competition and how UNCCH will have a favorable impact upon cost effectiveness, quality and access to PET services. If approved, UNCCH will have 3 fixed PET scanners, adding to the disproportionate number of scanners located in western HSA IV.

ATTACHMENT C

Competitive Review of J-012598-25: Raleigh PET Imaging

Overview

Associated Urologists of North Carolina, P.A. and Associated Urologists of NC Properties I, LLC, d/b/a Raleigh PET Imaging (referred to collectively in these comments as “AUNC”), proposes to acquire a PET/CT scanner and locate it in renovated space at AUNC’s Raleigh office on Ed Drive in Raleigh near UNC Rex Hospital. AUNC is managed by Solaris Health.

The applicants appear to be proposing to replace an existing CT scanner with a PET scanner, but this is not explicitly stated in either the Project Description in Section A.5 or in Section C.1. On Page 37, AUNC provides a photograph of an “Existing CT Scanner Room” and states that the quoted price for its proposed PET equipment “may decrease if AUNC trades-in the existing Siemens CT scanner or upgrades the existing Siemens CT scanner with the required PET scanner components.” This single reference was the only discussion to existing CT equipment.

The AUNC application is nonconforming with Review Criteria 1, 3, 3a, 4, 5, 8 and 18a. Please see the discussion below.

Criterion 3

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

The AUNC application does not adequately identify the population to be served. On Page 57, the application provides projected patient origin, but there were no assumptions provided to corroborate the proportions from each service area county.

Despite AUNC’s intent to provide diagnostic PET services, there was no discussion regarding coordination of care for cancer, cardiovascular, renal, or neurological patients who might utilize the proposed PET scanner. For example, AUNC did not describe how cancer patients who utilize its PET scanner would also receive medical and/or surgical oncology services.

AUNC’s projected utilization is skewed heavily toward PSMA (prostate) and renal cancer patients – less than 5 percent of cases will be non-prostate/renal cancer, cardiac, orthopaedic, or neurological patients. The focus on prostate/renal cancer patients does not appear to improve access for patients with other forms of cancer.

The AUNC projection methodology contains several mathematical errors and inconsistencies.

- On Page 64, the table “Fixed PET Scans Performed in HSA IV, FY2019-2023”, AUNC incorrectly calculates the utilization compound annual growth rate (CAGR) as 10.7 percent – the actual CAGR is 13.5 percent. This error is repeated in Section Q on Page 2.

This error is significant because this CAGR is used in the Need Methodology to calculate projected PET referrals per physician.

- On Page 64, the table titled “Fixed PET Scans Performed in North Carolina, FY2019-2023” provides the incorrect CAGRs for all HSAs and North Carolina average.
- AUNC’s projections are almost completely dependent on its own physicians’ projected referrals to PET scanners. There are no virtually no referrals slated to come from sources outside AUNC.

On Page 63, AUNC states “[t]he need for PET imaging increases with a person’s age” and cites Wake County historic life expectancies obtained from the State Center for Health Statistics by gender, race and 65+ age group for the time periods 1990-1992 and 2019-2021. It is not clear from this data how this life expectancy data corroborates this statement. AUNC provides no statistics for PET utilization by age group. Life expectancy is affected by many factors, including social determinants of health, nutrition, access to health care, etc. AUNC notes that life expectancy of African Americans over 75 declined from 1990-1992 to 2018-2020 but does not explain how its acquisition of a PET scanner would mitigate this. On Page 64, the AUNC application states “[t]his increase in life expectancy increase the chance of health conditions requiring cancer diagnosis”, without supporting documentation.

Criterion 3a

In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

As discussed in the “Overview” section above, the AUNC application appears to involve replacement of an existing CT scanner with a PET scanner; however, no details are provided regarding historic utilization of the existing CT scanner, or how its volume will be replaced if the PET scanner is approved.

Does AUNC have a second CT scanner at its Raleigh location, or will patients be referred to other providers? Although PET equipment can be used to perform CT scans, no “CT only” utilization was provided in the need methodology in Section Q or in the Pro Formas.

For these reasons, the AUNC application does not conform with Review Criterion 3a.

Criterion 4

Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

In Section E, AUNC listed two alternatives: develop a PET scanner at its Raleigh location, or at its location in Cary. The Raleigh alternative was selected, primarily because the project can be operationalized sooner and at lower cost. AUNC cites traffic issues at the Cary location as being potential barriers to access. Missing from the discussion in Section E was the status quo alternative; specifically, how patients are disadvantaged by the lack of a PET scanner at AUNC, and how working with existing providers of PET services in HSA IV is not a viable option. AUNC does not describe its current patient wait times for PET scans, or how continued referrals to existing providers is not an option for future consideration.

The AUNC application does not conform with Review Criterion 4.

Criterion 6

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

Approval of AUNC's proposal would add another PET scanner near UNC Rex Hospital in west Raleigh. Although AUNC would be a new competitor in HSA IV, it would do little to improve access for PET services in Wake County. The AUNC PET scanner would be the third unit of PET equipment located within 1 mile of UNC Rex; such a concentration of equipment is duplicative.

Criterion 7

The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

On page 86, the applicant indicates that it intends to bill globally. This means that the physician fee is included in the bill. However, the application provides no information in Section H or I to demonstrate who will provide the physician services. Cardiac PET requires the presence of a cardiologist. No cardiologists are mentioned in the application.

Criterion 8

The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

Radioisotopes with short half-lives are essential components of PET scans. Aside from a footnote to Form F.3b that does not identify a specific vendor, the AUNC application contains no information regarding the source of isotopes for the proposed scanner. There was no correspondence included from a prospective radioisotope vendor stating their willingness to work with AUNC should their project be developed. Likewise, there was no correspondence from ProScan Imaging, the radiology company identified in the application, of their willingness to contract with AUNC.

Criterion 18a

The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.

Although AUNC would be a new provider for PET services in Health Service Area IV, there is little evidence provided in the application suggesting that competition would be enhanced, or that the project would have a favorable impact on quality and access. The proposed site is less than 1 mile from UNC Rex Hospital, which has 2 PET scanners. Although AUNC proposes to serve Medicaid and Self-Pay patients, it will be located in an area that is far removed from localized populations of underserved residents. It is not clear in the application if the proposed location is accessible by public transportation.

ATTACHMENT D

Competitive Review of J-012602-25: WR Imaging, LLC and Wake Radiology Diagnostic Imaging, Inc.

Overview

WR Imaging, LLC and Wake Radiology Diagnostic Imaging, Inc. (“WR Imaging” or “Applicant”) proposes to replace an approved, non-operational PET scanner, whose CON was approved in 2019 as a hospital-based scanner (Project ID #J-011659-19), then approved for relocation to a freestanding site on the UNC Rex Hospital campus (Project ID #J-012402-23). This equipment is not yet operational. The applicants are proposing to **return the 2023 CON if they receive approval for this proposal** to locate a new Siemens Biograph Vision 450 PET/ CT scanner in an existing office building Wake Radiology UNC Rex Healthcare diagnostic imaging center in Garner at 300 Health Park Drive, near the intersection of U.S. Highway 70 and Interstate 40. The applicants imply that returning the 2023 CON would allow them to retain the 2019 CON for a hospital-based scanner.

Wake Radiology physicians and UNC Health Rex own WR Imaging, LLC.

This project should be found non-conforming to Review Criteria 1, 3, 6, and 18a for the following reasons.

Criterion 1

The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, ambulatory surgery operating rooms, or home health offices that may be approved.

The WR Imaging project is not consistent with the need determination in the 2025 SMFP. The application provides no evidence that the Agency has approved material compliance that would be required for the proposed swap to reactivate the 2019 CON. The WR Imaging application does not provide evidence that the original 2019 CON meets the conditions of N.C.G.S. §131-189(e), which states:

Notwithstanding subsections (a), (b), or (c) of this section, a certificate of need issued by the Department for the construction of a health service facility prior to October 1, 2021, expires if the holder of the certificate of need fails to execute or commit to a contract for design services for the project authorized by the certificate of need within the following time frames:

- (1) For a project that costs over fifty million dollars (\$50,000,000), the holder of the certificate of need shall execute or commit to a contract for design services for the project authorized by the certificate of need by October 1, 2025.*
- (2) For a project that costs fifty million dollars (\$50,000,000) or less, the holder of the certificate of need shall execute or commit to a contract for design services for the project authorized by the certificate of need by October 1, 2023. [emphasis added]*

Criterion 3

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

This project would reduce the number of freestanding PET scanners in HSA IV, because it would revert an approved freestanding to a hospital-based PET scanner. That part of the proposal will increase the customer cost of PET services in Wake County and HSA IV.

WR Imaging asserts that under this proposal, UNC Health Rex would retain and operate two hospital-based PET scanners on its Raleigh main campus, both of which are expected to sustain high utilization. Simultaneously, the Wake Radiology UNC Rex Healthcare-Garner facility would provide a long-awaited freestanding *diagnostic center, enhancing service availability for patients in Wake County and surrounding communities*" (page 36).

Notably, per WR Imaging's own assertion, Wake County would not be lacking access to a freestanding diagnostic center with PET scanning services had it developed its own project in a timely manner. At best, there has been a two-year delay in development of its approved project from 2023 which was originally approved in 2019. This calls into question WR Imaging's credibility for completing the proposed project.

The methodology in Section Q addresses need for a PET scanner in HSA IV counties. History of the Wake Radiology UNC Rex Healthcare-Garner site identifies service to residents of only two HSA IV counties: Wake and Johnston (page 38). The WR Imaging application stresses need to serve eastern parts of the HSA, but proposes relatively little service to residents of Johnston County, which has no PET scanner. Based on information provided in Section C.3b and Section Q of the WR Imaging application:

$$(415 \text{ PET scans (Johnston County-Year 3)} / 283,825 \text{ total population (Johnston County-Year 3)}) * 1,000 = \underline{1.46 \text{ scans per } 1,000}$$

WR Imaging proposes an identical level of service to Wake County residents, as demonstrated below:

$$(1,949 \text{ PET scans (Wake County-Year 3)} / 1,334,164 \text{ total population (Wake County-Year 3)}) * 1,000 = \underline{1.46 \text{ scans per } 1,000}$$

The WR Imaging application does not explain what the applicant will do to alter the use pattern of Wake Radiology UNC Rex Healthcare-Garner to serve the other HSA IV counties. Rather, patient origin appears to be configured to maximize the application's position in a comparative analysis.

With regard to payer mix of Medicaid patients, the application conjectures that Wake Radiology UNC Rex Healthcare-Garner will be a destination for Medicaid patients who are enrolled in managed care plans. It does not explain why Medicaid patients would bypass other options to seek out PET services when they do not do the same for other Wake Radiology services.

Criterion 3a

In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

On page 73, the WR Imaging application notes that Review Criterion 3a is not applicable. However, the application proposes to remove a freestanding PET scanner from UNC Rex Hospital but does not address this criterion in the application.

Criterion 4

Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

On page, 34, WR Imaging discusses the alternative of keeping the approved fixed freestanding at UNC Rex Hospital, but fails to explain on page 78 in its discussion of maintain status quo why this doing so would not be the least costly or more effective alternative.

Criterion 5

Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs, as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

Charges are based on Wake Radiology's history of PET charges in Wake County. The WR Imaging application does not indicate any adjustments for costs associated with newer radioisotopes. WR Imaging notes on page 132 that its most recent history is for the year 2020. Pharmacy charges described on page 133 reflect only the FDG isotope.

PET staffing in Form H includes only 1.0 FTE PET Technologist in Project Year1. There is no time allocated to time off coverage.

Criterion 6

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

WR Imaging has demonstrated by its history and the proposed scope discussion in Section C that it delays implementation of PET scanners. See Criterion 3 above.

Criterion 18a

The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.

This applicant has a history of delaying CON projects, which it acknowledges with regard to PET scanners in its response to Section C.1 of the application. Approval of the WR Imaging project would keep at least 5 of the 11 approved PET scanners in HSA IV (accounting for 2 scanners approved in the 2025 SMFP) under control of the UNC Health System, which would not enhance competition within the service area.

ATTACHMENT E

Competitive Review of J-012607-25: Duke University Health System, Inc. (Duke Cary)

Overview

Duke University Health System, Inc. (“Duke Cary” or “Applicant”) applied to acquire one PET scanner to be located at the undeveloped Duke Green Level Hospital in Cary via a change of scope to Project ID# J-012029-21. Duke Health System is currently operating or approved for four PET scanners in HSA IV, including one dedicated research-only PET scanner that is temporarily approved to operate as a clinical/diagnostic unit.

The Duke application to acquire a PET scanner at Duke Green Level Hospital fails to establish that it is either conforming with or comparatively superior to other applicants for multiple Review Criteria, namely Criteria 3, 4, 6 and 18a, and should be denied.

Criterion 3

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

The Duke Cary PET scanner application is predicated on changing the scope of Duke Green Level Hospital, which received approval in 2021. At the time of that approval, Duke Green Level Hospital was proposed to open on 7/1/2026, but has yet to break ground. Therefore, the proposed project would only become operational approximately 2 years after all other applicants in this review.

The criticality of DUHS’s need for additional PET capacity is questionable. In addition to the CON awarded to DUHS for Duke Green Level, DUHS has also held a CON to develop an additional PET scanner since 12/2021 and has made negligible progress. If DUHS felt strongly that there was a lack of access for patients or that their growth was being hindered, there would have been proportionate effort to operationalize their many CONs. **At present, DUHS holds CONs for, at least, an acute care hospital (J-012029-21), a PET scanner (J-012083-21), a linear accelerator (J-012000-20), and an ambulatory surgery center (J-011557-18), without development.** This pattern of applying for assets, only to hold the CON undeveloped, while simultaneously applying for even more, comes at the expense of patient access and other capable organizations that are willing to develop the project in a timely manner.

The methodology provided in Duke Cary’s application appears to be based on an unreasonable shell game of shifting patients, rather than truthfully supported mathematics. On Page 107 in Duke Cary’s application, it is determined that, after all the unsupported shifts, both Duke Raleigh and Duke Cary would perform exactly the same number of scans in all three project years. The probability of this assertion is objectively arbitrary and illogical. Furthermore, this assertion that a brand-new PET scanner would operate at the same volume as a PET scanner that had been in existence for approximately 6 years, is unsupported and renders the entirety of the methodology non-conforming.

Disproportionate Access to HSA IV Counties Proposed

The 2025 SMFP defines the PET service area as the HSA in which the equipment is located.¹ While it is reasonable to assume that a provider may serve more patients from one county than another within the HSA, the Applicant has the responsibility to show that it proposes to serve patients from all counties in the HSA. DUHS fails to do this.

As seen on page 36, **the Duke Cary application only identifies six of the 11 HSA IV counties in its proposed PET patient origin**, which is based on patient origin of Duke Raleigh Hospital. The Analyst is left to assume that some unspecified number of patients from the remaining five counties – Lee, Person, Chatham, Orange and Warren – are lumped into “Other NC Counties.” Without that detail, there is no way to determine if or how many patients Duke Cary plans to serve from those counties. Attachment G shows that the Duke Cary site is located in western HSA IV only a few miles from rapidly-growing Chatham County and is in close proximity to Lee County, which suggests that Duke Cary did not fully evaluate the need of the entire service area.

Criterion 4

Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

Duke Cary does not support why it is in the patient’s best interest for this asset to be hospital-based; and, with competing applications providing patients with a value-based option, this project could not be found as the most effective alternative to development of PET capacity in the service area.

Among the applicants in this review, the Duke Cary application has the highest capital cost, will be the costliest to patients, and has the latest operational date. None of these factors are in the best interest of patients. Furthermore, there is no guarantee that the proposed PET scanner will be operational at the date stated in Section P based on DUHS’s history of not developing projects they have been awarded in a timely manner. For all these reasons, the DUHS Cary application should be denied.

Criterion 6

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

Duplication of Services

First, as detailed in Criterion 3 above, the concentration of PET scanners in the western half of HSA IV is disproportionate to that of the east. This imbalance causes access issues for patients in places such as Johnston, Warren, and eastern Wake Counties, and duplicates services for patients in Durham and its adjacent counties in western HSA IV.

Furthermore, DUHS proposes hospital-based PET services. As detailed in Criterion 4 above, demand for outpatient services is higher. Development of more clinical PET services at the

¹ Chapter 15F, 2025 SMFP, p363

hospital duplicates the existing three clinical PET scanners already available while simultaneously ignoring the need for more outpatient services in other areas of HSA IV.

Criterion 18a

The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.

The Duke Cary application maintains that development of an additional PET scanner in western Wake County, an area that is “a part of the county that is relatively underserved and by alleviating capacity constraints that currently may limit appointment availability and patient choice” (page 94), will enhance competition in the service area. However, no further information is provided to support this assertion. Duke Cary does not project to serve patients from Chatham or Lee Counties, both of which are located near western Wake County. DUHS already controls four of the nine existing PET scanners in HSA IV – approval of a fifth scanner would give Duke control of one-half of the service area’s scanners, which would do nothing to improve competition.

Competitive Review of J-012610-25: Duke University Health System, Inc.

Overview

Duke University Health System, Inc. (“DUHS” or “Applicant”) currently operates a research-only PET scanner acquired via research exemption (N.C.G.S. §131E-179) in 2019. DUHS received a CON for a third clinical PET in 2021 (Project ID# J-012083-21). In 2024, DUHS filed a Material Compliance to use the research PET for clinical purposes while the scanner approved in J-012083-21 was under development. The condition of the Material Compliance was that following completion of J-012083-21 the existing PET would return to research-only use. This application seeks to allow the research-only scanner to remain permanently clinical and develop J-012083-21, for a total of four clinical PET scanners on the DUHS main campus in Durham County.

DUHS fails to adequately demonstrate the need for the proposed services and should be found non-conforming with multiple Review Criteria and should be denied. In particular, the DUHS application does not conform with Review Criteria 3, 4, 6 and 18a.

Criterion 3

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

Overview

DUHS fails to demonstrate that the identified population has a need for additional PET services in Durham County and that locating this limited resource at DUHS increases access to residents of HSA IV.

Historical Volume vs. Need

DUHS reports on page 38 of its application that “volumes documented in Table 15F-1 of the 2025 SMFP reflect that Duke University Hospital is the most highly utilized PET service in the state.” The Applicant therefore concludes that because it is highly used, it needs more capacity. However, the logic behind this argument is flawed. As explained in the following section, population in HSA IV, particularly in Wake and Johnston Counties, is both growing rapidly and aging. With limited resources throughout the entire HSA, the exponential growth experienced at DUHS is not necessarily attributable to its own patient growth, but instead limited access to an important service. In other words, patients may not choose DUHS for PET services because that is their provider of choice, but because it is their only choice.

Durham County vs. Wake County: Geographic Access

The standard methodology in the 2025 SMFP supports two additional PET scanners in HSA IV. HSA IV includes 11 counties and approximately 2.6 million residents. It is imperative that the location of this important diagnostic tool be in a location with access by the largest number of underserved patients. While DUHS does acknowledge the four existing scanners in Wake County, it fails to demonstrate why Durham County is a more suitable location.

First, DUHS's own data support Wake County as a more favorable location. Population data on page 40 list some of the fastest growing counties in the state. The list includes seven of the 11 HSA IV counties, including Durham and Wake. DUHS implies that because Durham is on this list, its growth justifies the additional services. However, the table on page 40 shows that while Durham will rank third in total new residents between 2020 and 2030, its growth rate is barely half that of Johnston County, and less than 20 percent of Wake County. For reference, the number of residents projected to be added to Wake and Johnston Counties is over 80 percent of the entire population of Durham County. In other words, the new residents in Wake and Johnston Counties alone will almost match that of the Durham County's total population. See detail in Table 1 below.

Table 1: Net New Residents 2020-2030: Durham, Johnston, and Wake Counties Compared

County	April 2020 Population	July 2030 Population	Numeric Change
Wake	1,129,352	1,358,482	229,130
Johnston	215,994	290,489	74,495
Durham	324,846	365,472	40,626

Source: DUHS application, page 40

Table 2: Wake and Johnston Net New Residents Compared to Durham County Population

a. Wake + Johnston Net-New Residents, 2020-2030	303,625
b. Estimated Durham County Population, 2030	365,472
c. Total Durham Population as a Percent of Wake + Johnston Net-New Population	83.1%

Notes:

- a. Table 1, Wake + Johnston Counties
- b. Table 1
- c. a/b

The map in Figure 1 below shows that travel distances from eastern Wake County and Johnston County to DUHS is much farther compared to other proposed PET scanner locations, such as Raleigh PET, LLC in east Raleigh. Placing this limited resource farther away from the fastest growing population, as reported by the Applicant, does not increase access.

Figure 1: East HSA IV vs West HSA IV, Select Cities Distance to Proposed DUHS, Compared to Existing PET Scanners

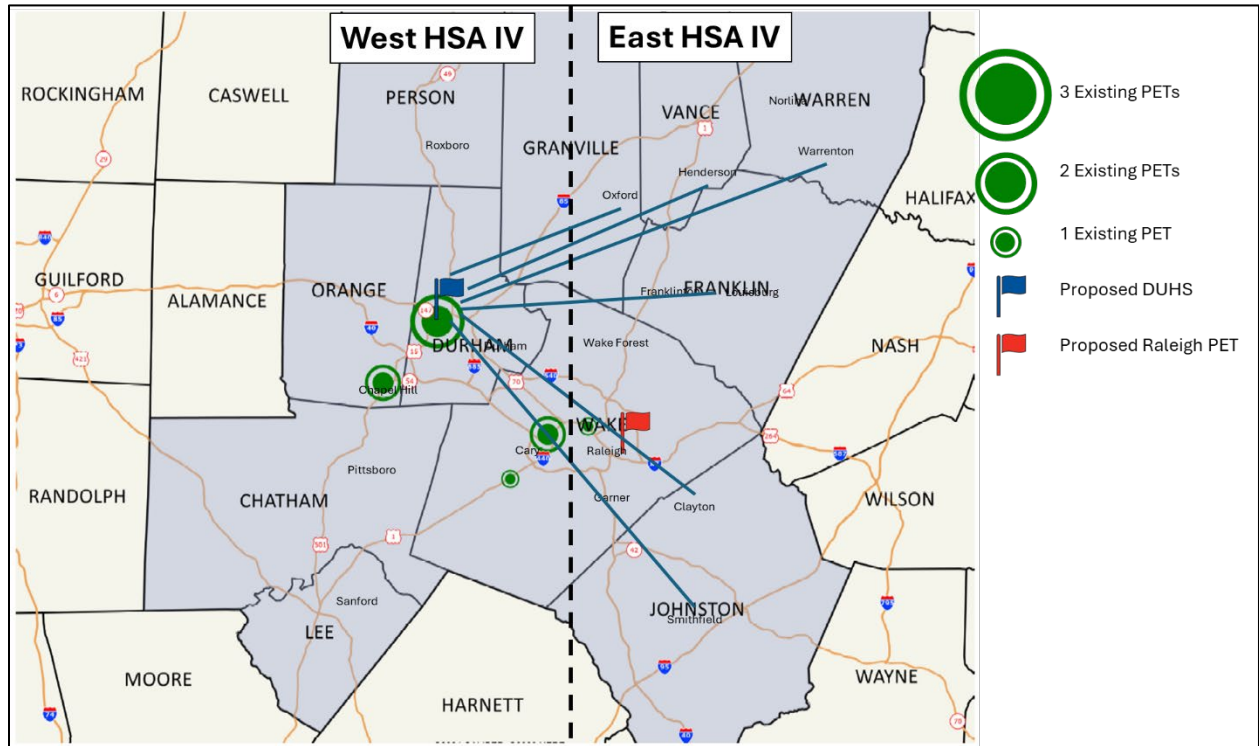


Table 3: Distance from Select HSA IV Cities to Proposed DUHS PET Scanner, Miles, and Minutes, Compared with Raleigh PET, LLC

County	City	DUHS		Raleigh PET, LLC	
		Miles	Minutes	Miles	Minutes
Franklin	Louisburg	42.2	59.0	30.6	45.0
Granville	Oxford	32.5	35.0	41.9	55.0
Johnston	Clayton	44.0	51.0	15.5	23.0
Johnston	Smithfield	57.5	63.0	29.0	32.0
Vance	Henderson	42.9	43.0	42.7	58.0
Warren	Norlina	56.8	55.0	57.1	71.0
Warren	Warrenton	57.5	61.0	54.5	72.0

Source: Google Maps, accessed 03.13.25

Finally, the Applicant details on page 40 that the National Cancer Institute identifies “aging as the most important risk factor for cancer overall...” The Applicant infers that an older population is more likely to have a higher incidence of cancer and therefore would require additional access to PET services. However, NCOSBM lists Durham County with median ages notably younger than Wake and Johnston. Again, the Applicant’s own argument does not support locating the proposed PET scanner in Durham County. See detail in Table 4 below.

Table 4: HSA IV Counties’ Median Ages Compared, 2020 and 2030

County	CY20	CY30
Orange	35.16	36.97
Vance	40.24	38.31
Durham	35.75	39.19
Johnston	38.10	39.51
Wake	36.87	40.05
Lee	39.14	40.86
Granville	42.29	41.45
Person	44.44	42.59
Franklin	41.33	42.69
Warren	48.81	45.51
Chatham	47.58	49.95

Source: NCOSBM, accessed March 2025

Disproportionate Access to HSA IV Counties Proposed

The 2025 SMFP defines the PET service area as the HSA in which the equipment is located.¹ While it is reasonable to assume that a provider may serve more patients from one county than another within the HSA, the Applicant has the responsibility to show that it proposes to serve patients from all counties in the HSA. DUHS fails to do this.

As shown on page 35, **the Applicant only identifies eight of the 11 HSA IV counties in its proposed PET patient origin.** The Analyst is left to assume that patients from the remaining three counties – Lee, Johnston, and Warren – are combined into “Other NC.” Without that breakout, there is no way to determine if or how many patients DUHS plans to serve from those counties.

This is particularly concerning given that one overlooked county is Johnston. As detailed in the previous section, Johnston is one of the fastest growing counties, not only in HSA IV, but the entire state. It would appear that DUHS has no plans for outreach or service to the third most populous largest and fourth oldest county in the service area. This blatant disregard for over a quarter million residents suggests that DUHS did not in fact evaluate the need of the service area when determining where to locate the proposed equipment.

¹ Chapter 15F, 2025 SMFP, p363

Finally, the patient origin on page 35 suggests that this proposal is more self-serving to DUHS than to the service area in need. According to NCOSBM, in 2025 Wake County has approximately 1.24 million residents. This accounts for 52.4 percent of the total HSA IV population. However, DUHS proposes that only 15 percent of its PET patients will originate from Wake County. “Other NC” and named counties adjacent to HSA IV total 35.3 percent of proposed patients, more than double that of Wake County.

It is clear that DUHS has not prioritized service to the patients with an identified need over that of their own convenience.

Criterion 4

Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

Hospital-Based vs Freestanding

DUHS states on page 58 that developing a “freestanding location would not serve inpatients and would not provide the same range of services that will be available on the hospital campus.” This argument is flawed.

First, DUHS provides no evidence that inpatients are higher users of PET services compared to outpatients. On the contrary, the nuclear medicine industry suggests that outpatient settings are more beneficial to patients. For example,

1. **Reimbursement Policies:** Medicare and many insurance companies often bundle inpatient costs, which can result in reduced or no specific reimbursement for high-cost items like PET/CT scans. This financial structure discourages the use of PET scans for inpatients.²
2. **Scheduling and Resource Allocation:** Scheduling inpatient PET/CT scans is challenging due to the need to accommodate these studies on short notice, often requiring the cancellation of outpatient appointments. This disruption can lead to prolonged hospital stays, increasing overall costs and the risk of healthcare-associated adverse events.³
3. **Imaging Quality:** Studies have shown that inpatient PET/CT scans are more frequently of suboptimal quality compared to outpatient scans. Factors such as patients being heavily medicated, unable to follow instructions, or having older IV lines can lead to artifacts and reduced image clarity.⁴

Providing a fourth clinical PET scanner on the DUHS campus is not the most cost-effective alternative.

² Whitacre, J. (2024b, November 1). *Expensive, inferior, and protracting-inpatient FDG PET/CT*. ARRS InPractice. https://arrsinpractice.org/expensive-inferior-and-protracting-inpatient-fdg-pet-ct/?utm_source=chatgpt.com

³ Ibid

⁴ Mangiore, A., Hampton, S., & Voslar, A. (2022, August 1). *Inpatient PET scans: Why we should screen orders*. Journal of Nuclear Medicine. https://jnm.snmjournals.org/content/63/supplement_2/4084?utm_source=chatgpt.com

Criterion 6

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

Duplication of Services

DUHS failed to demonstrate that conversion of the research PET scanner to clinical use along with the development of J-012083-21 would not result in unnecessary duplication.

First, as detailed in Criterion 3 above, the concentration of PET scanners in the western half of HSA IV is disproportionate to that of the east. This imbalance causes access issues for patients in places such as Johnston, Warren, and eastern Wake Counties, and duplicates services for patients in Durham and its adjacent counties in western HSA IV.

Furthermore, DUHS proposes hospital-based PET services. As detailed in Criterion 4 above, demand for outpatient services are higher. Development of more clinical PET services at the hospital duplicates the existing three clinical PET scanners already available while simultaneously ignoring the need for more outpatient services in other areas of HSA IV.

Criterion 18a

The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.

Competition

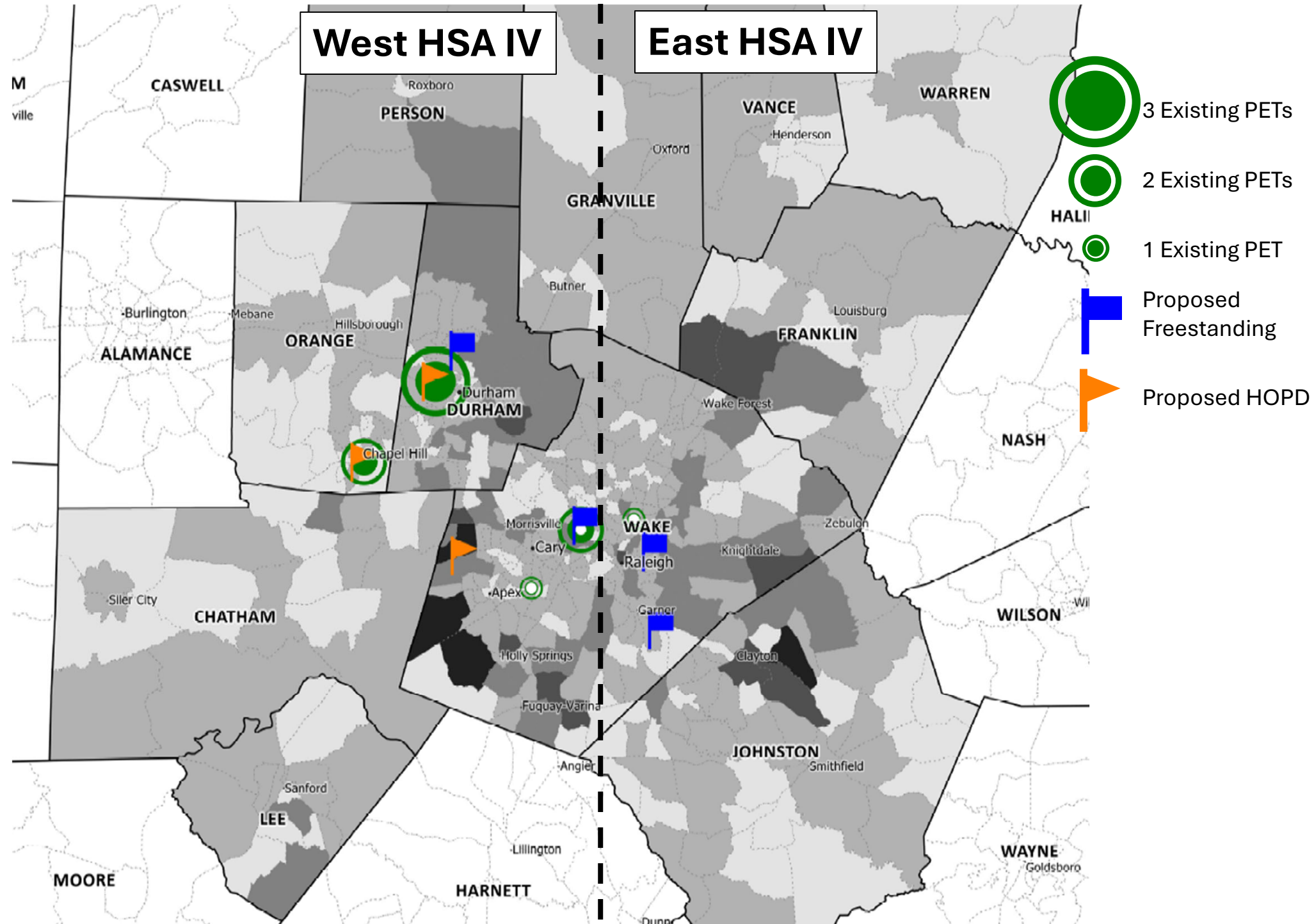
Criterion 18a requires the applicant to demonstrate the expected effect of the proposed services on competition in the service area. According to the 2025 SMFP, the service area is HSA IV, which has nine PET scanners owned by three providers: Duke University, UNC, and Wake PET Services. Of those, DUHS has the largest share, with four of the nine scanners, or 44 percent of existing PETs. Approval of another PET scanner at DUHS would not introduce competition into the service area.

Because DUHS proposes maintaining its HOPD structure with the proposed equipment, it will not have a positive impact on access with regard to cost. Medicare typically reimburses PET scans at lower rates in outpatient settings compared to inpatient settings. For example, the national average cost for a PET scan in an outpatient facility is \$920, with Medicare covering 80% of this amount, leaving beneficiaries responsible for approximately \$183. In contrast, the average cost for the same scan as a hospital outpatient procedure is \$1,599, resulting in a higher out-of-pocket expense of about \$319 for beneficiaries.⁵

⁵ Medicare and PET scans: Coverage and costs. Humana. (n.d.). https://www.humana.com/medicare/medicare-resources/medicare-pet-scans?utm_source=chatgpt.com

Additional Errors

The DUHS application had one additional error: the Applicant it failed to pay a sufficient filing fee to cover the true capital cost of the project. This application proposes to convert a capital investment, the cost of which received an Exemption from CON Review under N.C.G.S. §131E-179 -- for "research only" purposes. Per Form F.1a, the DUHS application proposes a nominal cost to convert this asset to clinical service, and the applicant paid a filing fee sufficient to cover only the nominal cost, not the equivalent cost of a new scanner.



ATTACHMENT H

PET / CT Comparative Matrix

METRICS

Comparative Factor	Rating Explanation	Agency Comparative Notes
Conformity to stat rev criteria		
Scope of Services	higher best	specialty comparison or in equipment types of scans if clear
Historical Utilization	higher best	no new: highest historical use
Geographic Accessibility	higher best	do not have providers of services
Access by Underserved Groups	higher best	Medicare Gross Revenue
Access by Underserved Groups	higher best	Medicare % of Total Revenue / Patients
Access by Underserved Groups	higher best	Medicaid Gross Revenue
Access by Underserved Groups	higher best	Medicaid % of Total Patients / Revenue
Competition	lower best	new provider
Projected Avg Net Rev per Procedure, PY3	lower best	per procedure, lowest is best
Projected Avg Op Exp per Procedure, PY3	lower best	per procedure, lowest is best

Agency Scoring: More Effective

SUGGESTIONS

HOPD tech only vs Freestanding tech only vs Global	Global best	Global Pricing is more cost effective for patients
Total Number of PET Scanners Owned by Applicant / System	lower best	Fewer PET scanners within the system supports competition

Agency Scoring: Most Effective

Agency Scoring: More Effective

Total Score: Agency Metrics + Suggested, Most & More Included

RAW DATA

DDI / Novant	UNCCH	AUNC	WR Garner
onc, card, neuro	onc, card, neuro	onc, card, neuro	onc, card, neuro
-	4,744.0	-	-
Durham / Durham	Chapel Hill / Orange	Raleigh / Wake	Garner / Wake
\$ 7,914,710	\$ 32,874,105	\$ 1,942,547	\$ 8,443,631
42.9%	55.1%	10.2%	63.0%
\$ 403,849	\$ 4,845,855	\$ 138,753	\$ 938,181
2.2%	8.1%	0.7%	7.0%
new	existing	new	existing provider, new location
\$ 2,289.84	\$ 3,196.66	\$ 6,300.50	\$ 1,461.13
\$ 1,460.85	\$ 2,379.39	\$ 5,581.18	\$ 921.89

Global	HOPD tech	Freestanding tech	Global
1.0	6.0	1.0	6.0

ATTACHMENT H

PET / CT Comparative Matrix

METRICS

Comparative Factor	Rating Explanation	Agency Comparative Notes
Conformity to stat rev criteria		
Scope of Services	higher best	specialty comparison or in equipment types of scans if clear
Historical Utilization	higher best	no new: highest historical use
Geographic Accessibility	higher best	do not have providers of services
Access by Underserved Groups	higher best	Medicare Gross Revenue
Access by Underserved Groups	higher best	Medicare % of Total Revenue / Patients
Access by Underserved Groups	higher best	Medicaid Gross Revenue
Access by Underserved Groups	higher best	Medicaid % of Total Patients / Revenue
Competition	lower best	new provider
Projected Avg Net Rev per Procedure, PY3	lower best	per procedure, lowest is best
Projected Avg Op Exp per Procedure, PY3	lower best	per procedure, lowest is best

Agency Scoring: More Effective

SUGGESTIONS

HOPD tech only vs Freestanding tech only vs Global	Global best	Global Pricing is more cost effective for patients
Total Number of PET Scanners Owned by Applicant / System	lower best	Fewer PET scanners within the system supports competition

Agency Scoring: Most Effective

Agency Scoring: More Effective

Total Score: Agency Metrics + Suggested, Most & More Included

RAW DATA

Duke Cary	DUHS	Raleigh PET
onc, card, neuro	onc, card, neuro,	onc, card, neuro
-	8,457.0	-
Cary / Wake	Durham / Durham	Raleigh / Wake
\$ 15,267,926	\$ 69,545,613	\$ 13,788,263
58.9%	56.1%	47.6%
\$ 906,088	\$ 4,750,135	\$ 2,139,501
3.5%	3.8%	7.4%
existing provider, new location	existing	new
\$ 4,016.56	\$ 3,534.25	\$ 4,889.46
\$ 2,660.61	\$ 2,880.21	\$ 3,794.09

HOPD tech	HOPD Tech	Global
6.0	6.0	2.0

ATTACHMENT H

PET / CT Comparative Matrix

METRICS

Comparative Factor	Rating Explanation	Agency Comparative Notes
Conformity to stat rev criteria		
Scope of Services	higher best	specialty comparison or in equipment types of scans if clear
Historical Utilization	higher best	no new: highest historical use
Geographic Accessibility	higher best	do not have providers of services
Access by Underserved Groups	higher best	Medicare Gross Revenue
Access by Underserved Groups	higher best	Medicare % of Total Revenue / Patients
Access by Underserved Groups	higher best	Medicaid Gross Revenue
Access by Underserved Groups	higher best	Medicaid % of Total Patients / Revenue
Competition	lower best	new provider
Projected Avg Net Rev per Procedure, PY3	lower best	per procedure, lowest is best
Projected Avg Op Exp per Procedure, PY3	lower best	per procedure, lowest is best

Agency Scoring: More Effective

SUGGESTIONS

HOPD tech only vs Freestanding tech only vs Global	Global best	Global Pricing is more cost effective for patients
Total Number of PET Scanners Owned by Applicant / System	lower best	Fewer PET scanners within the system supports competition

Agency Scoring: Most Effective

Agency Scoring: More Effective

Total Score: Agency Metrics + Suggested, Most & More Included

EXPECTED AGENCY SCORE

DDI / Novant	UNCCH	AUNC	WR Garner	Duke Cary	DUHS	Raleigh PET
Equal	Equal	Equal	Equal	Equal	Equal	Equal
Equal	Equal	Equal	Equal	Equal	Equal	Equal
					More	
			More			More
Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.
Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.
Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.
Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.
More		More				
Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.
Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.	Inconc.

1.0 - 1.0 1.0 - 1.0 1.0

More			More			More
Most		Most				More

1.0 - 1.0 - - - -

1.0 - - 1.0 - - 2.0

3.0 - 2.0 2.0 - 1.0 3.0