

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 25, 2025

Findings Date: July 25, 2025

Project Analyst: Tanya M. Saporito

Co-Signer: Michael J. McKillip

### COMPETITIVE REVIEW

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Project ID #:	J-12593-25
Facility:	Durham Diagnostic Imaging-Independence Park
FID #:	250149
County:	Durham
Applicants:	Durham Diagnostic Imaging Novant Health, Inc. Novant Health-Norfolk, LLC
Project:	Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

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Project ID #:	J-12595-25
Facility:	University of North Carolina Medical Center
FID #:	923517
County:	Orange
Applicant:	University of North Carolina Hospitals at Chapel Hill
Project:	Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

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Project ID #:	J-12598-25
Facility:	Raleigh PET Imaging
FID #:	250150
County:	Wake
Applicants:	Associated Urologists of North Carolina, P.A. Associated Urologists of NC Properties I, LLC
Project:	Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

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Project ID #:	J-12602-25
Facility:	Wake Radiology UNC REX Healthcare-Garner
FID #:	250152
County:	Wake
Applicants:	Wake Radiology Diagnostic Imaging, Inc. WR Imaging, LLC

Project: Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

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Project ID #: J-12607-25  
Facility: Duke Cary Hospital  
FID #: 210092  
County: Wake  
Applicant: Duke University Health System, Inc.  
Project: Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

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Project ID #: J-12610-25  
Facility: Duke University Hospital  
FID #: 943138  
County: Durham  
Applicant: Duke University Health System, Inc.  
Project: Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

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Project ID #: J-12611-25  
Facility: WakeMed Raleigh Medical Park 2  
FID #: 250651  
County: Wake  
Applicant: Raleigh PET, LLC  
Project: Acquire a fixed PET scanner pursuant to the 2025 SMFP need determination

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Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

### **REVIEW CRITERIA**

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (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, operating rooms, or home health offices that may be approved.

## C – All Applications

### **Need Determination**

The 2025 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional dedicated fixed PET scanners in North Carolina by service area. Application of the need methodology in the 2025 SMFP identified a need for two additional dedicated fixed PET scanners in Health Service Area (HSA) IV. Seven applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) proposing to develop a total of seven new fixed PET scanners in HSA IV. However, pursuant to the need determination, only two fixed PET scanners may be approved in this review.

### **Policies**

There are two policies in the 2025 SMFP that apply to this review. *Policy GEN-4* applies to three of the seven applications, and *Policy GEN-5* applies to all seven applications.

#### **Policy GEN-4**

*Policy GEN-4* on page 30 of the 2025 SMFP states:

*“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

*Policy GEN-5*, on pages 30-31 of the 2025 SMFP states:

*“A certificate of need (CON) applicant applying to offer or develop a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities. The delivery of culturally competent healthcare requires the implementation of systems and training to provide responsive, personalized care to individuals with diverse backgrounds, values, beliefs, customs, and languages. A certificate of need applicant shall identify the underserved populations and communities it will serve, including any disparities or unmet needs of either, document its strategies to provide culturally competent programs and services, and articulate how these strategies will reduce existing disparities as well as increase health equity.*

*CON applications will include the following:*

*The applicant shall, in its CON application, address each of the items enumerated below:*

***Item 1:*** *Describe the demographics of the relevant service area with a specific focus on the medically underserved communities within that service area. These communities shall be described in terms including, but not limited to: age, gender, racial composition; ethnicity; languages spoken; disability; education; household income; geographic location and payor type.*

***Item 2:*** *Describe strategies it will implement to provide culturally competent services to members of the medically underserved community described in Item 1.*

***Item 3:*** *Document how the strategies described in Item 2 reflect cultural competence.*

***Item 4:*** *Provide support (e.g., best-practice methodologies, evidence-based studies with similar communities) that the strategies described in Items 2 – 3 are reasonable pathways for reducing health disparities, increasing health equity and improving the health outcomes to the medically underserved communities within the relevant service area.*

***Item 5:*** *Describe how the applicant will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities in underserved communities.”*

**Project ID #J-12593-25 / Durham Diagnostic Imaging, LLC, Novant Health, Inc. and Novant Health Norfolk, LLC** (hereinafter collectively referred to as “the applicant” or “DDI”) operates Durham Diagnostic Imaging Independence Park (DDI), an existing outpatient diagnostic imaging center in Durham. The applicant proposes to acquire one fixed PET scanner to be located at DDI.

*Need Determination.* The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA IV fixed PET scanner service area.

*Policy GEN-4.* The proposed capital expenditure for this project is less than \$4 million; therefore, *Policy GEN-4* does not apply to this application.

*Policy GEN-5.* In Section B, pages 26-33, the applicant explains why it believes the application is conforming to Policy GEN-5.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more fixed PET scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-5 based on the following:
  - The applicant adequately documents how the project will provide culturally competent health care that integrates principles to increase health equity and reduce health disparities in underserved communities.

**Project ID #J-12595-25 / University of North Carolina Hospitals at Chapel Hill** (hereinafter referred to as “the applicant” or “UNC Medical Center”) operates University of North Carolina Medical Center (UNC Medical Center), an acute care hospital in Chapel Hill that provides acute, emergency and imaging services. The applicant proposes to acquire one fixed PET scanner to be located at UNC Medical Center. Following project completion, the applicant will operate two fixed PET scanners.

*Need Determination.* The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA IV fixed PET scanner service area.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$4 million but less than \$5 million. In Section B, pages 27-28, the applicant the applicant explains why it believes its application is conforming to Policy GEN-4.

*Policy GEN-5.* In Section B, pages 29-41, the applicant explains why it believes the application is conforming to Policy GEN-5.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more fixed PET scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 and Policy GEN-5 based on the following:
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation; and
  - The applicant adequately documents how the project will provide culturally competent health care that integrates principles to increase health equity and reduce health disparities in underserved communities.

**Project ID #J-12598-25 / Associated Urologists of North Carolina, P.A. and Associated Urologists of NC Properties I, LLC** (hereinafter collectively referred to as “the applicant” or “AUNC”) proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP in an existing medical office building and develop a diagnostic center, Raleigh PET Imaging (RPI).

*Need Determination.* The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA IV fixed PET scanner service area.

*Policy GEN-4.* The proposed capital expenditure for this project is less than \$4 million; therefore, *Policy GEN-4* does not apply to this application.

*Policy GEN-5.* In Section B, pages 27-33, the applicant explains why it believes the application is conforming to Policy GEN-5.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more fixed PET scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-5 based on the following:
  - The applicant adequately documents how the project will provide culturally competent health care that integrates principles to increase health equity and reduce health disparities in underserved communities.

**Project ID #J-12602-25 / Wake Radiology UNC REX Healthcare-Garner and WR Imaging, LLC** (hereinafter collectively referred to as “the applicant” or “WR Imaging-Garner”) proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP to be located in an existing diagnostic center, Wake Radiology UNC REX Healthcare-Garner (WR Imaging-Garner).

*Need Determination.* The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA IV fixed PET scanner service area.

*Policy GEN-4.* The proposed capital expenditure for this project is less than \$4 million; therefore, *Policy GEN-4* does not apply to this application.

*Policy GEN-5.* In Section B, pages 27-33, the applicant explains why it believes the application is conforming to Policy GEN-5.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more fixed PET scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-5 based on the following:

- The applicant adequately documents how the project will provide culturally competent health care that integrates principles to increase health equity and reduce health disparities in underserved communities.

**Project ID #J-12607-25 / Duke University Health System, Inc.** (hereinafter referred to as “the applicant” or DUHS) proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP at Duke Cary Hospital, which is a change of scope for Project ID #J-12029-21 (Develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital). Following project completion, Duke Cary Hospital would operate one fixed PET scanner.

*Need Determination.* The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA IV fixed PET scanner service area.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$5 million. In Section B, page 27, the applicant explains why it believes its application is conforming to Policy GEN-4.

*Policy GEN-5.* In Section B, pages 27-32, the applicant explains why it believes the application is conforming to Policy GEN-5.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more fixed PET scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 and Policy GEN-5 based on the following:
  - The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation; and
  - The applicant adequately documents how the project will provide culturally competent health care that integrates principles to increase health equity and reduce health disparities in underserved communities.



**Project ID #J-12610-25 / Duke University Health System, Inc.** (hereinafter referred to as “the applicant” or DUHS) proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP to be located at Duke University Hospital. Following project completion, Duke University Hospital would operate four fixed PET scanners.

*Need Determination.* The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA IV fixed PET scanner service area.

*Policy GEN-4.* The proposed capital expenditure for this project is less than \$4 million; therefore, *Policy GEN-4* does not apply to this application.

*Policy GEN-5.* In Section B, pages 27-31, the applicant explains why it believes the application is conforming to Policy GEN-5.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more fixed PET scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-5 based on the following:
  - The applicant adequately documents how the project will provide culturally competent health care that integrates principles to increase health equity and reduce health disparities in underserved communities.

**Project ID #J-12611-25 / Raleigh PET, LLC** (hereinafter referred to as “the applicant” or Raleigh PET) proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP in a physician office building currently under development (Raleigh Medical Park 2) and develop a diagnostic center.

*Need Determination.* The applicant does not propose to develop more fixed PET scanners than are determined to be needed in the HSA IV fixed PET scanner service area.

*Policy GEN-4.* The proposed capital expenditure for this project is more than \$4 million but less than \$5 million. In Section B, page 26, the applicant explains why it believes the application is conforming to *Policy GEN-4*.

*Policy GEN-5.* In Section B, page 27 and in Exhibit B-20, the applicant explains why it believes the application is conforming to *Policy GEN-5*.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more fixed PET scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 and Policy GEN-5 based on the following:
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation; and
  - The applicant adequately documents how the project will provide culturally competent health care that integrates principles to increase health equity and reduce health disparities in underserved communities.

- (2) Repealed effective July 1, 1987.
- (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, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed.

#### C – All Applications

**Project ID #J-12593-25 / Durham Diagnostic Imaging, LLC, Novant Health, Inc. and Novant Health Norfolk, LLC** - The applicant proposes to acquire one fixed PET scanner to be located at DDI.

#### **Patient Origin**

On page 363, the 2025 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s **service area** is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original) Thus, the service area for this proposal is HSA IV. Facilities may also serve residents of counties not included in their service area.

The applicant does not currently offer fixed PET services at DDI but provides historical patient origin for the entire facility for the last full fiscal year (FY), 2024 September 1, 2023-October 1, 2024, as shown in the following table:

**Durham Diagnostic Imaging Historical Patient Origin FY 2024**

County	# Patients	% of Total
Durham	15,035	55.4%
Person	4,449	16.3%
Granville	2,136	7.8%
Orange	1,898	7.0%
Wake	966	3.5%
Vance	341	1.3%
Franklin	217	0.8%
Chatham	95	0.4%
Warren	69	0.3%
Lee	31	0.1%
Johnston	28	0.1%
Alamance	865	3.2%
Caswell	163	0.6%
Other—NC and out of state	860	3.2%
<b>Total</b>	<b>27,153</b>	<b>100.0%</b>

Source: Application Section C, page 46

In Section C, page 47 the applicant provides projected patient origin for the first three full operating years following project completion, FYs 2027-2029 for fixed PET services at DDI, as shown in the following table:

**Durham Diagnostic Imaging Projected Patient Origin for PET Services, FYs 2027-2029**

County	PY 1 (FY 2027)		PY 2 (FY 2028)		PY 3 (FY 2029)	
	# Pts	% of Total	# Pts	% of Total	# Pts	% of Total
Durham	17,003	55.4%	17,542	55.4%	17,880	55.4%
Person	5,003	16.3%	5,161	16.3%	5,261	16.3%
Granville	2,394	7.8%	2,470	7.8%	2,517	7.8%
Orange	2,148	7.0%	2,216	7.0%	2,259	7.0%
Wake	1,074	3.5%	1,108	3.5%	1,130	3.5%
Vance	399	1.3%	412	1.3%	420	1.3%
Franklin	246	0.8%	235	0.8%	258	0.8%
Chatham	123	0.4%	127	0.4%	129	0.4%
Warren	92	0.3%	95	0.3%	97	0.3%
Lee	31	0.1%	32	0.1%	32	0.1%
Johnston	31	0.1%	32	0.1%	32	0.1%
Alamance	982	3.2%	1,013	3.2%	1,033	3.2%
Caswell	184	0.6%	190	0.6%	194	0.6%
Other–NC and out of state	982	3.2%	1,013	3.2%	1,033	3.2%
<b>Total</b>	<b>30,692</b>	<b>100.0%</b>	<b>31,664</b>	<b>100.0%</b>	<b>32,725</b>	<b>100.0%</b>

In Section C, page 48 the applicant provides the assumptions and methodology used to project patient origin for the proposed fixed PET scanner. The applicant states projected patient origin for fixed PET services would mirror the historical patient origin for the entire facility.

The applicant’s assumptions are reasonable and adequately supported because they are based on historical patient origin for all imaging modalities currently offered at DDI for FY 2024 (October 1, 2023-September 30, 2024).

### **Analysis of Need**

In Section C.4, pages 49-61, the applicant explains why it believes the population projected to utilize the proposed fixed PET services needs the proposed services, as summarized below:

- There is a need determination in the 2025 SMFP for two additional fixed PET scanners in the HSA IV service area, and the applicant proposes to locate the proposed fixed PET scanner in HSA IV (page 49).
- Growing demand for PET services in North Carolina and in HSA IV – The applicant states PET imaging and advances in the radiopharmaceuticals combine to make PET imaging an increasingly effective diagnostic tool. Additionally, population growth and aging, increasing incidence of cancer, cardiac disease and neurological disorders contribute to the high demand for PET services in the service area (pages 49-53).
- Projected aging of the service area population – The applicant states that the population in the service area is aging, as is the incidence of disease in this population, which impacts the increasing demand for PET services (page 54).

- Prevalence rate of diseases in HSA IV – The applicant cardiovascular disease, cancer and Alzheimer’s Disease are pervasive and increasing in the service area. Additionally, the applicant cites reports that indicate people are living longer, which increases the demand for health services such as PET imaging. The applicant states CMS recently proposed changes in Medicare coverage that would include increased access to PET services for Medicare patients (pages 55-58).
- Physician support and need for a new provider of PET services in HSA IV – The applicant states DDI is an existing diagnostic center that currently provides diagnostic imaging services to patients with lung, prostate and breast cancer. The applicant provides letters from DDI physicians that indicate strong support for the proposed fixed PET scanner. The applicant states the service area will benefit from a new outpatient provider of fixed PET services (pages 58-61).
- The applicant states the proposed PET scanner at DDI will provide a more convenient and less costly outpatient option for PET imaging services in HSA IV (page 61).

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2025 SMFP for two additional PET scanners in HSA IV, which includes Durham County.
- The applicant provides data to illustrate the increasing demand for PET services in the service area.
- The applicant provides evidence of physician support to support the need for a fixed PET scanner at DDI.

### **Projected Utilization**

In Section Q, Form C.2a, the applicant provides projected utilization for the proposed fixed PET scanner, as shown in the following table:

<b>DURHAM DIAGNOSTIC IMAGING</b>	<b>1<sup>ST</sup> FULL FY FFY 2027</b>	<b>2<sup>ND</sup> FULL FY FFY 2028</b>	<b>3<sup>RD</sup> FULL FY FFY 2029</b>
# PET Scanners	1	1	1
# Procedures	2,000	2,398	2,875

Source: Application Section Q, Form C.2a, page 2.

In Section Q, “*Form C.2 Utilization – Assumptions and Methodology*”, pages 1-6, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

- *Step 1: Historical Utilization* – The applicant examined historical utilization of fixed PET scanners in the state as a whole and in HSA IV specifically. The applicant

calculated a compound annual growth rate (CAGR) in PET services of 15.2% in the state, and 19.9% in HSA IV from 2020-2023 (page 1).

- *Step 2: Projected Utilization in HSA IV* - The applicant applied one-half of the state-wide PET utilization CAGR to the 2023 number of PET procedures in HSA IV to project HSA IV PET utilization in project year one (pages 1-2).
- *Step 3: Determine Capacity of the Proposed Fixed PET Scanner* – Based on consultation with the manufacturer of the proposed fixed PET scanner and consideration of DDI's facility design and proposed operational schedule, the applicant determined that the maximum capacity of the proposed fixed PET scanner at DDI is 4,000 scans annually (pages 2-3).
- *Step 4: Projected Volume of the New Proposed PET/CT Scanner in Project Year 1* – The applicant states project year one will be FFY 2027 (10/1/26-9/30/27). In the first year of operation, the applicant assumes it will provide 2,000 scans (one-half of the projected 4,000 scan capacity) on the proposed fixed PET scanner (pages 3-4).
- *Step 5: Project Volume of the New Proposed PET/CT Scanner in Project Years 2 and 3* – The applicant's experience with similar projects indicates volume increases in project years two and three. Therefore, the applicant applied the historical HSA IV CAGR for PET services to the project year one projected volume to project utilization in project years two and three (page 4).
- *Step 6: Evaluate Utilization as a Percentage of Maximum Capacity for Project Years 1-3* – The applicant calculated DDI's projected utilization based on the projected annual capacity. See the following table from page 4 that illustrates the projected percent capacity (page 4):

**Projected Utilization as a Percent of Maximum Capacity**

TIME	ESTIMATED PET VOLUME	MAXIMUM EQUIPMENT CAPACITY	% OF MAXIMUM CAPACITY
PY 1 (10/1/26-9/30/27)	2,000	4,000	50%
PY 2 (10/1/27-9/30/28)	2,398	4,000	60%
PY 3 (10/1/28-9/30/29)	2,875	4,000	72%

- *Step 7: Evaluate DDI's Utilization as a Percentage of Capacity for Project Years 1-3* –The applicant projects the following utilization of DDI's proposed fixed PET scanner in Project Years one-three based on a 7.6% annual growth rate, which the applicant states is one-half the state-wide growth rate from 2020-2023.:

**Projected Utilization, First Three Project Years**

	ESTIMATED PET VOLUME	MAXIMUM EQUIPMENT CAPACITY	% OF MAXIMUM CAPACITY
Number of Units	1	1	1
Number of Procedures	2,000	2,398	2,875

Projected utilization is reasonable and adequately supported based on the following:

- The applicant makes reasonable and adequately supported assumptions regarding projected PET utilization based on documented population data, statewide PET use rates, and HSA IV historical PET utilization.
- The applicant makes reasonable and adequately supported assumptions regarding disease incidence in the service area and the need that population has for healthcare, including fixed PET services.

### **Access to Medically Underserved Groups**

In Section C.6, page 67, the applicant states:

*“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients and other underserved groups, will ... continue to have access to DDI. DDI does not discriminate based on race, ethnicity, age, gender, or disability.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from Section C, page 67:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons*	--
Racial and ethnic minorities*	--
Women	60.1%
Persons with Disabilities*	--
Persons 65 and older	42.0%
Medicare beneficiaries	42.0%
Medicaid recipients	5.5%

\*The applicant states it does not request or track patient information on these data.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents projected access to PET services at DDI for all residents of the service area, including underserved groups.

- The applicant's projected payor mix includes underserved groups as listed above.

### **Conclusion**

The agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to Comments

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12595-25 / UNC Medical Center** – The applicant proposes to acquire one fixed PET scanner to be located at UNC Medical Center. UNC Medical Center also operates two fixed PET scanners acquired pursuant to Policy AC-3, but these scanners are not counted in the fixed PET scanner inventory in the SMFP.

### **Patient Origin**

On page 363, the 2025 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s **service area** is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Orange County which, according to Appendix A on page 369 of the 2025 SMFP is in HSA IV. Thus, the service area for this proposal is HSA IV. Facilities may also serve residents of counties not included in their service area.

The following table, from Section C page 49 illustrates UNC's historical patient origin for fixed PET services in the last full fiscal year of operation, state fiscal year (SFY) 2024 (July 1, 2023-June 30, 2024:



**UNC Medical Center Historical Patient Origin, Fixed PET Services**

COUNTY	SFY 2024	
	# OF PATIENTS	% OF TOTAL
Wake	665	16.1%
Orange	597	14.5%
Alamance	291	7.1%
Chatham	257	6.2%
Durham	221	5.4%
Cumberland	152	3.7%
Lee	151	3.7%
Harnett	120	2.9%
Johnston	113	2.7%
Moore	86	2.1%
Other*	1,467	35.6%
<b>Total</b>	<b>4,120</b>	<b>100.0%</b>

\*On page 49 the applicant states "other" includes "Sampson, Wayne, Nash, Guilford, Bladen, New Hanover, Randolph, Robeson, Brunswick, Craven and other counties in NC as well as other states."

The following table, from Section C page 51 illustrates UNC's projected patient origin for fixed PET services in the first three full fiscal years of operation, SFYs 2027-2029:

**UNC Medical Center Projected Patient Origin**

COUNTY	PY 1 SFY 2027		PY 2 SFY 2028		PY 3 SFY 2029	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Wake	823	16.1%	885	16.1%	951	16.1%
Orange	739	14.5%	794	14.5%	853	14.5%
Alamance	360	7.1%	387	7.1%	416	7.1%
Chatham	317	6.2%	341	6.2%	367	6.2%
Durham	273	5.4%	293	5.4%	315	5.4%
Cumberland	187	3.7%	202	3.7%	217	3.7%
Lee	187	3.7%	201	3.7%	216	3.7%
Harnett	149	2.9%	160	2.9%	172	2.9%
Johnston	139	2.7%	150	2.7%	161	2.7%
Moore	107	2.1%	115	2.1%	123	2.1%
Other*	1,817	35.6%	1,952	35.6%	2,099	35.6%
<b>Total</b>	<b>5,098</b>	<b>100.0%</b>	<b>5,480</b>	<b>100.0%</b>	<b>5,890</b>	<b>100.0%</b>

\*On page 51 the applicant states "other" includes "Sampson, Wayne, Nash, Guilford, Bladen, New Hanover, Randolph, Robeson, Brunswick, Craven and other counties in NC as well as other states."

In Section C, page 51 the applicant provides the assumptions and methodology used to project patient origin for the proposed fixed PET scanner. The applicant states projected patient origin for fixed PET services is based on FY 2024 patient origin for fixed PET services, increased by the Orange County projected population growth rate published by the North Carolina OSBM from 2025-2030.

The applicant's assumptions are reasonable and adequately supported because they are based on historical patient origin for fixed PET services at UNC and account for population growth in Orange County.

### **Analysis of Need**

In Section C, pages 53-66 the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- The 2025 SMFP identified a need in HSA IV for two additional fixed PET scanners. The applicant states the 2025 SMFP inaccurately indicates that UNCH owns and operates a total of two fixed PET scanners included in the inventory of HSA IV fixed PET scanners. UNCH owns one fixed PET scanner that was awarded pursuant to a need determination in a previous SMFP, and two fixed PET scanners that were awarded pursuant to Policy AC-3<sup>1</sup>, one of which is located at the main hospital and one at the Cancer Hospital on the main UNC Medical Center campus. The fixed PET scanners that were awarded pursuant to Policy AC-3 are excluded from the SMFP inventory as described in the language of the policy. The applicant provides documentation between UNCH and the Healthcare Planning Section, DHSR to confirm the discrepancy. The applicant notes that the high utilization of fixed PET scanners in HSA IV as reported in the 2025 SMFP is based on utilization by both service area residents and patients who reside outside of the service area (pages 54-56).
- Population growth and aging in HSA IV and North Carolina – The applicant cites data from the North Carolina Office of State Budget and Management (NCOSBM) to illustrate population growth projections in the counties that comprise HSA IV. The applicant notes that the population in HSA IV counties is projected to increase by a CAGR of 1.7% between 2025 and 2030, while the population in the state as a whole is projected to increase by a CAGR of 1.1% during that same time. The applicant states population growth projections of persons age 65+ during the same time is projected to increase by 3.9% in the counties that comprise HSA IV and by 2.7% in the state as a whole (pages 56-58).
- Increasing incidence and prevalence of chronic disease in HSA IV – The applicant cites data from the North Carolina State Center for Health Statistics as well as the Center for Disease Control that demonstrate that the incidence of heart disease, various types of cancer, and Alzheimer's and Parkinsons Diseases are prevalent in the state as a whole and in HSA IV. The applicant states CT imaging, often used to diagnose and treat some cardiac, oncological and neurological diseases, are limited in their diagnostic ability, whereas PET services are uniquely crucial in the early detection of these and other diseases (pages 58-60).
- Expansion of clinical applications of PET imaging – The applicant proposes to locate

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<sup>1</sup> Policy AC-3 can be found on pages 19-21 in the 2025 SMFP.

the proposed fixed PET scanner in the Cancer Hospital on the main UNC Medical Center campus. The applicant discusses the varied application of PET technology in clinical areas such as oncology, cardiology and neurological disease detection and treatment, and how the proposed fixed PET scanner would benefit UNC Medical Center’s ability to more effectively serve its patients (pages 60-64).

- Need for additional fixed PET scanner capacity at UNC Medical Center – The applicant states that locating the proposed fixed PET scanner in the Cancer Hospital on UNC Medical Center’s main campus would provide UNCH with the opportunity to maintain optimal efficiency for its patients who will need fixed PET services (pages 64-67).

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2025 SMFP for two additional PET scanners in HSA IV, which includes Orange County.
- The applicant provides data to illustrate the increasing demand for PET services in the service area, the incidence of disease for which PET services are appropriate and the projected growth of the service area population.

### **Projected Utilization**

In Section Q, Form C.2a, the applicant provides projected utilization for the existing and proposed fixed PET scanners, as shown in the following table:

UNC MEDICAL CENTER	1 <sup>ST</sup> FULL FY SFY 2027	2 <sup>ND</sup> FULL FY SFY 2028	3 <sup>RD</sup> FULL FY SFY 2029
# PET Scanners	2	2	2
# Procedures	5,098	5,480	5,890

Source: Application Section Q, Form C.2a, page 128.

In Section Q, “*Form C Utilization - Assumptions and Methodology*”, pages 129-133 the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

- Determine historical utilization of UNCH’s fixed PET scanner – The applicant states the proposed project is projected to be operational on July 1, 2026, and UNCH’s fiscal year is the SFY (July 1 – June 30). The applicant examined its internal historical utilization data from SFY 2021-2025. The applicant determined that the “*need acquired*” fixed PET scanner has historically performed more than 75% of the total PET procedures. Applying that percentage to total PET scans performed from SFY 2021-2025 indicates that PET utilization at UNCH increased by a CAGR of 7.5% during that time (pages 129-130).
- Project fixed PET scanner utilization – The applicant examined historical utilization data as described above and extracted data representing patients from the counties that

comprise HSA IV to calculate the historical CAGR of HSA IV patients who received PET services during SFY 2021-2025. The applicant calculated a 29.5% CAGR of PET utilization in HSA IV. The applicant applied its own historical growth rate of 7.5% to project PET utilization in all three project years, as shown in the following table from Section Q, page 131:

	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	CAGR
# PET Procedures	4,414	4,744	5,098	5,480	5,890	7.5%

The applicant states that the Performance Standards for fixed PET scanners require that all existing, approved and proposed fixed PET scanners perform a minimum of 2,080 PET procedures per fixed PET scanner during the third full year of operation. In FY 2029, the applicant projects to perform 5,890 on its two fixed PET scanners, which exceeds the minimum threshold [ $5,890 / 2 = 2,945$ ] (pages 131-132).

- For information purposes, the applicant projects utilization of the fixed PET scanner at UNC Health Rex, although it is not required to pursuant to 10A NCAC 14C .3703. See the tables that illustrate these projections on page 133.

Projected utilization is reasonable and adequately supported because projected PET utilization is based on the applicant's historical utilization and state-wide and HSA IV utilization and growth rates.

### **Access to Medically Underserved Groups**

In Section C.6, page 72, the applicant states:

*“As North Carolina’s only state-owned, comprehensive, full-service hospital system, UNC Health has the obligation to accept any North Carolina citizen requiring medically necessary treatment. UNC Hospitals is a quaternary academic medical center, trauma center, and provider of specialty care of complex diseases for patients from all 100 North Carolina counties, including acute care services [footnote omitted]. No North Carolina citizen is presently denied access to non-elective care because of race, creed, age, handicap, financial status, or lack of medical insurance.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from Section C, page 73:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons*	--
Racial and ethnic minorities	35.8%
Women	57.9%
Persons with Disabilities*	--
Persons 65 and older	34.0%
Medicare beneficiaries	39.5%
Medicaid recipients	21.8%

\*the applicant states it does not maintain data that includes the number of low-income or disabled persons it serves and thus does not have a reasonable basis with which to estimate the percentage of those same populations it proposes to serve.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents historical and projected access to UNC Medical Center for all residents of the service area, including underserved groups.
- The applicant projects its payor mix, which includes underserved groups, based on its historical experience.

### **Conclusion**

The agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to Comments

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12598-25 / AUNC** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Patient Origin**

On page 363, the 2025 SMFP defines the service area for fixed PET scanners as follows: “A fixed PET scanner’s **service area** is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Wake County which, according to

Appendix A on page 369 of the 2025 SMFP is in HSA IV. Thus, the service area for this proposal is HSA IV. Facilities may also serve residents of counties not included in their service area.

In Section C, page 56 the applicant states AUNC is an existing medical office practice with no historical patient origin for PET or imaging services to report. The following table, from Section C page 57 illustrates AUNC's projected patient origin for fixed PET services in the first three full fiscal years of operation, SFYs 2027-2029:

**AUNC Projected Patient Origin**

COUNTY	PY 1 SFY 2027		PY 2 SFY 2028		PY 3 SFY 2029	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Wake	1,423	67.0%	1,631	67.0%	1,774	67.0%
Johnston	172	8.1%	197	8.1%	214	8.1%
Franklin	84	3.9%	96	3.9%	104	3.9%
Lee	76	3.6%	87	3.6%	95	3.6%
Durham	67	3.1%	76	3.1%	83	3.1%
Orange	24	1.1%	27	1.1%	30	1.1%
Chatham	20	1.0%	23	1.0%	25	1.0%
Vance	13	0.6%	14	0.6%	16	0.6%
Granville	12	0.6%	13	0.6%	15	0.6%
Warren	9	0.4%	10	0.4%	11	0.4%
Person	9	0.4%	10	0.4%	11	0.4%
<b>Total HSA IV</b>	<b>1,908</b>	<b>89.9%</b>	<b>2,187</b>	<b>89.9%</b>	<b>2,378</b>	<b>89.9%</b>
Harnett	92	4.3%	105	4.3%	114	4.3%
Other HSAs	124	5.8%	142	5.8%	154	5.8%
<b>Total</b>	<b>2,123</b>	<b>100.0%</b>	<b>2,434</b>	<b>100.0%</b>	<b>2,646</b>	<b>100.0%</b>

\*On page 51 the applicant states "other" includes "Sampson, Wayne, Nash, Guilford, Bladen, New Hanover, Randolph, Robeson, Brunswick, Craven and other counties in NC as well as other states."

In Section C, page 57, in response to application question 3, which requests an applicant to provide all assumptions and methodology used to project patient origin, the applicant responds by stating that AUNC has an office in Dunn, in Harnett County. The applicant further states that RPI will only offer PET scans. The applicant does not provide assumptions or methodology to support its projected patient origin; however, the applicant is an existing urology practice that provides diagnostic imaging services. It is reasonable to conclude that projected patient origin would be consistent with its existing diagnostic imaging services.

### **Analysis of Need**

In Section C, pages 59-65, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- Service area population growth and aging trends – The applicant examined NCOSBM data that shows the overall HSA IV population increased by 8.9% from 2020-2025 and is projected to increase by 8.7% from 2025-2030. The 65+

population in HSA IV increased by 24.7% from 2020-2025 and is projected to increase by 20.9% from 2025-2030 (page 60).

- Wake County specifically population growth and aging trends – The applicant examined NCOSBM data that shows the population of Wake County increased by 9.1% from 2020-2025 and is projected to increase by 9.7% from 2025-2030. The 65+ population in Wake County increased by 27.8% from 2020-2025 and is projected to increase by 24.5% from 2025-2030. Older age groups, according to the applicant’s research, are more at risk for many types of cancers (pages 61-62).
- Life Expectancy in Wake County – The applicant states the Life Expectancy of Wake County residents is increasing (pages 62-63).
- PET scanner utilization increased by a CAGR of 7.5% from FY 2019-2023 in North Carolina and by 10.7% in HSA IV. Increasing demand for fixed PET services and advancements in radiotracers used in PET procedures, according to the applicant, will continue to create increasing demand for fixed PET services.

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2025 SMFP for two additional PET scanners in HSA IV, which includes Wake County.
- The applicant provides data to illustrate the increasing demand for PET services in the service area.
- The applicant provides data to illustrate increasing life expectancy and PET utilization to support the need for a fixed PET scanner at RPI.

### **Projected Utilization**

In Section Q, Form C.2b, the applicant provides projected utilization for the proposed fixed PET scanner, as shown in the following table:

AUNC	1 <sup>ST</sup> FULL FY SFY 2027	2 <sup>ND</sup> FULL FY SFY 2028	3 <sup>RD</sup> FULL FY SFY 2029
# PET Scanners	1	1	1
# Procedures	2,123	2,434	2,646

Source: Application Section Q, Form C.2b, page 1.

In Section Q, “*Utilization Methodology and Assumptions*”, pages 1-6, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

- The applicant states AUNC currently employs 14 physicians and beginning in FY 2025 through all three project years, there will be 18 physicians (page 1).

- The applicant examined AUNC physicians' historical referral patterns for PSMA, Renal and Cardiac-Ortho-Neuro PET procedures in FY 2024 and the anticipated number of new physicians who will join the practice in 2025. The applicant calculated the number of PSMA PET referrals projected per physician based on historical referral patterns and determines the number of bone scans that could be referred to PET scans on the proposed fixed PET scanner (pages 2-4).
- The applicant projects the number of renal PET scans based AUNC physician experience, historical referral patterns of AUNC physicians and the number of physicians projected to join the practice (pages 4-5).
- Based on the AUNC experience, the applicant projects the percentage of renal PET scans that could be converted to PET scans (page 5).
- The applicant projects the number of cardiac-ortho-neurological PET scans to be performed on the proposed fixed PET scanner and provides letters of support from physicians that provide referral estimates (pages 5-6).

Projected utilization is reasonable and adequately supported because it is based on historical state-wide PET use rates, historical AUNC physician referral patterns and historical PET utilization in the state and in HSA IV.

### **Access to Medically Underserved Groups**

In Section C.6, page 73, the applicant states:

*“Raleigh PET Imaging will not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay. Raleigh PET Imaging will participate in both the Medicaid and Medicare programs. In the third year of the project, Medicare patients are projected to account for 29.4 percent of total PET scanner patients.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from Section C, page 74:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	5.0%
Racial and ethnic minorities	22.9%
Women	26.9%
Persons with Disabilities	20.0%
Persons 65 and older	37.2%
Medicare beneficiaries	29.4%
Medicaid recipients	2.1%



The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents projected access to PET services at RPI for all residents of the service area, including underserved groups.
- The applicant's projected payor mix includes underserved groups as listed above.

### **Conclusion**

The agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to Comments

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12602-25 WR Imaging Garner** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Patient Origin**

On page 363, the 2025 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s **service area** is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Wake County which, according to Appendix A on page 369 of the 2025 SMFP is in HSA IV. Thus, the service area for this proposal is HSA IV. Facilities may also serve residents of counties not included in their service area.

In Section C, page 37 the applicant states WR Imaging-Garner does not currently offer fixed PET services; therefore, there is no historical patient origin for fixed PET services to report. In Section C, page 38, the applicant provides the following historical patient origin for diagnostic imaging services at the facility for the last full year of operation, calendar year (CY) 2024:

**Wake Radiology UNC REX Healthcare-Garner  
Historical Patient Origin CY 2024**

County	# Patients	% of Total
Wake	14,189	55.74%
Johnston	7,929	31.1%
Harnett	1,323	5.2%
Sampson	738	2.9%
Wayne	282	1.1%
Other*	1,021	4.0%
<b>Total</b>	<b>25,482</b>	<b>100.0%</b>

\*In Section C, page 38 the applicant states "other" includes "<1 percent patient origin from the remaining counties in North Carolina and other states."

In Section C, page 39 the applicant provides projected patient origin for the first three years of operation, FFYs 2027-2029, for the proposed fixed PET scanner as illustrated in the following table:

**WR Imaging-Garner Projected Patient Origin CY 2024**

County						
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Chatham	19	2.2%	41	2.3%	44	1.6%
Durham	62	7.0%	66	3.7%	70	2.5%
Franklin	39	4.4%	83	4.6%	135	4.9%
Granville	14	1.6%	30	1.7%	32	1.2%
Johnston	119	13.5%	257	14.3%	415	15.0%
Lee	16	1.8%	34	1.9%	36	1.3%
Orange	28	3.1%	29	1.6%	31	1.1%
Person	9	1.0%	19	1.0%	20	0.7%
Vance	9	1.0%	19	1.1%	20	0.7%
Wake	564	64.0%	1,211	67.4%	1,949	70.6%
Warren	4	0.5%	9	0.5%	9	0.3%
<b>Total</b>	<b>882</b>	<b>100.0%</b>	<b>1,798</b>	<b>100.0%</b>	<b>2,761</b>	<b>100.0%</b>

\*In Section C, page 39 the applicant states "other" includes "<1 percent patient origin from the remaining counties in North Carolina and other states."

In Section Q, *Form C.2 Utilization -Assumptions and Methodology*, the applicant provides the assumptions and methodology used to project its patient origin, which is based on historical patient origin for diagnostic imaging services. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In C.4, pages 41-62 the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- Need in the 2025 SMFP for two fixed PET scanners in HSA IV, and the many

applications of PET technology in disease diagnosis (pages 41-49).

- Increasing demand for PET services in North Carolina – The applicant states the North Carolina PET use rate from FY 2016-2023 increased in each year, notwithstanding the time during which the Governor issued a Stay-at-Home order during the COVID-19 pandemic. The use rate in HSA IV increased as well, and from FY 2021-2023 increased by a CAGR of over 21% (pages 49-52).
- The need for enhanced geographic access to PET services in the service area – The applicant states the fixed PET scanners in HSA IV are currently concentrated in the central and western portions of the area, with no existing scanners in the eastern portion of the area. Citing data from the NCOSBM, the applicant states the entire population of HSA IV will increase from 2025-2029, with the greatest growth occurring in the eastern portion of the HSA and in the over 65 population group (pages 52-55).
- The need to enhance access for the medically underserved populations – The applicant states there is a significant portion of service area residents who are either underinsured or uninsured who also need access to health care, including PET services (page 56).
- Incidence of disease for which PET services are utilized – The applicant states that incidence of diseases like cancer, neurological and cardiovascular disease is increasing in HSA IV, evidencing the increasing need for additional fixed PET services for the service area residents (pages 56-61).
- Documented support from healthcare providers in the service area – The applicant states that, as an existing diagnostic imaging center, it has community and physician support for the proposed fixed PET scanner, particularly since it will be freestanding and provide a lower cost option for its patients. The applicant provides letters of support in Exhibit I.2 (pages 61-62).

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2025 SMFP for two additional PET scanners in HSA IV, which includes Wake County.
- The applicant provides reliable published data to illustrate the increasing demand for PET services in the service area.
- The applicant provides reasonable and clearly identified information as well as physician support to support the need for a fixed PET scanner at WR Imaging, LLC.

### **Projected Utilization**

In Section Q, Form C.2b, the applicant provides projected utilization for the proposed fixed PET scanner, as shown in the following table:

WR IMAGING, LLC	1 <sup>ST</sup> FULL FY FFY 2027	2 <sup>ND</sup> FULL FY FFY 2028	3 <sup>RD</sup> FULL FY FFY 2029
# PET Scanners	1	1	1
# Procedures	882	1,798	2,761

Source: Application Section Q, Form C.2b, page 119.

In Section Q, “*Form C.2 Utilization – Assumptions and Methodology*”, pages 120-126, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

- *Step 1: Population Projections* – The applicant cited data from the NCOSBM to show projected population growth in HSA IV from 2025-2029, the third project year (page 120).
- *Step 2: Procedure Use Rate* - The applicant consulted prior SMFPs and the data from the NCOSBM to calculate the statewide historical PET use rate from FY 2016-2023. The applicant states the number of statewide PET procedures increased by a CAGR of 8.0% from FY 2019-2023. Additionally, the applicant states that, based on information in the 2023-2025 SMFPs, PET volume increased by a CAGR of 21.4%. The applicant projects the future PET use rate in the service area will increase by two-thirds of the 8.0% historical rate, or 5.3%. (page 121).
- *Step 3: Projected PET Procedure Demand Based on PET Use Rate* – The applicant projects future PET scan demand by applying the projected statewide PET use rate to the projected population in each county that comprises HSA IV (page 122).
- *Step 4: PET Market Share* – Based on population demographics, aging and disease incidence in HSA IV, as well as its established referral patterns with existing providers, the applicant projects its market share of fixed PET procedures in each county within HSA IV (pages 122-124).
- *Step 5: Projected Fixed PET Procedures* – Based on the projected annual market share of HSA IV PET utilization, the applicant provides a table that summarizes the number of PET procedures projected to be performed at WR Imaging in each of the project years. The applicant provides projections of the existing PET scanner at UNC Health Rex.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant makes reasonable and adequately supported assumptions regarding projected PET utilization based on documented population data, statewide PET use rate data, and HSA IV historical PET utilization.

- The applicant makes reasonable and adequately supported assumptions regarding disease incidence in the service area and the need that population has for healthcare, including fixed PET services.

### **Access to Medically Underserved Groups**

In Section C.6, page 66, the applicant states:

*“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will have access to the proposed fixed PET services, as clinically appropriate. WR Imaging does not discriminate based on race, ethnicity, age, gender, or disability.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from Section C, page 67:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	10.5%
Racial and ethnic minorities	42.9%
Women	51.0%
Persons with Disabilities*	--
Persons 65 and older	63.0%
Medicare beneficiaries	63.0%
Medicaid recipients	7.0%

\*the applicant states it does not retain data on the number of disabled persons it serves and thus has no basis with which to project the same.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents projected access to PET services at WR Imaging for all residents of the service area, including underserved groups.
- The applicant’s projected payor mix includes underserved groups as listed above.

### **Conclusion**

The agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to Comments

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12607-25 / Duke Cary Hospital** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP at Duke Cary Hospital, which is a change of scope for Project ID# J-12029-21 (Develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital).

### **Patient Origin**

On page 363, the 2025 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s **service area** is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Wake County which, according to Appendix A on page 369 of the 2025 SMFP is in HSA IV. Thus, the service area for this proposal is HSA IV. Facilities may also serve residents of counties not included in their service area.

In Section C, page 33 the applicant states Duke Cary Hospital is not an existing hospital; therefore, there is no historical patient origin to report. In Section C, page 34, the applicant provides the following historical patient origin for PET services at Duke Raleigh Hospital for the last full fiscal year of operation, SFY 2024:

**Duke Raleigh Hospital PET Historical Patient Origin SFY 2024**

<b>County</b>	<b># Patients</b>	<b>% of Total</b>
Wake	1,455	58.8%
Johnston	124	5.0%
Franklin	115	4.7%
Cumberland	65	2.6%
Durham	52	2.1%
Harnett	47	1.9%
Nash	44	1.8%
Brunswick	44	1.8%
New Hanover	34	1.4%
Vance	29	1.2%
Wilson	28	1.1%
Granville	25	1.0%
Wayne	21	0.8%
Moore	19	0.8%
Halifax	19	0.8%
Other NC Counties	271	11.0%
VA	31	1.3%
SC	21	0.8%
All Other	29	1.2%
<b>Total</b>	<b>2,473</b>	<b>100.0%</b>

In Section C, page 36 the applicant provides projected patient origin for the first three years of operation, SFYs 2031-2032, for the proposed fixed PET scanner as illustrated in the following table:

Duke Cary Hospital PET Projected Patient Origin First Three Project Years						
County	1 <sup>st</sup> PY (SFY 2030)		2 <sup>nd</sup> PY (SFY 2031)		3 <sup>rd</sup> PY (SFY 2032)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Wake	1,052	63.4%	1,273	67.0%	1,505	70.0%
Johnston	74	4.5%	76	4.0%	79	3.7%
Franklin	69	4.1%	71	3.7%	73	3.4%
Cumberland	39	2.3%	40	2.1%	41	1.9%
Durham	31	1.9%	32	1.7%	33	1.5%
Harnett	28	1.7%	29	1.5%	30	1.4%
Nash	26	1.6%	27	1.4%	28	1.3%
Brunswick	26	1.6%	27	1.4%	28	1.3%
New Hanover	20	1.2%	21	1.1%	22	1.0%
Vance	17	1.0%	18	0.9%	18	0.9%
Wilson	17	1.0%	17	0.9%	18	0.8%
Granville	15	0.9%	15	0.8%	16	0.7%
Wayne	13	0.8%	13	0.7%	13	0.6%
Moore	11	0.7%	12	0.6%	12	0.6%
Halifax	11	0.7%	12	0.6%	12	0.6%
Other NC Counties	162	9.7%	167	8.8%	172	8.0%
VA	19	1.1%	19	1.0%	20	0.9%
SC	13	0.8%	13	0.7%	13	0.6%
All Other	17	1.0%	18	0.9%	18	0.9%
<b>Total</b>	<b>1,660</b>	<b>100.0%</b>	<b>1,899</b>	<b>100.0%</b>	<b>2,150</b>	<b>100.0%</b>

In Section C, page 36, the applicant provides the assumptions and methodology used to project its patient origin, which it states is based on FY 2024 historical patient origin for Duke Raleigh Hospital, adjusted for patients who are projected to shift to Duke Cary Hospital for PET services. The applicant provides detailed assumptions in Section Q. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C, pages 39-46 the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- Need in the 2025 SMFP for two fixed PET scanners in HSA IV, and the many applications of PET technology in disease diagnosis (page 39).
- *High and Increasing Utilization of DUHS PET-CT Scanners* – The applicant states the DUHS system's total PET utilization (Duke University Hospital and Duke Raleigh Hospital) from 2021-2024 has increased by 56%, while PET utilization for Wake County patients increased by 70% during the same period (pages 39-40).
- *Service Area Population Growth and Aging* – Citing data from different sources, the

applicant states the population in the state as a whole and in nine of the 11 counties that comprise HSA IV is projected to increase from 2020-2029, with some counties experiencing higher growth rates than others and than the state as a whole. Additionally, the over 65 age group, the group more likely to seek PET services, is projected to increase as well (pages 40-42).

- *Geographic Need for Services in Duke Cary Hospital Area* – The applicant states that, within Wake County, there are currently three fixed PET scanners in Raleigh and one in Cary (Raleigh and Cary are both in Wake County). The applicant proposes to locate its fixed PET scanner at the previously approved Duke Cary Hospital, which will be located approximately ten miles from the current location of the PET scanner in Cary, thereby providing increased access to PET services in that portion of Wake County (pages 43-44).
- *DUHS Provider Network Strength and Growth* – The applicant states projected demand for the proposed fixed PET scanner is also supported by the growth of the Duke Health provider network. The applicant states that DUHS continues to grow its provider network across multiple specialties, thus supporting the need for an additional fixed PET scanner. The applicant provides letters of support in Exhibit C.4 (pages 44-46).

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2025 SMFP for two additional PET scanners in HSA IV, which includes Wake County.
- The applicant provides data to illustrate the increasing demand for PET services in the service area.
- The applicant provides reasonable and clearly identified information regarding its own utilization as well as physician support to support the need for a fixed PET scanner at Duke Cary Hospital.

### **Projected Utilization**

In Section Q, Form C.2a, page 4 the applicant provides projected utilization for the proposed fixed PET scanner at Duke Cary Hospital, as shown in the following table:

DUKE CARY HOSPITAL	1 <sup>ST</sup> FULL FY SFY 2027	2 <sup>ND</sup> FULL FY SFY 2028	3 <sup>RD</sup> FULL FY SFY 2029
# PET Scanners	1	1	1
# PET Procedures	1,660	1,899	2,150

Source: Application Section Q, Form C.2a, page 4.

In Section Q, “*Form C Assumptions*”, pages 102-107 the applicant provides the assumptions and methodology used to project utilization, summarized as follows:



- The applicant states its fiscal year is the SFY, from July-June. Duke Cary Hospital and the proposed fixed PET scanner are projected to begin operation on July 1, 2029; therefore, the first three project years are SFY 2030-2032 (page 102).
- *1: Projection of DUHS PET-CT Volumes* – The applicant states that DUHS PET utilization increased by 16% from 2021-2024, even after the development of an additional fixed PET scanner at Duke Raleigh Hospital in 2020. To be conservative, the applicant projects future PET utilization by 3% (pages 102-103).
- *2: Shift of Patients from Durham County (DUH) to Wake County (Raleigh and Cary) Scanners* - The applicant states that, historically, Wake County patients comprise 15% of DUH PET volume. The applicant anticipates a shift of patients from existing DUH hospitals to the Duke Cary Hospital based on capacity constraints at DUH, expanded access to additional southern Wake County PET scanners, DUHS's recruitment and growth, and centralized scheduling and radiologists. The applicant projects PET the volume shift to Duke Cary Hospital beginning with the historical 15% of projected DUHS PET volume, consistent with its historical Wake County patient percentage, ramping up to 75% by the third project year, as shown in the following table from page 106:

**Projected Shift from DUH to Wake County Fixed PET Scanners**

	2024	2025	2026	2027	2028	2029	2030	2031	2032
DUH "shiftable" volume of 15% of total volume attributable to Wake County patients	1,229	1,266	1,304	1,343	1,383	1,425	1,467	1,512	1,557
Anticipated percentage of "shiftable" volume from DUH to Wake County locations.							25%	50%	75%
DUH volume shifting to Wake County locations.							367	756	1,168
Total percent shift from DUH to Wake County							3.7%	7.5%	11.2%

- *3: Allocation of Volume Between Duke Raleigh and Duke Cary Campuses* – The applicant projects that, by the time the Duke Cary Hospital begins serving patients, the Duke Raleigh PET scanner will be fully utilized, thus facing capacity constraints. The applicant states the ratio of PET procedures per hospital campus is based on the applicant's historical utilization (pages 106-107). The following table, from page 107, illustrates total DUHS projected utilization:

**Total Projected Volume by Location, DUHS**

	2024	2025	2026	2027	2028	2029	2030	2031	2032
Projected DUH PET volume on four PET scanners	8,211	8,457	8,711	8,972	9,242	9,519	9,437	9,343	9,234
Projected Wake County PET Volume bot sites	2,473	2,547	2,624	2,702	2,783	2,867	3,320	3,797	4,300
# Procedures DRH*	2,473	2,547	2,624	2,702	2,783	2,867	1,660	1,899	2,150
# Procedures DCH^							1,660	1,899	2,150

\*Duke Raleigh Hospital

^Duke Cary Hospital

Projected utilization is reasonable and adequately supported based on the information in these findings, the application, exhibits to the application, remarks at the public hearing, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the following points:

- The applicant makes reasonable and adequately supported assumptions regarding projected PET utilization based on documented population data, statewide PET use rates, and DUHS's historical PET utilization.
- The applicant makes reasonable and adequately supported assumptions regarding disease incidence in the service area and the need that population has for additional fixed PET services.

### **Access to Medically Underserved Groups**

In Section C.6, page 51, the applicant states:

*“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will have access to this service, as clinically appropriate. DUHS does not and will not discriminate based on race, ethnicity, age, gender, or disability.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from Section C, page 52:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	10.4%
Racial and ethnic minorities*	34.9%
Women	53.4%
Persons with Disabilities*	--
Persons 65 and older	53.3%
Medicare beneficiaries	46.3%
Medicaid recipients	6.8%

\*The applicant states it does not maintain data regarding the number of disabled persons it serves.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents projected access to PET services at Duke Cary Hospital for all residents of the service area, including underserved groups.
- The applicant's projected payor mix includes underserved groups as listed above.

### **Conclusion**

The agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Written comments
- Response to Comments

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12610-25 / Duke University Hospital** – The proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP to be located at Duke University Hospital (DUH).

### **Patient Origin**

On page 363, the 2025 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s **service area** is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original) The applicant proposes to locate the fixed PET scanner in Durham County which, according to Appendix A on page 369 of the 2025 SMFP is in HSA IV. Thus, the service area for this proposal is HSA IV. Facilities may also serve residents of counties not included in their service area.

In Section C, page 33 the applicant provides historical patient origin for SFY 2024 for PET services at DUH, as illustrated in the following table:

**DUH PET Historical Patient Origin SFY 2024**

<b>County</b>	<b># Patients</b>	<b>% of Total</b>
Durham	1,627	19.8%
Wake	1,229	15.0%
Orange	372	4.5%
Granville	318	3.9%
Cumberland	271	3.3%
Alamance	269	3.3%
Person	252	3.1%
Guilford	228	2.8%
Vance	184	2.2%
New Hanover	134	1.6%
Brunswick	126	1.5%
Franklin	99	1.2%
Moore	85	1.0%
Mecklenburg	76	0.9%
Chatham	75	0.9%
Other NC Counties	1,712	20.9%
VA	597	7.3%
SC	244	3.0%
All Other	313	3.8%
<b>Total</b>	<b>8,211</b>	<b>100.0%</b>

In Section C, page 35 the applicant provides projected patient origin for the first three years of operation, SFYs 2027-2029, for the proposed fixed PET scanner as illustrated in the following table:

**DUH Projected Patient Origin, PET Services, First Three Project Years**

County	1 <sup>st</sup> PY (SFY 2030)		2 <sup>nd</sup> PY (SFY 2031)		3 <sup>rd</sup> PY (SFY 2032)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	1,778	19.8%	1,831	19.8%	1,886	19.8%
Wake	1,343	15.0%	1,383	15.0%	1,425	15.0%
Orange	406	4.5%	419	4.5%	431	4.5%
Granville	347	3.9%	358	3.9%	369	3.9%
Cumberland	296	3.3%	305	3.3%	314	3.3%
Alamance	294	3.3%	303	3.3%	312	3.3%
Person	275	3.1%	284	3.1%	292	3.1%
Guilford	249	2.8%	257	2.8%	264	2.8%
Vance	201	2.2%	207	2.2%	213	2.2%
New Hanover	146	1.6%	151	1.6%	155	1.6%
Brunswick	138	1.5%	142	1.5%	146	1.5%
Franklin	108	1.2%	111	1.2%	115	1.2%
Moore	93	1.0%	96	1.0%	99	1.0%
Mecklenburg	83	0.9%	86	0.9%	88	0.9%
Chatham	82	0.9%	84	0.9%	87	0.9%
Other NC	1,871	20.9%	1,927	20.9%	1,985	20.9%
VA	652	7.3%	672	7.3%	692	7.3%
SC	267	3.0%	275	3.0%	283	3.0%
All Other	342	3.8%	352	3.8%	363	3.8%
<b>Total</b>	<b>8,972</b>	<b>100.0%</b>	<b>9,242</b>	<b>100.0%</b>	<b>9,519</b>	<b>100.0%</b>

In Section C, page 34, the applicant provides the assumptions and methodology used to project its patient origin, which it states is based on FY 2024 historical patient origin for DUH. The applicant provides detailed assumptions in Section Q. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C, pages 37-41 the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- Need in the 2025 SMFP for two fixed PET scanners in HSA IV, and the many applications of PET technology in disease diagnosis (pages 37-38).
- *High and increasing utilization of DUHS PET-CT scanners* – The applicant states the PET volume documented in the 2025 SMFP shows that DUH is the most highly utilized PET service in the state. During the reporting period for the 2025 SMFP (2022-2023), DUH operated two PET scanners, and added a third in 2021. Volumes have continued to grow even with three PET scanners, and patients in need of PET-CT services who seek those services at DUH continue to experience long wait times, necessitating this application for an additional PET-CT scanner at DUH (pages 38-39).
- *Population growth and aging in the service area* – The applicant cites data from the NCOSBM that indicates the counties within HSA IV are projected to increase from

2020-2030. Similarly, population growth in the state as a whole is projected to increase during the same time. Population growth in five of the 11 counties that comprise HSA IV will also increase between 2024-2029. As the population ages, the incidence of disease such as cancer increases, substantiating the continued demand for PET-CT services (pages 39-40).

- *Strength and growth of DUHS provider network* – The applicant states DUHS has a growing provider network across multiple specialties. The Duke Cancer Institute providers treat 40,000 new patients each year, and PET-CT technology is critical to cancer detection and diagnosis (pages 40-41).

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2025 SMFP for two additional PET scanners in HSA IV, which includes Wake County.
- The applicant provides data to illustrate the increasing demand for PET services in the service area.
- The applicant provides information to support the need for a fixed PET scanner at DUH.

### **Projected Utilization**

In Section Q, Form C.2a, the applicant provides the combined projected utilization for the proposed fixed PET scanner and the three existing DUH PET scanners, as shown in the following table:

DUKE UNIVERSITY HOSPITAL	PARTIAL FY SFY 2026	1 <sup>ST</sup> FULL FY SFY 2027	2 <sup>ND</sup> FULL FY SFY 2028	3 <sup>RD</sup> FULL FY SFY 2029
# PET Scanners	4	4	4	4
# PET Procedures	8,711	8,972	9,242	9,519
# CT Procedures on PET	2,785	2,868	2,954	3,043

Source: Application Section Q, Form C.2a, page 3.

In Section Q, “*Form C Assumptions*”, pages 93-94, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

- *Historical DUHS PET-CT Volumes* – The applicant states future PET volumes are based on FY 2024 volume for all DUHS facilities. PET volume at DUH increased by a CAGR of 15% between 2021-2024, and DUHS total PET volume increased by 16% during the same time. The applicant states these volumes continued to increase even on three fixed PET scanners (page 93).
- The applicant projects future PET volume based on a 3% growth in PET procedures, based on analytics data it consulted, to be conservative. The applicant states that DUHS’s 2024 volume would warrant five fixed PET scanners without any additional growth. The applicant states all of its PET scanners would be utilized above the

performance standard requirements beginning in 2025 (pages 93-94).

Projected utilization is reasonable and adequately supported based on the following:

- The applicant makes reasonable and adequately supported assumptions regarding projected PET utilization based on population growth projections and its own PET utilization.
- The applicant makes reasonable and adequately supported assumptions regarding disease incidence in the service area and the need that population has for fixed PET services.

### **Access to Medically Underserved Groups**

In Section C.6, page 46, the applicant states:

*“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will have access to this service, as clinically appropriate. DUHS does not and will not discriminate based on race, ethnicity, age, gender, or disability.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from Section C, page 47:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons*	15.5%
Racial and ethnic minorities*	38.3%
Women	60.0%
Persons with Disabilities*	--
Persons 65 and older	37.1%
Medicare beneficiaries	40.3%
Medicaid recipients	12.2%

\*The applicant states it does not maintain data on the number of disabled persons it serves.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents projected access to PET services at DUH for all residents of the service area, including underserved groups.
- The applicant’s projected payor mix includes underserved groups as listed above.

### **Conclusion**

The agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to Comments

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12611-25 / Raleigh PET** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Patient Origin**

In Section C, page 37 the applicant states Raleigh PET is not an existing facility; therefore, there is no historical patient origin to report.

In Section C, page 38 the applicant provides projected patient origin for the first three years of operation, FFYs 2028-2030, for the proposed fixed PET scanner as illustrated in the following table:

**Raleigh PET Projected Patient Origin, PET Services, First Three Project Years**

County	1 <sup>st</sup> PY (FFY 2028)		2 <sup>nd</sup> PY (FFY 2029)		3 <sup>rd</sup> PY (FFY 2030)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Chatham	9	0.7%	12	0.7%	16	0.7%
Durham	38	3.0%	48	2.9%	65	2.9%
Franklin	39	3.0%	50	3.1%	68	3.1%
Granville	11	0.9%	18	1.1%	24	1.1%
Harnett	67	5.2%	84	5.1%	113	5.1%
Johnston	163	12.7%	208	12.7%	283	12.7%
Lee	15	1.2%	19	1.2%	26	1.2%
Nash	42	3.3%	53	3.2%	71	3.2%
Orange	8	0.6%	11	0.7%	14	0.6%
Person	2	0.2%	3	0.2%	4	0.2%
Vance	9	0.7%	11	0.7%	14	0.6%
Wake	774	60.03%	986	60.2%	1,339	60.3%
Warren	1	0.1%	1	0.1%	2	0.1%
Other	106	8.3%	135	8.2%	183	8.2%
<b>Total</b>	<b>1,284</b>	<b>100.0%</b>	<b>1,639</b>	<b>100.0%</b>	<b>2,222</b>	<b>100.0%</b>

In Section Q, *Raleigh PET, LLC Patient Need and Utilization Methodology*, the applicant provides the assumptions and methodology used to project its patient origin, which is based on historical PET utilization in the service area. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**



In Section C, pages 41-45 the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- *Population and strained capacity of HSA IV PET scanners* – The applicant examines the need methodology in the 2025 SMFP for fixed PET scanners and states the actual need for fixed PET services in the service area is actually greater than what the 2025 SMFP determined (pages 41-43).
- *PET scanner use rates* – The applicant examined fixed PET use rates in the state and in HSA IV and suggested that access plays a key role in utilization, perhaps more than age, based on data from the DHSR patient origin database for PET scans and population statistics from the NCOSBM. Additionally, the applicant states improved treatment plans and technology contribute to increased demand and wait times are high, supporting the need for additional fixed PET capacity (pages 43-44).
- *Tertiary care and WakeMed Raleigh patient care deficit* – The applicant states that WakeMed is the only specialized tertiary care hospital in HSA IV, treating cancer, cardiac and vascular patients; yet WakeMed does not have a fixed PET scanner on or near its campus (page 45).
- *Limited freestanding PET scanners* – The applicant states that most PET scans involve outpatients, yet HSA IV only has one existing freestanding fixed PET scanner. The applicant proposes a freestanding fixed PET scanner that will offer lower cost procedures for patients and payors (page 45).

The information is reasonable and adequately supported based on the following:

- There is a need determination in the 2025 SMFP for two additional PET scanners in HSA IV, which includes Wake County.
- The applicant provides data to illustrate the increasing demand for PET services in the service area.
- The applicant provides information to support the need for a fixed PET scanner at Raleigh PET, LLC.

### **Projected Utilization**

In Section Q, Form C.2a, the applicant provides projected utilization for the proposed fixed PET scanner, as shown in the following table:

RALEIGH PET, LLC	1 <sup>ST</sup> FULL FY FFY 2028	2 <sup>ND</sup> FULL FY FFY 2029	3 <sup>RD</sup> FULL FY FFY 2030
# PET Scanners	1	1	1
# Procedures	1,284	1,639	2,222

Source: Application Section Q, Form C.2a, page 1.

In Section Q, “*Raleigh PET, LLC Patient Need and Utilization Methodology*”, pages 114-128, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

- *Step 1: Determine Raleigh PET’s fiscal year* – The applicant states its FY is consistent with the FFY, from October to September. The applicant projects that the proposed fixed PET scanner will begin operating in FY 2028; therefore, the first three project years are FFY 2028-2030 (page 115).
- *Step 2: Identify Raleigh PET, LLC’s service area* - The applicant states utilization of the existing fixed PET scanner of which WakeMed owns 51% served patients from the 11 counties that comprise HSA IV and two contiguous counties: Harnett and Nash. The applicant defines its “*primary service area*” (“PSA”) as HSA IV and the two contiguous counties (page 115).
- *Step 3: Identify the population of the PSA* – The applicant examined data from the NCOSBM that shows the population of the 13 counties included in the applicant’s PSA is projected to increase by a CAGR of 1.66% from FY 2024-2030 (page 116).
- *Step 4: Estimate the need for PET services per 1,000 population in the PSA* – Based on data from the DHSR website and the NCOSBM, the applicant states statewide PET utilization increased between FY 2021-2023 and states the use rate per 1,000 population in FY 2023 was 7.14. The applicant opted to utilize one single use rate to project demand for PET services based on the FY 2023 use rate increased by one-third ( $7.14 \times 1.33 = 9.50$ ). The applicant states historical utilization and use rates support this growth factor (pages 117-118).
- *Step 5: Estimate annual PSA PET procedures needed FY 2024-2030* – The applicant’s experience with similar projects indicates volume increases in project years two and three. Therefore, the applicant applied the historical HSA IV CAGR for PET services to the project year one projected volume to project utilization in project years two and three (page 4).
- *Step 6: Estimate the PSA PET Procedure Use Rates per 1,000 Population, FY 2024-FY 2030* – The applicant assumes a PET use rate in the service area of 8.93 per 1,000 residents from FY 2027 through FY 2030 based on historical data. The applicant projects a gradual increase in use rates between FY 2024 and FY 2027 and then holds that rate constant through the third project year, FY 2030 (page 120)
- *Step 7: Estimate Annual PET Patient Utilization in PSA, FY 2024-FY 2030* – The applicant estimated annual PET utilization in the service area by multiplying projected populations from Step 3 by the use rates in Step 6, and divide by 1,000 (page 121).
- *Step 8: Estimate Raleigh PET Market Share of PET Patients, FY 2028-FY 2030* – The applicant assigned a different market share value to each of the counties within HSA

IV based on historical utilization data. The applicant multiplies the PSA county's projected utilization from Step 7 by the market share from Step 8 to estimate the number of patients who will be served in Project Years 1-3 (pages 122-124).

- *Step 9: Calculate Raleigh PET In-migration and Total Patients* – The applicant examined historical immigration rates from its other free-standing fixed PET scanner in the service area (210 PET Imaging) and calculated an 8.2% five-year average immigration rate from service area counties and counties outside the service area. The applicant assumes its immigration rate will equal the historical average (page 125).
- *Step 10: Estimate Patients To Be Served by 210 PET Imaging, FY 2025-FY 2030* – The applicant applies utilization of the fixed PET scanner at 210 PET Imaging assuming PET utilization will increase by 20% of the historical CAGR by county in HSA IV (pages 126-127).
- *Step 11: Performance Standard Threshold Test* – The applicant applied Steps 1-10 to project the number of PET scans at 210 PET Imaging and Raleigh PET LLC for FY 2025 through FY 2030 to illustrate the two fixed PET scanners will meet the Performance Standard set forth in 10A NCAC 14C .3703(a)(7) (pages 127-128).

Projected utilization is reasonable and adequately supported based on following:

- The applicant makes reasonable and adequately supported assumptions regarding projected PET utilization based on documented population data, statewide PET use rates, and HSA IV historical PET utilization.
- The applicant makes reasonable and adequately supported assumptions regarding disease incidence in the service area and the need that population has for healthcare, including fixed PET services.

### **Access to Medically Underserved Groups**

In Section C.6, page 50, the applicant states:

*“Raleigh PET is wholly owned by WakeMed. All WakeMed facilities utilize the same policies and procedures with respect to access to care for all patients, including medically underserved patients.*

...

*The policies apply irrespective of a patient's residential address. As a private, not-for-profit hospital system, WakeMed applies the policies to ensure access to health care services, regardless of income, payer status, gender, sexual orientation, race, ethnicity, culture, disability, or age.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table from Section C, page 52:

MEDICALLY UNDERSERVED GROUPS	PERCENT OF TOTAL PATIENTS
Low Income Persons	10.9%
Racial and ethnic minorities	46.2%
Women	62.3%
Persons with Disabilities	11.2%
Persons 65 and older	47.6%
Medicare beneficiaries	47.6%
Medicaid recipients	7.4%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents projected access to PET services at Raleigh PET for all residents of the service area, including underserved groups.
- The applicant's projected payor mix includes underserved groups as listed above.

### **Conclusion**

The agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to Comments

Based on the review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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, persons with disabilities, and other underserved groups and the elderly to obtain needed health care.

NA – All Applications

None of the applicants in this review proposes to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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.

### C – All Applications

**Project ID #J-12593-25 DDI** - The applicant proposes to acquire one fixed PET scanner to be located at DDI.

In Section E, pages 78-79, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states the demand for fixed PET services in HSA IV is significant, as demonstrated by the need in the 2025 SMFP for two fixed PET scanners in HSA IV. Therefore, the applicant states this is not an effective alternative because it fails to provide service area residents with an opportunity to receive fixed PET services from a new freestanding provider.
- Utilize mobile PET services – The applicant states available capacity of mobile PET scanners across the state is lacking. The applicant states demand for fixed capacity is evident in the 2025 SMFP need determination in the service area. Thus, providing fractional capacity with mobile PET services is not a reasonable alternative to serve existing and future demand for PET services in the service area.
- Develop fixed PET services at another location – The applicant considered the dynamics of the counties in HSA IV in which fixed PET scanners are currently located and determined that DDI's existing location in Durham County would be offer service area residents a choice of fixed PET services providers in HSA IV. Thus, another location for the proposed fixed PET scanner was not considered an effective alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional fixed PET scanner in HSA IV.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Response to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

**Project ID #J-12595-25 UNC Medical Center** - The applicant proposes to acquire one fixed PET scanner at UNC Medical Center.

In Section E, pages 84-85, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states maintaining the status quo is not an effective alternative because the current capacity at UNCH outpaces fixed PET scanner capacity. Given current demand and projected population growth in the service area, maintaining the status quo would result in patient treatment delays that are not only inconvenient, but also stressful to patients who would be forced to delay diagnosis and treatment options. Thus, this is not an effective alternative to meet the need for additional fixed PET services in the service area.
- Develop the proposed fixed PET scanner at another location – The applicant states locating the proposed fixed PET scanner at an alternate location would be more costly and would fail to address the high utilization of existing fixed PET services at the cancer hospital. Additionally, another location would require costly renovation or new construction. Thus, locating the fixed PET scanner at another location is not an effective alternative.
- Utilize mobile PET services – The applicant states it considered contracting for mobile PET services, but states that is not an effective long-term solution for existing and future demand in the service area for fixed PET services.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional fixed PET scanner in HSA IV.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Response to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

**Project ID #J-12598-25 / AUNC** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP at RPI.

In Section E, pages 85-86, the applicant states the only alternatives it considered involved the location of the proposed fixed PET scanner. The applicant states there are two locations the applicant considered: the Raleigh location at a physician office in Medical Park 2, and a Cary location. The reasons the proposed location was chosen included the following considerations:

- HSA IV Accessibility – The applicant states the proposed Raleigh location avoids congestion and accessibility issues that would be present at the Cary location, since major thoroughfares in the Cary/Apex area are heavily traveled and are planned for construction improvement, which would create accessibility issues for patients seeking PET services.
- Cost efficiency and resource utilization – The applicant states the Cary location would require new construction to create space to accommodate the proposed fixed PET scanner, which would be more costly than the renovation needed at the Raleigh location. Thus, locating the fixed PET scanner at another location is not an effective alternative.

On page 85, the applicant states the proposed Raleigh location is the most effective alternative to effectively meet patient demand for fixed PET services.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional fixed PET scanner in HSA IV.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

**Project ID #J-12602-25 WR Imaging-Garner** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section E, pages 77-79, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states maintaining the status quo is not an effective alternative to meet the identified need for a fixed PET scanner in HSA IV, because a mobile unit would require patients to wait outside for PET scans and would be available on a limited basis, both of which are inconvenient for patients and do not present a long-term solution for access to fixed PET services.
- Develop the proposed fixed PET scanner at a different location – The applicant states the existing fixed PET scanners in HSA IV are concentrated in the central and western portions of HSA IV, leaving the eastern portion of the service area underserved. The applicant states the eastern portion of the service area is projected to increase exponentially, and the applicant's imaging center in Garner is an ideal location from which to offer fixed PET services to those patients who live east and south of the existing fixed PET scanners in HSA IV. Additionally, the cost associated with the renovation to accommodate the proposed fixed PET scanner is lower than new construction. Thus, locating the fixed PET scanner at another location is not an effective alternative.

On page 80, the applicant states the proposed Garner location is the most effective alternative to effectively meet patient demand for fixed PET services.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional fixed PET scanner in HSA IV.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments



- Response to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

**Project ID #J-12607-25 / Duke Cary Hospital** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section E, pages 62-63, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – DUHS currently operates a total of four fixed PET scanners. The applicant states maintaining the status quo is not an effective alternative to meet current and projected demand for fixed PET services in HSA IV. The applicant states that, even without any additional growth, current utilization is sufficient to justify 5 fixed PET scanners under the applicable performance standards. Thus, maintaining the status quo would not be sufficient to even meet current demand and was determined not to be an effective alternative.
- Develop the proposed fixed PET scanner at a different location – The applicant considered locating the proposed fixed PET scanner at Duke Raleigh Hospital, which currently operates one fixed PET scanner (Duke University Hospital operates three fixed PET scanners). The applicant states the Cary hospital campus location will increase patient choice and coordination of care with other services to be located on that campus. The applicant states it considered a freestanding location, but determined that would not serve inpatients, and would not provide the same range of services and coordination of care that will be available on the hospital campus. Thus, the applicant determined that Duke Cary Hospital was a more effective location than Duke Raleigh Hospital or another location.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional fixed PET scanner in HSA IV.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Response to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

**Project ID #J-12610-25 / Duke University Hospital** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section E, pages 57-58, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – DUHS currently operates a total of four fixed PET scanners: three at DUH and one at Duke Raleigh Hospital. The applicant states maintaining the status quo is not an effective alternative to meet current and projected demand for fixed PET services in HSA IV. The applicant states that, even without any additional growth, current utilization is sufficient to justify 5 fixed PET scanners under the applicable performance standards. Thus, maintaining the status quo would not be sufficient to even meet current demand and was determined not to be an effective alternative.
- Develop the proposed fixed PET scanner at a different location – The applicant considered locating the proposed fixed PET scanner at Duke Raleigh Hospital and submitted a separate application to locate a fixed PET scanner at Duke Cary Hospital. The applicant states it considered a freestanding location, but determined that would not serve inpatients, and would not provide the same range of services and coordination of care that will be available on the hospital campus. Thus, the applicant determined that DUH was a more effective location than Duke Raleigh Hospital or another location.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional fixed PET scanner in HSA IV.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Response to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

**Project ID #J-12611-25 Raleigh PET** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section E, pages 61-62, the applicant states there is no alternative method that would meet the needs of the proposed project. The applicant states the WakeMed Raleigh campus is adjacent to Raleigh PET, and thus is the most effective location to serve current and future patients. Additionally, the applicant states there is only one freestanding (non-hospital based) fixed PET scanner in HSA IV. By offering fixed PET services in a freestanding facility, the applicant states it would offer patients who need PET services a lower-cost option for those services.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative to meet the need for an additional fixed PET scanner in HSA IV.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

**Project ID #J-12593-25 DDI** - The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

**Capital and Working Capital Costs**

In Section Q, Form F.1a the applicant projects the total capital cost of the project, as shown in the table below:

Durham Diagnostic Imaging Capital Cost	
Construction/Renovation	\$645,647
Medical Equipment	\$2,883,582
Construction Contingency	\$40,000
Miscellaneous Costs	\$87,000
<b>Total</b>	<b>\$3,656,229</b>

In Section F.3, page 82, the applicant states there are no start-up costs or initial operating expenses associated with the project because DDI is an existing outpatient diagnostic center.

In Section Q, at the bottom of Form F.1a, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant bases cost of construction, medical and other equipment acquisition and miscellaneous project costs on vendor quotations.
- The applicant provides copies of those vendor quotes in Exhibit F.1 that confirms the quoted costs.

**Availability of Funds**

In Section F, page 80 the applicant states that the capital cost will be funded with the accumulated reserves of Novant Health. In Exhibit F.2 the applicant provides a February 6, 2025 letter signed by the Senior Vice President, Operational Finance and Revenue Cycle for Novant Health, Inc. that confirms the availability of sufficient accumulated reserves for the project costs and commits the funds to the project. Exhibit F.2 also provides the audited financial statements of Novant Health, Inc. and Affiliates for the year ending December 31, 2023 that shows \$10.8 billion in total current assets.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate official confirming the availability of the funding proposed for the capital and working capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of sufficient accumulated reserves to fund the capital and working capital needs of the project.

### **Financial Feasibility**

In Section Q, Form F.2b, the applicant provides pro forma financial statements for the proposed fixed PET scanner at DDI for the first three fiscal years of operation following project completion. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full FYs, FFYs 2027-2029 as shown in the following table:

DDI	1 <sup>ST</sup> FULL FY (FFY 2027)	2 <sup>ND</sup> FULL FY (FFY 2028)	3 <sup>RD</sup> FULL FY (FFY 2029)
Total Scans (Form C)	2,000	2,398	2,875
Total Gross Revenue PET Services	\$12,828,251	\$15,381,073	\$18,440,611
Total Net Revenue	\$4,579,686	\$5,491,043	\$6,538,298
Average Net Revenue per Scan	\$2,290	\$2,290	\$2,274
Total Operating Expenses PET Service	\$3,072,919	\$3,720,505	\$4,199,934
Average Operating Expense per Scan	\$1,536	\$1,552	\$1,461
Net Income	\$1,506,767	\$1,770,538	\$2,338,364

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

**Project ID #J-12595-25 UNC Medical Center** - The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below.

<b>UNC Capital Cost</b>	
Construction/Renovation	\$683,100
Medical Equipment	\$3,334,368
Miscellaneous Costs	\$242,055
<b>Total</b>	<b>\$4,259,523</b>

In Section F.3, page 88, the applicant states there are no start-up costs or initial operating expenses associated with the project because the project does not involve a new facility.

In Section Q, page 135 the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant bases cost of construction, architect and engineering fees on the project architect's and the applicant's experience with similar projects.
- Medical equipment costs are based on vendor estimates and the applicant's experience with similar projects.
- Other project costs such as contingencies are based on the applicant's experience with similar projects.

### **Availability of Funds**

In Section F.2, page 86, the applicant states that the capital cost will be funded with the accumulated reserves of UNC Hospitals.

In Exhibit F.2-1 the applicant provides a February 17, 2025 letter signed by the Chief Financial Officer, UNC Hospitals, that documents the availability of sufficient funds to cover the capital cost of the project and commits the funds to the project if approved. In Exhibit F.2-1 the applicant provided consolidated balance sheet copies for UNC Hospitals for the year ending June 30, 2024 which showed UNC Hospitals had total assets of \$5.2 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate UNC Hospitals official confirming the availability of sufficient funding proposed for the project capital needs and the commitment to use those funds to develop the proposed project.
- The applicant provides documentation of sufficient accumulated reserves/current assets to fund the project capital needs.
- The applicant provided documentation that commits those funds to project development.

### **Financial Feasibility**

In Section Q, Form F.2b the applicant provides pro forma financial statements for the first three full fiscal years of operation following project completion, SFY 2027-2029 for fixed PET services at UNC Medical Center. In Form F.2b, page 137 the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the following table:

**UNC Medical Center Fixed PET Financial Projections, First Three Project Years**

	<b>1<sup>ST</sup> FULL FISCAL YEAR (SFY 2027)</b>	<b>2<sup>ND</sup> FULL FISCAL YEAR (SFY 2028)</b>	<b>3<sup>RD</sup> FULL FISCAL YEAR (SFY 2029)</b>
Total Scans (Form C.1b)	5,098	5,480	5,890
Total Gross Revenues (Charges)	\$48,677,929	\$53,888,065	\$59,655,858
Total Net Revenue	\$15,363,514	\$17,007,915	\$18,828,858
Average Net Revenue per Scan	\$3,014	\$3,104	\$3,197
Total Operating Expenses (Costs)	\$11,609,168	\$14,778,129	\$14,014,596
Average Operating Expense per Scan	\$2,277	\$2,332	\$2,379
Net Income	\$3,754,346	\$4,229,786	\$4,813,724

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

**Project ID #J-12598-25 / AUNC** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

#### **Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below.

<b>AUNC Capital Cost</b>	
Construction/Renovation	\$1,231,000
Medical Equipment	\$1,587,200
Miscellaneous Costs	\$284,050
<b>Total</b>	<b>\$3,102,250</b>

In Section Q, Form F.1a, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant bases cost of construction, architect and engineering fees on the project architect's and the applicant's experience with similar projects.
- Medical equipment costs are based on vendor estimates and the applicant's experience with similar projects.
- Other project costs such as contingencies are based on the applicant's experience with similar projects.

In Section F.3, page 89, the applicant projects that start-up costs will be \$148,300 and initial operating expenses will be \$675,000 for a total working capital of \$823,300. On pages 89-90 the applicant provides the assumptions and methodology used to project the working capital



needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states start-up costs include salaries, benefits, supplies, rent and lease payments.
- The applicant projects positive cash flow for fixed PET services within the first project year.

### **Availability of Funds**

In Section F.2, page 87 the applicant states that the capital cost will be funded as shown in the following table:

TYPE	ASSOCIATED UROLOGISTS OF NORTH CAROLINA, P.A.	AUNC, P.A.	TOTAL
Loan	\$1,419,050	\$96,000	\$96,000
Siemens Equipment Lease	\$0	\$1,587,200	\$1,587,200
<b>Total</b>	<b>\$1,419,050</b>	<b>\$1,683,200</b>	<b>\$3,102,250</b>

In Section F, page 90, the applicant states that the working capital needs of the project will be funded with a loan to Associated Urologists of North Carolina, P.A.

In Exhibit F.2 the applicant provides a copy of the capital lease for the proposed fixed PET scanner and documentation of loan for the capital and working capital cost. Exhibit F.2 also provides a February 10, 2025 letter signed by the Secretary, Associated Urologists of North Carolina, P.A. that commits the funds to the project.

In Exhibit F.2 also provides documentation of a loan in the amount necessary to fund Associated Urologists of NC Properties I, LLC's portion of the project capital cost. The same exhibit also provides a February 10, 2025 letter signed by the manager of Associated Urologists of NC Properties I, LLC. that commits the loan proceeds to fund its portion of the project capital cost.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides documentation of loan commitments for Associated Urologists of North Carolina, P.A. to fund its portion of the project capital and working capital needs of the project, as well as documentation that commits the loan proceeds to project development.

- The applicant provides documentation of loan commitments for Associated Urologists of NC Properties I, LLC. to fund its portion of the project capital and working capital needs of the project, as well as documentation that commits the loan proceeds to project development.

### **Financial Feasibility**

In Section Q, Form F.2b the applicant provides pro forma financial statements for the first three full fiscal years of operation following project completion, SFY 2027-2029 for fixed PET services. The applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the following table:

**AUNC Financial Projections, First Three Project Years**

	<b>1<sup>ST</sup> FULL FISCAL YEAR (SFY 2027)</b>	<b>2<sup>ND</sup> FULL FISCAL YEAR (SFY 2028)</b>	<b>3<sup>RD</sup> FULL FISCAL YEAR (SFY 2029)</b>
Total Scans (Form C.1b)	2,123	2,434	2,646
Total Gross Revenues (Charges)	\$15,196,210	\$17,506,018	\$19,086,884
Total Net Revenue	\$13,257,870	\$15,284,243	\$16,671,884
Average Net Revenue per Scan	\$6,245	\$6,279	\$6,300
Total Operating Expenses (Costs)	\$12,490,910	\$14,156,280	\$14,767,800
Average Operating Expense per Scan	\$5,884	\$5,816	\$5,581
Net Income	\$766,960	\$1,127,963	\$1,903,322

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q following Form F.2b. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

**Project ID #J-12602-25 / WR Imaging-Garner** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below.

<b>WR Imaging-Garner Capital Cost</b>	
Construction/Renovation	\$583,000
Medical Equipment	\$2,917,402
Miscellaneous Costs	\$245,000
<b>Total</b>	<b>\$3,745,402</b>

In Section Q, Form F.1a, page 132 the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant bases cost of construction, architect and engineering fees on the project architect's and the applicant's experience with similar projects.
- Medical equipment costs are based on vendor estimates and the applicant's experience with similar projects.
- Other project costs such as contingencies are based on the applicant's experience with similar projects.

In Section F.3, page 82, the applicant projects that start-up costs will be \$25,000 and no initial operating expenses. On pages 82-83 the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states start-up costs include salaries, benefits, supplies, rent and lease payments.
- The applicant states start-up costs will be minimal because those costs will be

incorporated into an existing diagnostic center.

- The applicant projects positive cash flow for fixed PET services within the first project year.

### **Availability of Funds**

In Section F.2, page 80 the applicant states that the capital cost will be funded as shown in the following table:

TYPE	WR IMAGING-GARNER	TOTAL
Cash and Cash Equivalents	\$3,745,402	\$3,745,402
<b>Total Capital Cost</b>		<b>\$3,745,402</b>

In Section F, page 84, the applicant states that the working capital needs of the project will be funded as shown in the following table:

SOURCE	WAKE RADIOLOGY DIAGNOSTIC IMAGING, INC.	TOTAL
Cash and Cash Equivalents	\$25,000	\$25,000
<b>Total Capital Cost</b>		<b>\$25,000</b>

In Exhibit F.2 the applicant provides a February 10, 2025 letter signed by the senior vice president, First Citizens Bank, that documents the availability of sufficient funds in WR Imaging, LLC's account to fully fund the project capital cost. Exhibit F.2 also provides a February 6, 2025 letter signed by the President and managing partner of WR Imaging, LLC that commits the funds to the project.

In Exhibit F.2 the applicant provides a February 10, 2025 letter signed by the senior vice president, First Citizens Bank, that documents the availability of sufficient funds in Wake Radiology Diagnostic Imaging, Inc.'s account to fully fund the project working capital cost. Exhibit F.2 also provides a February 6, 2025 letter signed by the President and managing partner of Wake Radiology Diagnostic Imaging, Inc. that commits the funds to the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides documentation of sufficient cash reserves to fund the capital cost of the project and a commitment to use those funds for the project.
- The applicant provides documentation of sufficient cash reserves to fund the working capital cost of the project and a commitment to use those funds for the project.

### **Financial Feasibility**

In Section Q, Form F.2b the applicant provides pro forma financial statements for the first three full fiscal years of operation following project completion, FFY 2027-2029 for fixed PET services at WRI Imaging-Garner. The applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the following table:

**WR Imaging-Garner Financial Projections, First Three Project Years**

	<b>1<sup>ST</sup> FULL FISCAL YEAR (FFY 2027)</b>	<b>2<sup>ND</sup> FULL FISCAL YEAR (FFY 2028)</b>	<b>3<sup>RD</sup> FULL FISCAL YEAR (FFY 2029)</b>
Total Scans (Form C.1b)	882	1,798	2,761
Total Gross Revenues (Charges)	\$4,036,131	\$8,471,426	\$13,402,589
Total Net Revenue	\$1,214,875	\$2,549,899	\$4,034,179
Average Net Revenue per Scan	\$1,377	\$1,418	\$1,461
Total Operating Expenses (Costs)	\$1,088,707	\$1,991,840	\$2,545,335
Average Operating Expense per Scan	\$1,234	\$1,108	\$922
Net Income	\$126,168	\$558,069	\$1,488,844

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q following Form F.2b. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

**Project ID #J-12607-25 / Duke Cary Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below.

Duke Cary Hospital Capital Cost	
Construction/Renovation	\$1,821,500
Medical Equipment	\$4,641,328
Miscellaneous Costs	\$655,848
<b>Total</b>	<b>\$7,128,67</b>

In Section Q, “*Form F.1a Assumptions*”, page 108 the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant bases cost of construction on the project architect’s letter and the applicant’s experience with similar projects.
- The applicant bases architect and engineering fees on 6% of the projected construction cost.
- Medical equipment costs are based on vendor estimates and the applicant’s experience with similar projects.

In Section F.3, page 66, the applicant states the working capital costs approved in Project ID #J-12029-21 apply to this change of scope application. On page 67 the applicant states the start-up costs related to the proposed fixed PET scanner total \$55,459. The applicant projects no increase in initial operating costs; therefore, the projected working capital cost for this project is \$55,459. On pages 66-67 the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states start-up costs include salaries, benefits, supplies, and other project costs associated with the proposed fixed PET scanner.
- The applicant projects positive cash flow for fixed PET services within the first project year.

### **Availability of Funds**

In Section F.2, page 64 the applicant states that the capital cost will be funded as shown in the following table:

TYPE	DUHS	TOTAL
Cash and Cash Equivalents	\$7,128,676	\$7,128,676
<b>Total Capital Cost</b>		<b>\$7,128,676</b>

In Section F, page 84, the applicant states that the working capital needs of the project will be funded as shown in the following table:

SOURCE	DUHS	TOTAL
Cash and Cash Equivalents	\$55,549	\$55,549
<b>Total Working Capital Cost</b>		<b>\$55,549</b>

In Exhibit F.2 the applicant provides a February 6, 2025 letter signed by the Chief Financial Officer, DUHS, that documents the availability of sufficient accumulated reserves to fully fund the project capital and working capital costs and a commitment to fund the project with available assets. Exhibit F.2 also provides consolidated balance sheets for Duke University Health System, Inc. and Affiliates which show that, as of June 30, 2024, DUHS and Affiliates had total assets of \$9.3 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides documentation of sufficient accumulated reserves to fund the capital and working capital costs of the project and a commitment to use those funds for the project.

### **Financial Feasibility**

In Section Q, Form F.2b the applicant provides pro forma financial statements for the first three full fiscal years of operation following project completion, SFY 2030-2032 for fixed PET services at Duke Cary Hospital. The applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the following table:

<b>Duke Cary Hospital Financial Projections, PET Services, First Three Project Years</b>			
	<b>1<sup>ST</sup> FULL FISCAL YEAR (SFY 2030)</b>	<b>2<sup>ND</sup> FULL FISCAL YEAR (SFY 2031)</b>	<b>3<sup>RD</sup> FULL FISCAL YEAR (SFY 2032)</b>
Total Scans (Form C.2a)	1,660	1,899	2,150
Total Gross Revenues (Charges)	\$20,007,988	\$22,888,657	\$25,913,961
Total Net Revenue	\$6,253,997	\$7,386,840	\$8,635,601
Average Net Revenue per Scan	\$3,767	\$3,890	\$4,017
Total Operating Expenses (Costs)	\$4,546,321	\$5,124,046	\$5,720,308
Average Operating Expense per Scan	\$2,739	\$2,698	\$2,661
Net Income	\$1,707,676	\$2,262,794	\$2,915,293

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q following Form F.2b. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

**Project ID #J-12610-25 / Duke University Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below:

Duke University Hospital Capital Cost	
Contingency	\$500,00
<b>Total</b>	<b>\$500,00</b>



In Section Q, page 95 the applicant provides the assumptions used to project capital and working capital costs. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states DUHS has allocated a budget of \$500,000 in the event there are minor upfits or repairs identified during the first project year that would otherwise require a cost overrun application.

In Section F.3, page 61, the applicant states the project will involve \$26,080 in start-up costs. On page 61 the applicant states the project will add equipment to an existing service and thus will not incur operating expenses; therefore, the total working capital cost is \$26,080. On page 62 the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states start-up costs include wages, staff benefits and contingency costs associated with developing the proposed fixed PET scanner.
- The applicant projects positive cash flow for fixed PET services within the first project year, since the hospital currently provides fixed PET services.

### **Availability of Funds**

In Section F.2, page 59 the applicant states that the capital cost will be funded as shown in the following table:

TYPE	DUHS, INC.	TOTAL
Cash and Cash Equivalents	\$500,000	\$500,000
<b>Total Capital Cost</b>		<b>\$500,000</b>

In Section F.3, page 62, the applicant states that the working capital needs of the project will be funded as shown in the following table:

SOURCE	DUHS, INC.	TOTAL
Cash and Cash Equivalents	\$26,080	\$26,080
<b>Total Capital Cost</b>		<b>\$26,080</b>

In Exhibit F.2(a) the applicant provides a February 6, 2025 letter signed by the Chief Financial Officer, DUHS, that documents the availability of sufficient accumulated reserves to fully fund the project capital and working capital costs and a commitment to fund the project with available assets. Exhibit F.2(b) provides consolidated balance sheets for Duke University Health System, Inc. and Affiliates which show that, as of June 30, 2024, DUHS and Affiliates had total assets of \$9.3 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

### **Financial Feasibility**

In Section Q, Form F.2b the applicant provides pro forma financial statements for the first three full fiscal years of operation following project completion, SFY 2027-2029 for fixed PET services at Duke University Hospital. The applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the following table:

<b>Duke University Hospital Financial Projections, PET Services, First Three Project Years</b>			
	<b>1<sup>ST</sup> FULL FISCAL YEAR (SFY 2027)</b>	<b>2<sup>ND</sup> FULL FISCAL YEAR (SFY 2028)</b>	<b>3<sup>RD</sup> FULL FISCAL YEAR (SFY 2029)</b>
Total Scans (Form C.2a)	8,972	9,242	9,519
Total Gross Revenues (Charges)	\$116,872,325	\$120,378,494	\$123,989,849
Total Net Revenue	\$29,736,974	\$31,628,229	\$33,642,562
Average Net Revenue per Scan	\$3,314	\$3,422	\$3,534
Total Operating Expenses (Costs)	\$24,967,982	\$26,141,602	\$27,416,693
Average Operating Expense per Scan	\$2,783	\$2,829	\$2,880
Net Income	\$4,768,992	\$5,486,627	\$6,225,869

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 96. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.

- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

**Project ID #J-12611-25 Raleigh PET** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project as shown in the table below:

<b>Raleigh PET, LLC Capital Cost</b>	
Construction/Renovation	\$1,418,934
Medical Equipment	\$1,822,060
Miscellaneous	\$1,017,545
<b>Total</b>	<b>\$4,258,539</b>

In Section Q the applicant provides the assumptions used to project capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The bases the cost of construction on its project architect's estimate and its experience with similar projects.
- The applicant bases medical and non-medical equipment costs on vendor quotes which are provided in Exhibit F.1.

In Section F.3, page 65, the applicant states the project will involve \$770,634 in start-up costs and \$823,362 in initial operating expenses, for a total working capital of \$1,593,993. On page 62 the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states start-up costs include two months of year one expenses, excluding depreciation.
- The applicant states initial operating expenses are based on patient expense and revenue through the first month of cumulative profitability, which is projected to occur within the first project year.

### **Availability of Funds**

In Section F.2, page 63 the applicant states that the capital cost will be funded as shown in the following table:

TYPE	RALEIGH PET, LLC	TOTAL
Cash and Cash Equivalents	\$4,258,539	\$4,258,539
<b>Total Capital Cost</b>		<b>\$4,258,539</b>

In Section F.3, page 66, the applicant states that the working capital needs of the project will be funded as shown in the following table:

SOURCE	RALEIGH PET, LLC	TOTAL
Cash and Cash Equivalents	\$823,362	\$823,362
<b>Total Capital Cost</b>		<b>\$823,362</b>

The table on page 66 includes only the initial operating costs, leaving out the start-up cost of \$770,634. In Section F, page 67 the applicant refers to Exhibit F.2 for the audited balance sheets of WakeMed to confirm the availability of sufficient cash and cash equivalents to fund the total working capital cost. The audited balance sheets in Exhibit F.2 indicate that WakeMed had over \$90 million in cash and cash equivalents as of September 30, 2024. The Project Analyst concludes that the omission of the start-up costs in the table that appears on page 66 of the application was a typographical error, and the applicant adequately demonstrates sufficient assets to fund the entire cost of the project, including working capital.

In Exhibit F.2 the applicant provides a February 10, 2025 letter signed by the Executive Vice President and Chief Financial Officer of WakeMed that documents the availability of sufficient funds to fully fund the project capital and working capital costs and commits to fund the project capital and working capital costs with available assets.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

### **Financial Feasibility**

In Section Q, Form F.2b the applicant provides pro forma financial statements for the first three full fiscal years of operation following project completion, FFY 2028-2030 for fixed PET services at Raleigh PET, LLC. The applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the following table:

**Raleigh PET, LLC Financial Feasibility, First Three Project Years**

	<b>1<sup>ST</sup> FULL FISCAL YEAR (SFY 2027)</b>	<b>2<sup>ND</sup> FULL FISCAL YEAR (SFY 2028)</b>	<b>3<sup>RD</sup> FULL FISCAL YEAR (SFY 2029)</b>
Total Scans (Form C.2a)	1,284	1,639	2,222
Total Gross Revenues (Charges)	\$15,777,860	\$20,744,322	\$28,966,871
Total Net Revenue	\$5,917,685	\$7,780,420	\$10,864,390
Average Net Revenue per Scan	\$4,069	\$4,747	\$4,889
Total Operating Expenses (Costs)	\$4,858,304	\$6,354,444	\$8,430,460
Average Operating Expense per Scan	\$3,784	\$3,877	\$3,794
Net Income	\$1,059,381	\$1,425,976	\$2,433,930

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 132. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

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

### C – All Applications

The 2025 SMFP includes a need determination for two fixed PET scanner in HSA IV.

On page 363, the 2025 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s **service area** is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original)

Each of the seven applications proposes to locate its proposed fixed PET scanner in a county which, according to Appendix A on page 369 of the 2025 SMFP is in HSA IV. Thus, the service area for all proposals is HSA IV. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing dedicated fixed PET scanners in HSA IV, and the number of procedures for each PET scanner in 2022-2023 as found in Table 15F-1 on page 365 of the 2025 SMFP:

Fixed PET Scanners HSA IV		
SITE/PROVIDER	# SCANNERS	TOTAL PROCEDURES 2022-2023
Duke Raleigh Hospital	1	2,002
Duke University Hospital	3	7,442
Rex Hospital	2	4,772
University of North Carolina Hospitals*	1	5,375
Wake PET Services	1	1,660
<b>Total HSA IV fixed PET scanners / Procedures</b>	<b>8</b>	<b>21,251</b>

\*The 2025 SMFP indicates a total of two fixed PET scanners in the UNC inventory; however, that total is inaccurate. UNC is approved for a total of three fixed PET scanners, two of which are excluded from the planning inventory because they were approved pursuant to Policy AC-3. The applicant provides correspondence from the DHSR Healthcare Planning Section in Exhibit A.5

**Project ID #J-12593-25 / DDI** - The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section G.2, page 89, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanners in the HSA IV fixed PET scanner service area. The applicant states:

*“DDI’s proposed project represent a new stage in the provision of fixed PET services in HSA IV and will not result in a duplication of existing services. DDI will acquire a state-of-the-art fixed PET/CT scanner at its existing outpatient imaging center in Durham, North Carolina. ... In HSA IV, the existing PET scanners are predominantly owned and operated by two entities, Duke and UNC. Of the nine existing PET*

*scanners, eight scanner or 89% are located within hospitals in HSA IV. ... DDI's project would provide fixed PET imaging services at a convenient outpatient setting."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2025 SMFP for two fixed PET scanners in HSA IV.
- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved fixed PET services in the HSA IV fixed PET scanner service area.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing and approved fixed PET scanners in HSA IV. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12595-25 / UNC Medical Center** - The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section G.2, pages 95-96, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanners in the HSA IV fixed PET scanner service area. The applicant states:

*"... the 2025 SMFP determined there was a need for two additional PET scanners in the service area based on a higher regular inventory of PET scanners than actually exists [see note following the table above]. ... Additionally, ... UNC hospitals is the only state-owned teaching hospital in North Carolina as well as the only public NCI-Designated Comprehensive Cancer Center in North Carolina. As such, it is essential that UNC Hospitals have adequate resources and capacity."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2025 SMFP for two fixed PET scanners in HSA IV.
- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved fixed PET services in the HSA IV fixed PET scanner service area.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing and approved fixed PET scanners. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12598-25 / AUNC** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section G.2, page 97, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanners in the HSA IV fixed PET scanner service area. The applicant states:

*The demand for PET imaging services in HSA IV is growing due to population increases, advancements in PET imaging technology, and expanded clinical indications for its use. AUNC's proposal to operate a PET scanner in Wake County aims to address the rising need while offering a more accessible and cost-effective option for patients.*

*The existing PET service providers listed in the tables in Section G.1.b. perform thousands of PET scans annually, which indicates substantial demand and is further supported by the 2025 SMFP's need determination for two (2) PET scanners in HSA IV."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2025 SMFP for two fixed PET scanners in HSA IV.



- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved fixed PET services in the HSA IV fixed PET scanner service area.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing and approved fixed PET scanners. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12602-25 / WR Imaging-Garner** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section G.2, pages 90-91, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanners in the HSA IV fixed PET scanner service area. On page 90 the applicant states:

*The 2025 SMFP has identified a need for two additional fixed PET scanner in the multi-county service area because PET utilization in the service area is projected to exceed the capacity of the existing and approved providers.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2025 SMFP for two fixed PET scanners in HSA IV.
- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved fixed PET services in the HSA IV fixed PET scanner service area.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing and approved fixed PET scanners. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12607-25 / Duke Cary Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section G.2, page 73, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanners in the HSA IV fixed PET scanner service area. The applicant states:

*“Duke Raleigh Hospital’s scanner operated at a utilization greater than 80% in FY 2024. DUHS projects that it will fully utilize all existing and proposed equipment based on continued growth and without assuming any shift in utilization from other providers. This project will add capacity that will ameliorate scheduling constraints for patients seeking DUHS care. It is therefore not unnecessarily duplicating any existing or approved health service facilities in HSA IV.*

*In addition, the new location will increase geographic access. It is approximately 10 miles from the closest PET scanner in the health service area, will be located in a fast growing and populous part of Wake County, and will increase convenience for patients from that part of the health service area.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2025 SMFP for two fixed PET scanners in HSA IV.
- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved fixed PET services in the HSA IV fixed PET scanner service area.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing and approved fixed PET scanners. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12610-25 / Duke University Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section G.2, page 68, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanners in the HSA IV fixed PET scanner service area. The applicant states:

*“DUHS’s utilization growth since the time period reflected demonstrates even more urgently the need for additional capacity. DUHS’s current utilization would justify 5 PET scanners without any additional growth under the applicable performance thresholds. This project is designed to immediately address capacity constraints driven by existing utilization and conservative growth projections, which will mitigate scheduling challenges for the current patient population. It is therefore not unnecessarily duplicating any existing or approved health service facilities in HSA IV.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2025 SMFP for two fixed PET scanners in HSA IV.
- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved fixed PET services in the HSA IV fixed PET scanner service area.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing and approved fixed PET scanners. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

**Project ID #J-12611-25 / Raleigh PET** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section G.2, page 73, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed PET scanners in the HSA IV fixed PET scanner service area. The applicant states:

*“... this project is in response to the need determination the 2025 SMFP for two PET scanners in HSA IV. That need is based on capacity and utilization of existing providers in FY 2023. The methodology is conservative and does not account for the fact that in 2023, three PET scanners in HSA IV operated above 80 percent occupancy. The population is growing and PET use rates per 1,000 residents are increasing throughout the HSA.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2025 SMFP for one fixed PET scanner in HSA IV.
- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved fixed PET services in the HSA IV fixed PET scanner service area.
- The applicant adequately demonstrates that the proposed fixed PET scanner is needed in addition to the existing and approved fixed PET scanners. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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.

## C – All Applications

**Project ID #J-12593-25 / DDI** - The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for DDI's imaging services in each of the first three project years, FFYs 2027-2029, as shown in the following table:

POSITION	1 <sup>ST</sup> FULL FY (FFY 2027)	2 <sup>ND</sup> FULL FY (FFY 2028)	3 <sup>RD</sup> FULL FY (FFY 2029)
Lead Tech	1.0	1.0	1.0
CT Tech	1.0	1.0	1.0
MRI Tech	1.0	1.0	1.0
Mammography Tech	3.1	3.1	3.1
Multimodality Tech	4.2	4.2	4.2
Ultrasound Tech	2.2	2.2	2.2
X Ray Tech	1.0	1.0	1.0
PET CT Tech	2.0	2.0	2.0
Patient Coordinator	6.0	6.0	6.0
Patient Insurance Navigator	2.0	2.0	2.0
Technical Assistant	3.0	3.0	3.0
Radiology Sales Specialist	0.5	0.5	0.5
<b>Total</b>	<b>27.0</b>	<b>27.0</b>	<b>27.0</b>

The assumptions and methodology used to project staffing are provided in Section Q following Form H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In F.2, pages 91-92, the applicant describes the methods used to recruit or fill new positions and its existing and proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant does not currently offer PET/CT services and states it will add 2.0 FTE PET/CT Techs and 1 FTE Tech Assistant to accommodate the addition of fixed PET services.
- The applicant's projections for FTEs are based on its own experience with recruiting and hiring staff at other Novant Health facilities.
- The applicant will offer new training for staff that includes computer and software skills, HIPPA requirements,, and additional continuing education opportunities.

**Conclusion** – The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons described above.

**Project ID #J-12595-25 UNC / Medical Center** - The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

On Form H in Section Q, page 130 the applicant projects full-time equivalent (FTE) staffing for the proposed fixed PET services in each of the first three FYs of operation, SFY 2027-2029, as illustrated in the following table:

POSITION	1 <sup>ST</sup> FULL FY (SFY 2027)	2 <sup>ND</sup> FULL FY (SFY 2028)	3 <sup>RD</sup> FULL FY (SFY 2029)
Nuclear Medicine Tech.	6.0	6.0	6.0
Registered Nurses	1.3	1.5	1.5
Administrative Specialist	1.3	1.5	1.5
<b>Total</b>	<b>8.6</b>	<b>9.0</b>	<b>9.0</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 143. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In Section F.2, pages 97-98 the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services because it is based on the applicant's experience in staffing and operating the existing fixed PET services.

**Conclusion** – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons described above.

**Project ID #J-12598-25 / AUNC** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

On Form H in Section Q, the applicant projects full-time equivalent (FTE) staffing for the proposed fixed PET services in each of the first three FYs of operation, SFY 2027-2029, as illustrated in the following table:

POSITION	1 <sup>ST</sup> FULL FY (SFY 2027)	2 <sup>ND</sup> FULL FY (SFY 2028)	3 <sup>RD</sup> FULL FY (SFY 2029)
Nuclear Medicine Tech.	2.0	2.0	2.0
Medical Assistant	2.0	2.0	2.0
<b>Total</b>	<b>4.0</b>	<b>4.0</b>	<b>4.0</b>

The assumptions and methodology used to project staffing are provided in Section Q following Form H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In Section F.2, pages 99-101 the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- Projected staffing is based on projected volumes and the staff necessary to provide the proposed fixed PET services.
- The applicant adjusts projected staff salaries and salary increases, taxes and benefits on its experience and the local market wherein the proposed fixed PET services would be offered.

**Conclusion** – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons described above.

**Project ID #J-12602-25 / WR Imaging-Garner** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

On Form H in Section Q, the applicant projects full-time equivalent (FTE) staffing for the proposed fixed PET services in each of the first three FYs of operation, FFY 2027-2029, as illustrated in the following table:

POSITION	1 <sup>ST</sup> FULL FY (FFY 2027)	2 <sup>ND</sup> FULL FY (FFY 2028)	3 <sup>RD</sup> FULL FY (FFY 2029)
Nuclear Medicine Tech.	1.0	2.0	2.0
<b>Total</b>	<b>1.0</b>	<b>2.0</b>	<b>2.0</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 134. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In Section F.2, pages 92-93 the applicant describes the methods used to recruit or fill new positions and its existing and proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant states projected staffing reflects estimated full-time staffing equivalents necessary to provide services based on expected volume.
- The applicant states minimal staffing for the proposed fixed PET services is required because those services would be developed in an existing diagnostic center that is currently staffed.

**Conclusion** – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons described above.

**Project ID #J-12607-25 / Duke Cary Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

On Form H in Section Q, the applicant projects full-time equivalent (FTE) staffing for the proposed fixed PET services in each of the first three FYs of operation, SFY 2030-2032, as illustrated in the following table:

POSITION	1 <sup>ST</sup> FULL FY (SFY 2030)	2 <sup>ND</sup> FULL FY (SFY 2031)	3 <sup>RD</sup> FULL FY (SFY 2032)
Nuclear Medicine Tech.	2.80	2.80	2.80
Physicians Assistant	1.12	1.12	1.12
Clinical Nurse II	0.56	0.56	0.56
Financial Care Counselor	0.22	0.22	0.22
<b>Total</b>	<b>4.70</b>	<b>4.70</b>	<b>4.70</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 111. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In Section F.2, pages 75-77 the applicant describes the methods used to recruit or fill new positions and its existing and proposed training and continuing education programs.



The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant states FTEs were projected by DUHS Imaging based on anticipated annual volume.
- The applicant states benefit and salary inflation rates are based on DUHS experience.

**Conclusion** – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons described above.

**Project ID #J-12610-25 / Duke University Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

On Form H in Section Q, the applicant projects full-time equivalent (FTE) staffing for the proposed fixed PET services in each of the first three FYs of operation, SFY 2030-2032, as illustrated in the following table:

POSITION	1 <sup>ST</sup> FULL FY (SFY 2030)	2 <sup>ND</sup> FULL FY (SFY 2031)	3 <sup>RD</sup> FULL FY (SFY 2032)
Nuclear Medicine Tech.	19.98	19.98	19.98
Physicians Assistant	2.00	2.00	2.00
Radiology Supervisor	1	1	1
Patient Service Associate	4	4	4
<b>Total*</b>	<b>28.00 [27.00]</b>	<b>28.00 [27.00]</b>	<b>28.00 [27.00]</b>

\*The applicant's totals did not sum according to the data in the table. The Project Analyst's totals are in brackets.

The assumptions and methodology used to project staffing are provided in Section Q, page 98. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In Section F.2, pages 70-72 the applicant describes the methods used to recruit or fill new positions and its existing and proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant states FTEs were projected by DUHS Imaging based on anticipated annual volume.
- The applicant states benefit and salary inflation rates are based on DUHS experience.

**Conclusion** – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons described above.

**Project ID #J-12611-25 / Raleigh PET** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

On Form H in Section Q, the applicant projects full-time equivalent (FTE) staffing for the proposed fixed PET services in each of the first three FYs of operation, FFY 2028-2030, as illustrated in the following table:

POSITION	1 <sup>ST</sup> FULL FY (FFY 2028)	2 <sup>ND</sup> FULL FY (FFY 2029)	3 <sup>RD</sup> FULL FY (FFY 2030)
PET Scanner Technologist	3.0	3.0	3.0
PET Scanner Supervisor	1.1	1.1	1.1
<b>Total</b>	<b>4.1</b>	<b>4.1</b>	<b>4.1</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 136. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In Section F.2, pages 75-76 the applicant describes the methods used to recruit or fill new positions and its existing and proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services because the applicant projects staffing based on FY 2024 and on projected volumes and hours of operation.

**Conclusion** – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons described above.

- (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.

### C – All Applications

**Project ID #J-12593-25 / DDI** - The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

#### **Ancillary and Support Services**

In Section I.1, page 94, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will be made available. The applicant provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

#### **Coordination**

In Section I.2, page 952, the applicant describes its existing and proposed relationships with other local health care and social service providers. DDI is part of Novant Health, an existing hospital network that currently has established relationships with local health care and social service providers, and those same relationships will continue following project completion. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12595-25 / UNC Medical Center** - The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

#### **Ancillary and Support Services**

In Section I.1, page 99, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will continue to be made available. UNC Hospitals is an existing healthcare system that currently provides fixed PET services and necessary ancillary and support services, and those same services will

continue to be made available upon project completion. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I.2, page 100, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. UNC Hospitals is an existing healthcare system that currently has established relationships with local health care and social service providers, and those same relationships will continue following project completion. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12598-25 / AUNC** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Ancillary and Support Services**

In Section I.1, pages 103-105, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will continue to be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I.2, page 105, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant states on page 105 that RPI associated physicians have established relationships with local health care and social services providers and will establish a transfer agreement with UNC Rex Hospital. The applicant provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12602-25 / WR Imaging-Garner** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Ancillary and Support Services**

In Section I.1, page 94, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will continue to be made available. UNC REX Garner is an existing diagnostic center that currently provides ancillary and support services, and the applicant states those same services will continue to be made available upon project completion. The applicant provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I.2, page 95, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. UNC REX Garner is an existing diagnostic center that currently has established relationships with local health care and social service providers, and those same relationships will continue following project completion. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12607-25 / Duke Cary Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Ancillary and Support Services**

In Section I.1, page 78, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will continue to be made available, consistent with the approved application for which this application is a COS. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I.2, page 79, the applicant describes its existing and proposed relationships with other local health care and social service providers. DUHS is an existing healthcare system that currently has established relationships with local health care and social service providers, and those same relationships will continue following project completion. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12610-25 / Duke University Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Ancillary and Support Services**

In Section I.1, page 73, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will continue to be made available. DUHS is an existing healthcare system that currently provides fixed PET services and necessary ancillary and support services, and those same services will continue to be made available upon project completion. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I.2, page 74, the applicant describes its existing and proposed relationships with other local health care and social service providers. DUHS is an existing healthcare system that currently has established relationships with local health care and social service providers, and those same relationships will continue following project completion. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12611-25 / Raleigh PET** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

### **Ancillary and Support Services**

In Section I.1, page 78, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will continue to be made available. WakeMed is an existing healthcare system that currently provides fixed PET services and necessary ancillary and support services, and those same services will continue to be made available upon project completion. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I.2, page 79, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.1. WakeMed is an existing healthcare system that currently has established relationships with local health care and social service providers, and those same relationships will continue following project completion. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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.

NA – All Applications

None of the applicants in this review project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, none of the applicants in this review project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA – All Applications

None of the applicants in this review is an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (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.

NA – Duke University Hospital  
C – All Other Applications

**Project ID #J-12593-25 / DDI** - The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section K, page 98 the applicant states the project involves renovating approximately 1,100 square feet of existing space in a modular unit that will be attached to DDI's existing outpatient facility. Line drawings are provided in Exhibit K.2.

On page 98, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information in the application and exhibits and on the following:

- The applicant states it has worked with experienced healthcare architects who are experienced with similar projects and consulted published construction cost data.
- The applicant provides a construction cost estimate from the project architect in Exhibit K.3-1.

On page 99 the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the information in the application and exhibits and on the following:

- The applicant has experience developing and operating PET services and has confirmed that the associated project costs are necessary to developing the service.
- The applicant states the project will not increase charges or projected reimbursement for the proposed fixed PET services.

In Section K, page 99, the applicant identifies any applicable energy saving features that will be incorporated into the renovation and upfit plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12595-25 / UNC Medical Center** - The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section K, page 103 the applicant states that the project involves renovating 792 square feet of existing space to accommodate the proposed fixed PET scanner. Line drawings are provided in Exhibit C.1-1.

On page 104 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information in the application and exhibits and on the following:

- The applicant states the project does not involve major demolition or new construction, because the proposed fixed PET scanner will be developed in existing vacant space within the existing cancer hospital.
- The applicant states the proposed fixed PET scanner will be developed in space that has already been upfitted with the necessary supporting features required for the proposed fixed PET scanner.

On page 104, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the information in the application and exhibits and on the following:

- The applicant states the costs incurred to develop and operate this project are necessary and appropriate to promote competition and enhance access for service area patients.
- The applicant states UNCH has capital funds set aside for the project without necessitating increases in costs or charges

In Section B, pages 27-28 the applicant describes the applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12598-25 / AUNC** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section K, page 108 the applicant states that the project involves renovating 1,375 square feet of existing space to accommodate the proposed fixed PET scanner. Line drawings are provided in Exhibit K.2.

On page 108 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information in the application and exhibits and on the following:

- The applicant states the project architect has reviewed the proposed facility renovations and has estimated the project cost based on his experience with similar projects.
- The applicant provides a copy of the architect's construction cost estimate in Exhibit F.1.

On page 109, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the information in the application and exhibits and on the following:

- The applicant states the project architect has experience developing the necessary space and has confirmed that the size and scope of renovation associated with the proposed project renovation are reasonable and necessary.

In Section K, pages 109-110 the applicant describes the applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12602-25 / WR Imaging-Garner** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP pursuant to the need determination in the 2025 SMFP.

In Section K, page 98 the applicant states that the project involves renovating 1,130 square feet of existing space to accommodate the proposed fixed PET scanner. Line drawings are provided in Exhibit K.2.

On page 98 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information in the application and exhibits and on the following:

- The applicant states the development of the proposed fixed PET service will be accomplished in a resource-responsible manner.
- The applicant proposes to develop the fixed PET service in existing available space, thereby representing a cost-effective option than new construction.

On page 99, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the information in the application and exhibits and on the following:

- The applicant states the project costs are necessary to ensure the proposed project can be developed to accommodate the proposed fixed PET services.
- The applicant states renovation of existing space is an efficient approach to develop and offer the proposed fixed PET services.
- The applicant states the project will facilitate economies of scale by utilizing existing staff and infrastructure, thereby containing costs.

In Section K, page 99 the applicant describes the applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12607-25 / Duke Cary Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP to be located at Duke Cary Hospital.

In Section K, page 82 the applicant states that the project involves constructing approximately 1,400 square feet of space within the previously approved hospital construction plans pursuant to Project ID #J-12029-21, without any increase in overall hospital square feet. Line drawings are provided in Exhibit K.1.

On page 83 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information in the application and exhibits and on the following:

- The applicant states that, since this project will be incorporated into the previously approved hospital project, it allows DUHS to make use of planned infrastructure for other imaging services proposed to be developed in the hospital.

On page 83, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the information in the application and exhibits and on the following:

- The applicant states this project will not increase charges to the public or projected reimbursement for the proposed fixed PET scanner.
- The applicant states the costs incurred to develop and operate this project are necessary and appropriate to add this imaging modality to this location, thus enhancing care to patients in the service area.

In Section K, page 83 the applicant describes the applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Project ID #J-12610-25 / Duke University Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP to be located at Duke University Hospital. In Section K, page 93 the applicant states that the project does not involve any new construction or renovation of existing space. Therefore, this Criterion is not applicable to this review.

**Project ID #J-12611-25 / Raleigh PET, LLC** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section K, page 83 the applicant states that the project involves renovating 1,500 square feet of existing space to accommodate the proposed fixed PET scanner. Line drawings are provided in Exhibit K.2.

On page 84 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information in the application and exhibits and on the following:

- The applicant states developing the project in existing space in a MOB rather than in WakeMed hospital lowers construction costs.
- The applicant states supporting infrastructure is already in place; and when combined with WakeMed's Construction and Design staff and the project architect, will ensure cost-containment.
- The applicant states the project will not require any outside financing, since the applicant will utilize existing reserve funds for the project.

On page 84, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the information in the application and exhibits and on the following:

- The applicant states the project is sized to meet demand for PET services in an HSA that needs the services.

In Section K, page 84 the applicant describes the applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and persons with disabilities, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C – DDI, UNC Medical Center, WR Imaging, DUH  
NA – AUNC, Duke Cary Hospital, Raleigh PET

### Project ID # J-12593-25 / DDI

The applicant does not currently provide fixed PET services at DDI. In Section L, page 102, the applicant provides historical payor mix for FFY 2024 for all imaging services provided at DDI, as shown in the following table:

Durham Diagnostic Imaging Total Historical Payor Mix, FFY 2024	
Payor Category	Percentage of Total Patients Served
Self-Pay	1.60%
Charity Care	0.27%
Medicare*	42.92%
Medicaid*	2.19%
Insurance*	48.10%
Workers Compensation	2.62%
TRICARE	0.55%
Other (Commercial, Auto/Liability)	1.76%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

In Section L, page 103, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	60.1%	51.1%
Male	39.9%	48.9%
Unknown		
64 and Younger	57.8%	81.1%
65 and Older	42.2%	18.9%
American Indian	NA*	
Asian	NA*	
Black or African American	NA*	
Native Hawaiian or Pacific Islander	NA*	
White or Caucasian	NA*	
Other Race	NA*	
Declined / Unavailable	Not Available	

\*In Section L, page 103 the applicant states DDI does not require patients to report their ethnicity.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

### **Project ID # J-12595-25 / UNC Medical Center**

In Section L, page 107, the applicant provides historical payor mix for the last full operating year, SFY 2024 for UNC Medical Center, as shown in the following table:

**UNC Medical Center Historical Payor Mix, SFY 2024**

<b>Payor Category</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	4.1%
Medicare*	39.5%
Medicaid*	20.8%
Insurance*	25.7%
Other (other govt, workers comp)	9.9%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

In Section L, page 108, the applicant provides the following comparison:

	<b>PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY</b>	<b>PERCENTAGE OF THE POPULATION OF THE SERVICE AREA</b>
Female	57.9%	52.2%
Male	42.1%	47.8%
Unknown	0.0%	
64 and Younger	66.0%	83.3%
65 and Older	34.0%	16.7%
American Indian	1.1%	0.7%
Asian	2.6%	8.1%
Black or African American	22.3%	12.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	62.0%	76.2%
Other Race	9.8%	2.8%
Declined / Unavailable	2.3%	0.0%

The Agency reviewed the:

- Application



- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

### **Project ID # J-12598-25 / AUNC**

In Section L, page 107, the applicant states AUNC is not an existing facility and thus has no historical payor mix to report.

### **Project ID # J-12602-25 / WR Imaging-Garner**

In Section L, page 102, the applicant provides historical payor mix for the last full operating year, CY 2024 for Wake Radiology UNC REX Healthcare - Garner, as shown in the following table:

**UNC REX Healthcare - Garner Historical Payor Mix, CY 2024**

<b>Payor Category</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	0.7%
Medicare*	39.9%
Medicaid*	5.1%
Insurance*	52.6%
Workers Compensation	0.1%
TRICARE	1.2%
Other (other govt and institutional)	0.4%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

In Section L, page 103, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	76.19%	51.0%
Male	23.9%	49.0%
Unknown		
64 and Younger	59.6%	86.6%
65 and Older	40.1%	13.4%
American Indian		0.8%
Asian		9.4%
Black or African American	0.1%	20.6%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian	0.4%	57.1%
Other Race	4.0%	2.9%
Declined / Unavailable	95.5%*	

\*The applicant states on page 103 that it is committed to providing care to all patients, regardless of income level, payment ability, race, ethnicity, gender, age or physical/mental health conditions. The majority of its patients elected not to disclose their race on intake forms.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

### **Project ID # J-12607-25 / Duke Cary Hospital**

In Section L, page 87, the applicant states Duke Cary Hospital is not an existing facility and thus has no historical payor mix to report.

### **Project ID # J-12610-25 / Duke University Hospital**

In Section L, page 79, the applicant provides historical payor mix for the last full operating year, SFY 2024 for DUH, as shown in the following table:

**DUH Historical Payor Mix, SFY 2024**

<b>Payor Category</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	1.3%
Charity Care^	2.3%
Medicare*	39.6%
Medicaid*	11.5%
Insurance*	42.0%
Workers Compensation	0.2%
TRICARE	1.4%
Other (other government)	1.7%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

In Section L, page 80, the applicant provides the following comparison:

	<b>PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY</b>	<b>PERCENTAGE OF THE POPULATION OF THE SERVICE AREA</b>
Female	60.0%	52.0%
Male	40.0%	48.0%
Unknown		
64 and Younger	62.9%	84.9%
65 and Older	37.1%	15.1%
American Indian	0.7%	1.2%
Asian	3.4%	6.1%
Black or African American	26.0%	34.5%
Native Hawaiian or Pacific Islander	0.1%	0.2%
White or Caucasian	61.7%	55.2%
Other Race	3.1%	
Declined / Unavailable	5.0%	

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

**Project ID # J-12611-25 / Raleigh PET**

In Section L, page 87, the applicant states Raleigh PET, LLC is not an existing facility and thus has no historical payor mix to report.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

### C – All Applications

#### **Project ID # J-12593-25 / DDI**

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 104, the applicant states it has no such obligation.

On page 104, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against DDI or any Novant Health facilities.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

#### **Project ID # J-12595-25 / UNC Medical Center**

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 109, the applicant states it has no such obligation.

On page 110, the applicant states that during the 18 months immediately preceding the application deadline, UNC Health Wayne received notice that a patient had filed a complaint alleging racial discrimination while receiving treatment at the Goldsboro facility. The applicant states the Office of Civil Rights found the allegations to be unsubstantiated and the case was closed with no further investigation.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

### **Project ID # J-12598-25 / AUNC**

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 115, the applicant states it has no such obligation.

On page 115, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against Raleigh PET Imaging.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

### **Project ID # J-12602-25 / WR Imaging-Garner**

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 104, the applicant states it has no such obligation.

On page 104, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against Wake Radiology UNC REX Healthcare - Garner.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

### **Project ID # J-12607-25 / Duke Cary Hospital**

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 88, the applicant states it has no such obligation.

On page 104, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against Duke University or Duke Raleigh Hospital.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

### **Project ID # J-12610-25 / Duke University Hospital**

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 80, the applicant states it has no such obligation.

On page 81, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against DUHS.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

### **Project ID # J-12611-25 / WR Imaging-Garner**

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 90, the applicant states it has no such obligation.

On page 90, the applicant states RPI is not an existing facility. The applicant states the sole owner of RPI, WakeMed, has had no civil rights equal access complaints filed in the 18 months preceding application submission.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C – All Applications

### **Project ID # J-12593-25 / DDI**

In Section L, page 105, the applicant projects the following payor mix for fixed PET services during the third full FY of operation (SFY 2029) following project completion, as shown in the following table:

**DDI Fixed PET Services Projected Payor Mix, SFY 2029**

<b>Payor Category</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	1.60%
Charity Care	1.00%
Medicare*	42.92%
Medicaid*	5.50%
Insurance*	44.10%
Workers Compensation	2.62%
TRICARE	0.55%
Other (Commercial, Auto/Liability)	1.76%
<b>Total</b>	<b>100.00%</b>

\*Including any managed care plans.

As shown in the tables above, during the third full fiscal year of operation, the applicant projects that 1.6% of fixed PET services will be provided to self-pay patients, 42.92% to Medicare patients and 5.50% to Medicaid patients.

On pages 105-106 the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for Novant Health and DDI and contemplates the impact of Medicaid expansion in North Carolina.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

### **Project ID # J-12595-25 / UNC Medical Center**

In Section L, page 111, the applicant projects the following payor mix for fixed PET services during the third full FY of operation (SFY 2029) following project completion, as illustrated in the following table:

**UNC Medical Center Fixed PET Projected Payor Mix, SFY 2029**

<b>Payor Category</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	3.0%
Medicare*	55.1%
Medicaid*	8.1%
Insurance*	23.2%
Other (other Govt, Workers Comp, TRICARE)	10.6%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.0% of fixed PET services will be provided to self-pay patients, 55.1% to Medicare patients and 8.1% to Medicaid patients.

On page 110, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following project completion. The projected payor mix is reasonable and adequately supported because



it is based on the FY 2024 payor mix for UNC Medical Center's fixed PET services and contemplates the impact of Medicaid expansion in North Carolina.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

### **Project ID # J-12598-25 / AUNC**

In Section L, page 116, the applicant projects the following payor mix for fixed PET services during the third full FY of operation (SFY 2029) following project completion, as illustrated in the following tables:

<b>AUNC Fixed PET Projected Payor Mix, SFY 2029</b>	
<b>Payor Category</b>	<b>Percentage of Total Patients Served</b>
Self-pay	1.0%
Medicare*	29.4%
Medicaid*	2.1%
Insurance*	66.0%
Other (Government)	1.5%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.0% of fixed PET services will be provided to self-pay patients, 29.4% to Medicare patients and 2.1% to Medicaid patients.

On page 116, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix of patient referred to local hospitals for PET scans by AUNC physicians.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

### **Project ID # J-12602-25 / WR Imaging-Garner**

In Section L, page 105, the applicant projects the following payor mix for fixed PET services during the third full FY of operation (FFY 2029) following project completion, as illustrated in the following tables:

**WR UNC REX Healthcare-Garner Fixed PET Projected Payor Mix, FFY 2029**

<b>Payor Category</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	3.5%
Medicare*	63.0%
Medicaid*	7.0%
Insurance*	25.5%
TRICARE	1.0%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.5% of fixed PET services will be provided to self-pay patients, 63.0% to Medicare patients and 7.0% to Medicaid patients.

On pages 105-107, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the CY 2024 payor mix for the diagnostic center and on fixed PET services at UNC Health Rex Hospital, and contemplates Medicaid expansion in North Carolina.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

### **Project ID # J-12607-25 / Duke Cary Hospital**

In Section L, pages 89-90, the applicant projects the following payor mix for fixed PET services during the third full FY of operation (SFY 2032) following project completion, as illustrated in the following tables:

**Duke Cary Hospital Fixed PET Projected Payor Mix, CY 2029**

Payor Category	Percentage of Total Patients Served
Charity Care	1.4%
Medicare*	58.9%
Medicaid*	3.5%
Insurance*	33.9%
Workers Compensation	0.1%
Other (other govt payors including TRICARE)	2.1%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.4% of fixed PET services will be provided to charity care patients, 58.9% to Medicare patients and 3.5% to Medicaid patients.

On page 89, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the FY 2024 payor mix for Duke Raleigh Hospital PET-CT services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

### **Project ID # J-12610-25 / Duke University Hospital**

In Section L, page 82, the applicant projects the following payor mix for fixed PET services during the third full FY of operation (SFY 2029) following project completion, as illustrated in the following tables:

**DUH Fixed PET Services Projected Payor Mix, SFY 2029**

<b>Payor Category</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	1.3%
Charity Care	0.1%
Medicare*	56.0%
Medicaid*	3.9%
Insurance*	34.4%
Other^	4.1%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

^The applicant states on page 82 that "other" includes "*other government payors including Tricare.*"

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.1% of fixed PET services will be provided to charity care patients, 56.0% to Medicare patients and 3.9% to Medicaid patients.

On page 82, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the FY 2024 payor mix for DUH fixed PET services, accounting for Medicaid expansion in North Carolina.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

### **Project ID # J-12611-25 / Raleigh PET**

In Section L, page 91, the applicant projects the following payor mix for the proposed fixed PET services during the third full FY of operation (FFY 2029) following project completion, as shown in the following table:

**Raleigh PET Fixed PET Projected Payor Mix, FFY 2029**

Payor Category	Percentage of Total Patients Served
Self-Pay	3.6%
Charity Care^	--
Medicare*	47.6%
Medicaid*	7.4%
Insurance*	40.3%
Other (VA, TRICARE, Govt, Other)	1.2%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

^The applicant states on page 82: *"Charity care is not a payor class. It is calculated as 5.5% of gross patient services revenue."*

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.6% of fixed PET services will be provided to self-pay patients, 47.6% to Medicare patients and 7.4% to Medicaid patients.

In Section Q and referenced exhibits, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the FY 2024 payor mix for Raleigh Oncology and Raleigh Cardiology patients.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C – All Applications

### **Project ID #J-12593-25 / DDI**

In Section L.5, page 109, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Project ID #J-12595-25 / UNC Medical Center**

In Section L.5, page 112 the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Project ID #J-12598-25 / AUNC**

In Section L.5, page 117 the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Project ID #J-12602-25 / WR Imaging-Garner**

In Section L.5, page 108 the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Project ID #J-12607-25 / Duke Cary Hospital**

In Section L.5, page 92 the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Project ID #J-12610-25 / Duke University Hospital**

In Section L.5, page 84 the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Project ID #J-12611-25 / Raleigh PET**

In Section L.5, page 93 the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

**All Applications.** In Section M, the applicants describe the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provide supporting documentation in the referenced exhibits.

The Agency reviewed the:

- Applications
- Exhibits to the applications

Based on that review, the Agency concludes that all of the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, all of the applications are conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (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 a service on which competition will not have a favorable impact.

#### C – All Applications

The 2025 SMFP includes a need determination for two fixed PET scanners in HSA IV.

On page 363, the 2025 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s **service area** is the HSA in which it is located (Table 15F-1). Appendix A identifies the multicounty groupings that comprise the HSAs.*” (emphasis in original) Thus, the service area for the facilities in this review is HSA IV. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing fixed PET scanners in HSA IV, and the number of procedures for each PET scanner in 2022-2023 as found in Table 15F-1 on page 365 of the 2025 SMFP:



**Fixed PET Scanners HSA IV**

<b>SITE/PROVIDER</b>	<b># SCANNERS</b>	<b>TOTAL PROCEDURES 2022-2023</b>
Duke Raleigh Hospital	1	2,002
Duke University Hospital	3	7,442
Rex Hospital	2	4,772
University of North Carolina Hospitals*	1	5,375
Wake PET Services	1	1,660
<b>Total HSA IV fixed PET scanners / Procedures</b>	<b>8</b>	<b>21,251</b>

\*The 2025 SMFP indicates a total of two fixed PET scanners in the UNC inventory; however, UNC is approved for a total of three fixed PET scanners, two of which are excluded from the planning inventory because they were approved pursuant to Policy AC-3. The applicant provides correspondence from the DHSR Healthcare Planning Section in Exhibit A.5

## **Project ID #J-12593-25 / DDI**

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 113, the applicant states:

*“DDI’s proposal to acquire a state-of-the-art fixed PET/CT scanner at its existing outpatient facility in Durham, North Carolina will have a positive impact on competition for residents of HSA IV. ... In HSA IV, the existing PET scanners are predominantly owned and operated by two entities, .... Of the nine existing PET scanners, eight scanners of 89%, are located within hospitals in HSA IV. ... If approved, DDI’s project would be the first such outpatient based PET/CT scanners in Durham County.”*

Regarding the expected effects of the proposal on cost effectiveness in the service area, in Section N, page 114, the applicant states:

*“The proposed service will benefit from DDI’s experience as a leading outpatient imaging center in the service area with existing infrastructure and support to provide this service at a lower rate than other providers. ... In addition to lower charges for this complete service, DDI abides by the Novant Health Charity Care policies and procedures.”*

See also Sections C, F and Q of the application and any exhibits.

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 114, the applicant states:

*“With a strong commitment to excellence, DDI hold accreditations from the American College of Radiology ... for MRI, CT, Breast MRI, Mammography, Breast Ultrasound, Ultrasound, and Stereotactic Breast Biopsy.*

...

*Novant Health is committed to delivering high-quality care at all of its facilities. Novant Health has quality-related policies and procedures that are applicable to DDI.”*

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 114, the applicant states:

*“DDI’s ability to offer fixed PET access to patients in a convenient outpatient setting cannot be overlooked. Many of these patients have ben in and out of hospitals, physician offices and other healthcare facilities. Most patients will require multiple PET procedures over the course of their treatment. By creating an environment that is easily accessible, calm and convenient for patients and their caregivers, it reduces stress for the patient.*

*DDI will further expand access to fixed PET services in a convenient and affordable outpatient setting for patients with a wide variety of medical conditions.”*

See also Sections B, C, L and Q of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care will be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

### **Project ID #J-12595-25 / UNC Medical Center**

Regarding the expected effects of the proposal on competition, cost-effectiveness, quality, and access by medically underserved groups in the service area, in Section N, page 117 the applicant states:

*“The proposed project will enhance competition by ensuring that there is adequate PET scanner capacity for all patients across North Carolina that choose UNC Hospitals, and UNC Medical Center, for their care. UNC Hospitals has a unique mission to serve patients from across the state and regularly cares for patients from all 100 counties in North Carolina.”*

Regarding the expected effects of the proposal on cost effectiveness in the service area, in Section N, page 117 the applicant states:

*“The proposed application is indicative of UNC Health’s commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended, while also ensuring that patients have sufficient access to acute care services. The proposed project will expand access to UNC Hospitals’ services in HSA IV – in particular, the services at UNC Medical Center, the flagship campus of an academic medical center and teaching hospital that has historically provided care to patients not only from HSA IV, but from throughout the state of North Carolina, as stated previously. By expanding PET services at the NC Cancer Center, UNC Hospitals will ensure that as many patients as possible have equitable access to the services available at UNC Medical Center, through the expansion of PET scanner resources at the facility and resulting increase in capacity to treat patients.”*

See also Sections C, F and Q of the application and any exhibits.

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 118 the applicant states:

*“The proposed project will expand patients’ ability to access these services through increasing the resources for PET imaging at UNC Medical Center, the flagship campus of UNC Hospitals, and one of the preeminent providers of healthcare services in North Carolina.*

*UNC Health has a demonstrated reputation for providing high quality healthcare services to its patients and is committed to continuing to provide excellent, high-*

*quality healthcare. UNC Health, including UNC Hospitals, has earned numerous rankings and awards that demonstrate its ability to provide ongoing quality care.”*

See also the remainder of Section N, Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 120 the applicant states:

*“The proposed project will promote access to healthcare services in the service area, particularly for the medically underserved. As North Carolina’s only state-owned, comprehensive, full-service hospital system, UNC Hospitals has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to nonelective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance....”*

See also the remainder of Section N and Sections B, C, L and Q of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care will be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

## **Project ID #J-12598-25 / AUNC**

Regarding the expected effects of the proposal on competition, cost-effectiveness, quality, and access by medically underserved groups in the service area, in Section N, page 121 the applicant states:

*“The development of a freestanding, non-hospital-owned PET scanner in HSA IV is expected to have significant and positive effects on competition within the local healthcare market. By providing an alternative to hospital-based PET imaging services, a freestanding provider introduces a competitive dynamic that can lead to enhanced cost-effectiveness, improved quality, and increased access to advanced imaging services for residents in the region. This competitive influence not only benefits patients but also incentivizes all imaging providers to improve their services, creating a more efficient and patient-focused healthcare system overall.”*

Regarding the expected effects of the proposal on cost effectiveness in the service area, in Section N, pages 122-123 the applicant states:

*“One of the most significant advantages of a freestanding PET scanner facility is its ability to offer cost-effective services, particularly in comparison to hospital-based imaging centers. Hospital settings often have higher operational costs driven by complex administrative structures, large staff rosters, and infrastructure overhead. These costs are typically passed on to patients through higher fees, even for outpatient services like PET scans. A freestanding PET scanner provider, on the other hand, operates with leaner overhead and streamlined workflows tailored specifically to outpatient care. As a result, patients can access imaging services at significantly lower prices, alleviating financial barriers, particularly for uninsured or underinsured individuals.”*

See also Sections C, F and Q of the application and any exhibits.

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 118 the applicant states:

*“... a freestanding PET scanner provider is well-positioned to deliver high-quality services by focusing exclusively on diagnostic imaging. Unlike hospitals, which must allocate resources across a broad spectrum of services, a specialized facility can prioritize investments in advanced imaging technologies, such as the Siemens Biograph mCT-S(64). This state-of-the-art PET scanner is renowned for its superior image resolution, reduced scanning times, and innovative software that enhances diagnostic accuracy. By utilizing cutting-edge technology, a freestanding provider ensures that patients receive the most precise and reliable imaging available. Furthermore, the specialization of freestanding centers extends to their staff. These facilities often employ technologists and radiologists with advanced training and expertise in PET imaging, ensuring a higher standard of care and*

*interpretation quality. Such an emphasis on specialization not only enhances diagnostic outcomes but also fosters trust and confidence among referring physicians and patients.”*

See also the remainder of Section N, Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 123 the applicant states:

*“Equitable access is another key benefit of a freestanding PET scanner provider. By offering lower-cost services and flexible payment options, such as sliding scale fees or financial assistance programs, these facilities can cater to patients who might otherwise forgo imaging due to financial constraints. This commitment to serving economically disadvantaged populations aligns with the broader goals of equitable healthcare access, ensuring that all residents of HSA IV, regardless of income or insurance status, can benefit from advanced diagnostic imaging. Moreover, freestanding facilities are more likely to accept a broader range of insurance plans, including Medicaid, further expanding access to underserved groups.”*

See also the remainder of Section N and Sections B, C, L and Q of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care will be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

### **Project ID #J-12602-25 / WR Imaging-Garner**

Regarding the expected effects of the proposal on competition, cost-effectiveness, quality, and access by medically underserved groups in the service area, in Section N, page 110 the applicant states:

*“The proposed project will enhance competition in the service area by promoting cost effectiveness, quality, and access to fixed PET services. ... the proposed project demonstrates the continued evolution of the joint venture partnership between Wake Radiology physicians and UNC Health Rex that has increased access to lower cost outpatient imaging since its inception. As a freestanding facility, Wake Radiology UNC REX Healthcare – Garner will provide quality fixed PET services at a lower out-of-pocket cost to most patients, promoting competitive access to lower cost PET services in HSA IV.”*

Regarding the expected effects of the proposal on cost effectiveness in the service area, in Section N, page 110 the applicant states:

*“The proposed application is indicative of the applicants’ commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended, even though the acquisition of the proposed fixed PET scanner necessitates the expenditure of capital costs. As discussed in Section C.1, the proposed project can be accomplished in a resource responsible manner through the upfit of space in an existing diagnostic center to accommodate the proposed PET scanner without new construction.*

*As a freestanding facility, Wake Radiology UNC REX Healthcare – Garner will provide PET services at a lower out-of-pocket cost to most patients. Insurance companies categorize hospital-based services in a higher tier than freestanding services, meaning that the patient’s out-of-pocket expenses are lower when receiving non-hospital based care. ... the proposed project will increase access to low-cost, freestanding fixed PET services in HSA IV, and the partnership between Wake Radiology and UNC Health Rex will help to ensure patients receive PET scans in the most appropriate setting, hospital-based or freestanding, based on each patient’s unique situation.”*

See also Sections C, F and Q of the application and any exhibits.

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 111 the applicant states:

*“The applicants have demonstrated a reputation for providing excellent, high quality imaging services to its patients. WR Imaging is a joint venture between UNC Health Rex and Wake Radiology physicians. UNC Health Rex is widely recognized as a distinguished hospital service provider in Wake County. Throughout its facilities and service offerings, UNC Health Rex relies on quality policies and procedures designed to maintain and improve the quality and safety of care provided to its patients. UNC Health Rex has a history of relying on comprehensive utilization review processes to monitor and manage the utilization of its services.*

*UNC Health Rex consistently demonstrates a commitment to high quality healthcare and its participation as a joint venture partner in the PET project proposed in this application can be expected to contribute to the provision of excellence in patient care.”*

See also the remainder of Section N, Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 112 the applicant states:

*“The applicants prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability, or the patient’s ability to pay. [Our non-discrimination policy] details the commitment to serve all patients regardless of age, race, sex, creed, religion, disability, or the patient’s ability to pay. [emphasis in original]*

*The applicants are fully committed to the health and well-being of the residents of HSA IV. To foster benefits for the community, the applicants seek to impact all of its residents through a variety of means to prevent illness and improve the quality of life in the area. Though these services do not provide a financial benefit to the applicants, they do assist the medically underserved by providing essential healthcare services, earlier detection of disease, and education.”*

See also the remainder of Section N and Sections B, C, L and Q of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.



- 2) Quality care will be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

### **Project ID #J-12607-25 / Duke Cary Hospital**

Regarding the expected effects of the proposal on competition, cost-effectiveness, quality, and access by medically underserved groups in the service area, in Section N, page 94 the applicant states:

*"The project will promote cost-effectiveness, quality, and access to services. By creating a new service location in a part of the county that is relatively underserved and by alleviating capacity constraints that currently may limit appointment availability and patient choice, it will promote competition in the health service area and particularly in Wake County."*

Regarding the expected effects of the proposal on cost effectiveness in the service area, in Section N, page 94 the applicant states:

*"This project will not affect the cost to patients or payors for the services provided by Duke Cary Hospital because reimbursement rates are set by the federal government and commercial insurers. The capital expenditure for this project is necessary to ensure that DUHS will have capacity to continue to provide high-quality services that are accessible to patients. At the same time, bringing the proposed services closer to where patients live and with greater scheduling availability may decrease transportation burdens and expenses for patients and their families."*

See also the remainder of Section N and Sections C, F and Q of the application and any exhibits.

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 95 the applicant states:

*“DUHS is committed to delivering high-quality care at all of its facilities and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its long history of providing high quality and state of the art patient care. DUHS has quality-related policies and procedures, and its quality management programs emphasize a customer-oriented perspective that is used to determine the needs of patients, physicians, and others who utilize hospital services.”*

See also the remainder of Section N, Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 95 the applicant states:

*“... Duke Cary Hospital, as a campus of Duke Raleigh Hospital, will have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. DUHS’s financial assistance policy will apply to the proposed services. By expanding acute care services to a growing population, it also makes them more accessible for patients with transportation challenges....”*

See also the remainder of Section N and Sections B, C, L and Q of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care will be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

### **Project ID #J-12610-25 / Duke University Hospital**

Regarding the expected effects of the proposal on competition, cost-effectiveness, quality, and access by medically underserved groups in the service area, in Section N, page 86 the applicant states:

*“The project will have a positive effect on competition by ensuring that Duke University Hospital has sufficient imaging capacity to accommodate patient choice. Currently, the hospital’s PET scanners are so highly utilized that patients may face scheduling delays for critical procedures. Capacity constraints can drive patients to seek care at other providers not due to individual preference or any other provider’s superior care, but simply because they are unable to wait for an appointment at DUH that fits their schedule.”*

Regarding the expected effects of the proposal on cost effectiveness in the service area, in Section N, page 86 the applicant states:

*“This project will not directly affect the charges or reimbursement for services for patients or payors for the proposed services because reimbursement rates are set by the federal government and commercial insurers. However, by decreasing scheduling delays, this project may allow patients to access and initiate their care more quickly, saving costs and improving patient experience.*

*DUHS will continue to participate in initiatives aimed at promoting cost-effectiveness and optimizing quality healthcare.”*

See also Sections C, F and Q of the application and any exhibits.

Regarding the expected effects of the proposal on quality in the service area, in Section N, pages 86-87 the applicant states:

*“DUHS is committed to delivering high-quality care at all of its facilities and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its long history of providing patient care. DUHS has robust quality-related policies and procedures, and its quality management programs emphasize a customer-oriented perspective that is used to*

*determine the needs of patients, physicians, and others who utilize hospital services.”*

See also the remainder of Section N, Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 87 the applicant states:

*“Duke University Hospital’s current capacity constraints create scheduling days and limit practical access for patients, including the medically underserved. As the demand for its PET services continues to grow, those limits on access will be exacerbated. Section L.3 includes payor mix projections that demonstrate DUHS’s commitment to ensuring access for medically underserved patients. The initiatives described in response to Policy GEN-5 questions are designed to promote equitable access to care, but this demands necessary capacity to provide the care that patients need. Therefore, this project will promote access.”*

See also the remainder of Section N and Sections B, C, L and Q of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care will be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

### **Project ID #J-12611-25 / Raleigh PET**

Regarding the expected effects of the proposal on competition, cost-effectiveness, quality, and access by medically underserved groups in the service area, in Section N, page 100 the applicant states:

*“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.*

*Raleigh PET will offer pricing that is competitive and will significantly improve options for access by medically underserved persons.*

*Raleigh PET will be a new value-based provider of PET services in HSA IV. This will enhance competition with lower charge and cost structures. Raleigh PET will be only the second such provider in HSA IV.”*

Regarding the expected effects of the proposal on cost effectiveness in the service area, in Section N, page 1017 the applicant states:

*“Raleigh PET’s proposal will be cost effective with regard to equipment, construction approach, funding, patient care protocols, service organization and payment value.*

*The proposed facility will involve upfit to a medical building owned by and on land owned by WakeMed, Raleigh PET’s sole owner. This will minimize up-charges associated with third party leases. Located on the WakeMed Raleigh Campus, the new program will have immediate access to ancillary services ranging from human resources to IT.*

*The Applicant proposes funding the project with accumulated reserves from its sole owner, thus eliminating the cost of borrowing, and limiting project costs.”*

See also the remainder of Section N and Sections C, F and Q of the application and any exhibits.

Regarding the expected effects of the proposal on quality in the service area, in Section N, page 102 the applicant states:

*“The Applicant will take advantage of WakeMed’s existing quality policies and procedures.*

*Quality takes many forms, including excellent clinical outcomes, exceeding accreditation standards, and providing a positive patient- and family-centered experience that is measured in patient satisfaction results. WakeMed employs a practicing physician as Chief Quality Officer, the person who oversees the system's quality, patient safety, risk management, infection prevention and control, and accreditation services. Having a practicing clinician serve in this role is important, as it allows the Chief Quality Officer to see the provision of care at the patient level."*

See also the remainder of Section N, Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 103 the applicant states:

*"Raleigh PET plans to serve a high proportion of Medicaid, Medicare, and Charity Care patients.*

*RMP2 is located in zip code 27610, which has the highest concentration of medically underserved residents in Wake County. FEMA produces an index of income, age, housing and other social measures. FEMA's HSA IV Social Vulnerability index for HSA IV and adjacent communities shows that, geographically, the largest proportion of high-risk groups are on the eastern side of the HSA, near the proposed Raleigh PET scanner."*

See also the remainder of Section N and Sections B, C, L and Q of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care will be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

NA – AUNC  
C – All Other Applications

**Project ID #J-12593-25 DDI** - The applicant proposes to acquire one fixed PET scanner to be located at DDI pursuant to the need determination in the 2025 SMFP.

In Section Q, Form O, the applicant identifies 37 hospitals and facilities located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.4, page 118, the applicant states that, during the 18 months immediately preceding the submittal of the application, there have been no quality of care issues at any of its facilities. After reviewing and considering information provided by the applicant and the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of the applicant's facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**Project ID #J-12595-25 UNC Medical Center** - The applicant proposes to acquire one fixed PET scanner at UNC Medical Center pursuant to the need determination in the 2025 SMFP.

In Section Q, Form O, page 144 the applicant identifies four hospitals located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.4, page 124 the applicant states that, during the 18 months immediately preceding the submittal of the application, there have been no quality of care issues at any of its facilities. After reviewing and considering information provided by the applicant and the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of the applicant's facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**Project ID #J-12598-25 AUNC** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

AUNC is an existing physician practice that would become a diagnostic center if approved for the proposed fixed PET scanner. Neither AUNC, Associated Urologists of North Carolina, P.A. nor Associated Urologists of NC Properties I, LLC own, operate or manage any other healthcare facilities in North Carolina. Therefore, this Criterion is not applicable to this application.

**Project ID #J-12602-25 WR Imaging-Garner** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section Q, Form O, page 131 the applicant identifies 14 healthcare facilities located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.4, page 115 the applicant states that, during the 18 months immediately preceding the submittal of the application, there have been no quality of care issues at any of its facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all of the applicant's facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**Project ID #J-12607-25 Duke Cary Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP at Duke Cary Hospital.

In Section Q, Form O, page 11 the applicant identifies three hospitals located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.4, page 99 the applicant states that, during the 18 months immediately preceding the submittal of the application, there have been no quality of care issues at any of its facilities. After reviewing and considering information provided by the applicant and the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of the applicant's facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**Project ID #J-12610-25 Duke University Hospital** – The applicant proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP to be located at Duke University Hospital.

In Section Q, Form O, page 11 the applicant identifies three hospitals located in North Carolina owned, operated or managed by the applicant or a related entity.



In Section O.4, page 90 the applicant states that, during the 18 months immediately preceding the submittal of the application, there have been no quality of care issues at any of its facilities. After reviewing and considering information provided by the applicant and the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of the applicant's facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**Project ID #J-12611-25 Raleigh PET** – The applicant proposes to acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

In Section Q, Form O the applicant identifies two hospitals located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.4, page 109 the applicant states that Raleigh PET, LLC is not an existing provider. The applicant states that, during the 18 months immediately preceding the submittal of the application, there have been no quality of care issues at any WakeMed facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all of the applicant's facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

#### C – All Applications

The Criteria and Standards for Positron Emission Tomography Scanners, promulgated in 10A NCAC 14C .3700, are applicable to this review.

### **SECTION .3700 CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER**

#### **10A NCAC 14C .3703 PERFORMANCE STANDARDS**

- (a) *An applicant proposing to acquire a fixed PET scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

(1) *identify the existing fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed fixed PET scanner service area;*

- NA- **DDI.** The applicant states neither DDI nor Novant Health own or operate any fixed PET scanners in the HSA IV fixed PET scanner service area.
- C- **UNC Medical Center.** The applicant states UNCH owns and operates three fixed PET scanners in HSA IV: one at UNC Medical Center in Orange County and two at UNC Health Rex in Wake County.
- NA- **AUNC.** The applicant states neither AUNC nor any related entities owns or operates a fixed PET scanner in the HSA IV fixed PET scanner service area.
- NA- **WR Imaging-Garner.** The applicant states UNC Health Rex operates two fixed PET scanners in the HSA IV fixed PET scanner service area.
- C- **Duke Cary Hospital.** The applicant states DUHS operates three fixed PET scanners at DUH and one fixed PET scanner at Duke Raleigh Hospital.
- C- **Duke University Hospital.** The applicant states DUHS operates three fixed PET scanners at DUH and one fixed PET scanner at Duke Raleigh Hospital.
- C- **Raleigh PET.** The applicant states WakeMed (Raleigh PET's sole owner) owns 51% of a fixed PET scanner at Wake PET Services.

(2) *identify the approved fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed fixed PET scanner service area;*

- NA- **DDI.** Neither the applicant nor any related entity has been approved to own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.
- NA- **UNC Medical Center.** Neither the applicant nor any related entity has been approved to own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.
- NA- **AUNC.** Neither the applicant nor any related entity has been approved to own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.
- NA- **WR Imaging.** Neither the applicant nor any related entity has been approved to own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.
- NA- **Duke Cary Hospital.** Neither the applicant nor any related entity has been approved to

own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.

**-NA- Duke University Hospital.** Neither the applicant nor any related entity has been approved to own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.

**-NA- Raleigh PET.** Neither the applicant nor any related entity has been approved to own or operate any fixed PET scanners in the proposed fixed PET scanner service area or in North Carolina.

*(3) identify the existing mobile PET scanners owned or operated by the applicant or a related entity that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period;*

**-NA- DDI.** Neither the applicant nor any related entity owns or operates any mobile PET scanners that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period.

**-NA- UNC Medical Center.** Neither the applicant nor any related entity owns or operates any mobile PET scanners that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period. In Section C, page 74 the applicant states that UNC Health Johnston provides mobile PET services at two locations in HSA IV via a contract with Akumin (f.k.a. Alliance), who owns the mobile PET scanner.

**-NA- AUNC.** Neither the applicant nor any related entity owns or operates any mobile PET scanners that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period.

**-NA- WR Imaging-Garner.** Neither the applicant nor any related entity owns or operates any mobile PET scanners that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period.

**-NA- Duke Cary Hospital.** Neither the applicant nor any related entity owns or operates any mobile PET scanners that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period.

**-NA- Duke University Hospital.** Neither the applicant nor any related entity owns or operates any mobile PET scanners that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period.

**-NA- Raleigh PET.** Neither the applicant nor any related entity owns or operates any mobile PET scanners that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period.

*(4) identify the approved mobile PET scanners owned or operated by the applicant or a related entity that will provide services at host sites located in the proposed fixed PET scanner service area;*

**-NA- DDI.** Neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that will provide services at host sites located in the proposed fixed PET scanner service area.

**-NA- UNC Medical Center.** Neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that will provide services at host sites located in the proposed fixed PET scanner service area.

**-NA- AUNC.** Neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that will provide services at host sites located in the proposed fixed PET scanner service area.

**-NA- WR Imaging-Garner.** Neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that will provide services at host sites located in the proposed fixed PET scanner service area.

**-NA- Duke Cary Hospital.** Neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that will provide services at host sites located in the proposed fixed PET scanner service area.

**-NA- Duke University Hospital.** Neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that will provide services at host sites located in the proposed fixed PET scanner service area.

**-NA- Raleigh PET.** Neither the applicant nor any related entity has been approved to own or operate any mobile PET scanners that will provide services at host sites located in the proposed fixed PET scanner service area.

*(5) provide projected utilization of the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner during each of the first three full fiscal years of operation following completion of the project;*

**-C- DDI.** In Section C, page 70 and in Section Q, Form C.2b, the applicant provides projected utilization of the proposed fixed PET scanner located or proposed to be located in HSA IV in each of the first three full fiscal years of operation.

- C- **UNC Medical Center.** In Section Q, Form C the applicant provides projected utilization of its existing fixed PET scanners and the proposed fixed PET scanner located or proposed to be located in HSA IV in each of the first three full fiscal years of operation.
  - C- **AUNC.** In Section C, page 76 and in Section Q, Form C.2b the applicant provides projected utilization of the proposed fixed PET scanner located or proposed to be located in HSA IV in each of the first three full fiscal years of operation.
  - C- **WR Imaging-Garner.** In Section Q, Form C.2b the applicant provides projected utilization of the proposed fixed PET scanner located or proposed to be located in HSA IV in each of the first three full fiscal years of operation.
  - C- **Duke Cary Hospital.** In Section Q, Form C.2a the applicant provides projected utilization of the proposed fixed PET scanner located or proposed to be located in HSA IV in each of the first three full fiscal years of operation.
  - C- **Duke University Hospital.** In Section Q, Form C the applicant provides projected utilization of its existing fixed PET scanners and the proposed fixed PET scanner located or proposed to be located in HSA IV in each of the first three full fiscal years of operation.
  - C- **Raleigh PET.** In Section Q, Form C the applicant provides projected utilization of the existing fixed PET scanner of which WakeMed owns 51%, and the proposed fixed PET scanner proposed to be located in HSA IV in each of the first three full fiscal years of operation.
- (6) *provide assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph; and*
- C- **DDI.** In Section Q, “*Form C.2 Utilization – Assumptions and Methodology*” the applicant provides the assumptions and methodology used to project utilization of the proposed fixed PET scanner to be located in HSA IV.
  - C- **UNC Medical Center.** In Section Q, “*Form C Utilization Assumptions and Methodology*” the applicant provides the assumptions and methodology used to project utilization of its existing and proposed fixed PET scanners located or to be located in HSA IV.
  - C- **AUNC.** In Section Q, “*Utilization Methodology and Assumptions*” the applicant provides the assumptions and methodology used to project utilization of the proposed fixed PET scanner to be located in HSA IV.
  - C- **WR Imaging-Garner.** In Section Q, “*Form C.2 Utilization – Assumptions and Methodology*” the applicant provides the assumptions and methodology used to project utilization of the proposed fixed PET scanner to be located in HSA IV.

- C- **Duke Cary Hospital.** In Section Q, *“Form C Assumptions”* the applicant provides the assumptions and methodology used to project utilization of the proposed fixed PET scanner to be located in HSA IV.
  - C- **Duke University Hospital.** In Section Q, *“Form C Assumptions”* the applicant provides the assumptions and methodology used to project utilization of the existing and proposed fixed PET scanners located or to be located in HSA IV.
  - C- **Raleigh PET.** In Section Q, *“Raleigh PET, LLC Patient Need and Utilization Methodology”* the applicant provides the assumptions and methodology used to project utilization of the proposed fixed PET scanner to be located in HSA IV.
- (7) *project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.*
- C- **DDI.** In Section Q, *“Form C.2 Utilization - Assumptions and Methodology”* the applicant projects that the proposed fixed PET scanner located or to be located in HSA IV shall perform more than 2,080 procedures per PET scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
  - C- **UNC Medical Center.** In Section Q, *“Form C Utilization – Assumptions and Methodology”* the applicant projects that the existing and proposed fixed PET scanners located or to be located in HSA IV shall perform more than 2,080 procedures per PET scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
  - C- **AUNC.** In Section Q, *“Utilization Methodology and Assumptions”* the applicant projects that the proposed fixed PET scanner to be located in HSA IV shall perform more than 2,080 procedures per PET scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
  - C- **WR Imaging-Garner.** In Section Q, *“Form C.2 Utilization - Assumptions and Methodology”* the applicant projects that the proposed fixed PET scanner to be located in HSA IV shall perform more than 2,080 procedures per PET scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
  - C- **Duke Cary Hospital.** In Section Q, *“Form C Assumptions”* the applicant projects that the proposed fixed PET scanner to be located in HSA IV shall perform more than 2,080 procedures per PET scanner during the third full fiscal year of operation following

project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- C- **Duke University Hospital.** In Section Q, “*Form C Assumptions*” the applicant projects that the existing and proposed fixed PET scanners located or to be located in HSA IV shall perform more than 2,080 procedures per PET scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **Raleigh PET.** In Section Q, “*Raleigh PET, LLC Patient Need and Utilization Methodology*” the applicant projects that the proposed fixed PET scanner to be located in HSA IV shall perform more than 2,080 procedures per PET scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(b) *An applicant proposing to acquire a mobile PET scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- (1) *identify the existing mobile PET scanners owned or operated by the applicant or a related entity that provided services at host sites located in the proposed mobile PET scanner service area during the 12 months before the application deadline for the review period;*
- (2) *identify the approved mobile PET scanners owned or operated by the applicant or a related entity that will provide services at host sites located in the proposed mobile PET scanner service area during the first three full fiscal years following completion of the project;*
- (3) *identify the existing fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed mobile PET scanner service area;*
- (4) *identify the approved fixed PET scanners owned and operated by the applicant or a related entity and located in the proposed mobile PET scanner service area;*
- (5) *identify the existing and proposed host sites for each mobile PET scanner identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile PET scanner;*
- (6) *provide projected utilization of the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile PET scanner during each of the first three full fiscal years of operation following completion of the project;*
- (7) *provide the assumptions and methodology used to project the utilization required by Subparagraph (6) of this Paragraph; and*
- (8) *project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.*

-NA- **All Applications.** None of the applicants in this review proposes to acquire a mobile

PET scanner.



## COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2025 State Medical Facilities Plan, no more than two fixed PET scanners may be approved for the HSA IV fixed PET scanner service area in this review. Because the applications in this review collectively propose to develop seven additional fixed PET scanners in the HSA IV fixed PET scanner service area, all of the applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to determine which proposals should be approved.

Below is a brief description of each project included in the Fixed PET Scanner Comparative Analysis.

- Project ID #J-12593-25 / **DDI** / Acquire one fixed PET scanner to be located at an existing diagnostic center.
- Project ID #J-12595-25 / **UNC Medical Center** / Acquire one fixed PET scanner to be located at the existing hospital.
- Project ID #J-12598-25 / **AUNC** / Acquire one fixed PET scanner to be located at a new diagnostic center.
- Project ID #J-126002-25 / **WR Imaging-Garner** / Acquire one fixed PET scanner to be located at an existing diagnostic center.
- Project ID #J-12607-25 / **Duke Cary Hospital** / Acquire one fixed PET scanner to be located at a new hospital.
- Project ID #J-12610-25 / **Duke University Hospital** / Acquire one fixed PET scanner to be located at the existing hospital.
- Project ID #J-12677-25 / **Raleigh PET** / Acquire one fixed PET scanner to be located at a new diagnostic center.

### Conformity with Review Criteria

An application that is not conforming or not conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

All applications are conforming to all applicable statutory and regulatory review criteria. Therefore, with regard to this comparative factor, all applications are equally effective alternatives.

### Scope of Services

Generally, the application offering a greater scope of services is the more effective alternative for this comparative factor, based on the assumption that a greater scope of services will potentially serve a greater patient base. The following table compares the scope of services proposed to be offered by each applicant on its proposed fixed PET scanner, based on information contained within each application and exhibits:

Facility	Proposed Scope of Proposed Scope of PET Services		
	Oncological PET	Cardiac PET	Neurologic PET
DDI	X	X	X
UNC Medical Center	X	X	X
AUNC	X	X	X
WR Imaging-Garner	X	X	X
Duke Cary Hospital	X	X	X
Duke University Hospital	X	X	X
Raleigh PET	X	X	X

Each of the applicants proposes to provide fixed PET services to oncology, cardiac and neurologic patients. Therefore, regarding scope of services, all applications are equally effective.

### **Geographic Accessibility (Location within the Service Area)**

The 2025 SMFP identifies the need for two fixed PET scanners in HSA IV, which includes 11 counties. The following table illustrates the location of the existing fixed PET scanners in HSA IV:

Location of Existing Fixed PET Scanners in HSA IV			
FACILITY	# OF PET SCANNERS	CITY	COUNTY
Duke Raleigh Hospital	1	Raleigh	Wake
Duke University Hospital	3	Durham	Durham
Rex Hospital	2	Raleigh	Wake
UNC Medical Center	1	Chapel Hill	Orange
Wake PET Services	1	Cary	Wake

Source: 2025 SMFP, Table 15F-1, page 365

As shown in the table above, three existing fixed PET scanners are located in Raleigh, three are located in Durham, one is located in Chapel Hill and one is located in Cary.

The following table illustrates the proposed location of each of the fixed PET scanners proposed by the applicants in this review:

Location of Proposed Fixed PET Scanners		
APPLICANT	CITY	COUNTY
DDI	Durham	Durham
UNC Medical Center	Chapel Hill	Orange
AUNC	Raleigh	Wake
WR Imaging-Garner	Garner	Wake
Duke Cary Hospital	Cary	Wake
Duke University Hospital	Durham	Durham
Raleigh PET	Raleigh	Wake

As shown in the table above, all of the applicants propose to locate the fixed PET scanner in a county within HSA IV that currently provides fixed PET services. DDI and Duke University Hospital propose to locate the fixed PET scanner in Durham; AUNC and Raleigh PET proposes to locate the fixed PET

scanner in Raleigh; UNC Medical Center proposes to locate the fixed PET scanner in Chapel Hill; and Duke Cary Hospital proposes to locate the fixed PET scanner in Cary.

The application submitted by **WRI Imaging-Garner** proposes to locate its proposed fixed PET scanner in Garner, which currently has no fixed PET scanners. Therefore, regarding this comparative factor, the application submitted by **WR Imaging-Garner** is the more effective alternative, and the applications submitted by **DDI**, **UNC Medical Center**, **AUNC**, **Duke Cary Hospital**, **Duke University Hospital** and **Raleigh PET** are less effective alternatives.

### **Access by Service Area Residents**

On page 363, the 2025 SMFP defines the service area for fixed PET scanners as follows: “*A fixed PET scanner’s service area is the HSA in which it is located (Table 17F-1). Appendix A identifies multicounty groupings that comprise the HSAs.*” According to Appendix A on page 369, HSA IV is comprised of 11 counties. Thus, the service area for each proposal is HSA IV. Each application proposes to locate the fixed PET scanner, if approved, in a county within HSA IV. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional fixed PET services in the service area where they live.

The following table shows the projected number of service area residents to be served by each applicant in each applicant’s third project year following project completion for the proposed fixed PET services based on information provided in Section C.3 of the applications:

COUNTY	DDI	UNC MC	AUNC	WR IMAGING	DUKE CARY	DUH	RALEIGH PET
Person	469	*	11	20	*	40	4
Granville	224	*	15	32	16	51	24
Vance	37	*	16	20	18	29	14
Warren	9	*	11	9	0	0	2
Orange	201	256	30	31	0	59	14
Durham	1593	94	83	70	33	259	65
Franklin	23	*	104	135	73	16	68
Chatham	12	*	25	44	*	12	16
Wake	101	286	1774	1949	1505	196	1339
Lee	3	65	95	36	*	*	26
Johnston	3	48	214	415	79	*	283
<b>Total SA</b>	<b>2675</b>	<b>970</b>	<b>2378</b>	<b>2761</b>	<b>1724</b>	<b>662</b>	<b>1855</b>

\*In each of these applications, the applicant provides an “Other” category which may or may not include counties within HSA IV.

Some of the applicants include an “*Other*” category which may or may not include patients who reside in HSA IV. Therefore, regarding this comparative factor, the results are inconclusive.

### **Competition (Patient Access to a New or Alternate Provider)**

Generally, the introduction of a new provider of fixed PET services in the service area would be the

more effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality and/or lower costs in order to compete for patients. The expansion of an existing provider that currently controls fewer fixed PET scanners than another provider in the service area would also encourage all providers in the service area to improve quality and/or lower costs in order to compete for patients.

There are eight existing and approved fixed PET scanners in HSA IV allocated between four providers, as shown in the following table, from Table 15F-1, page 365 of the 2025 SMFP:

Existing Fixed PET Scanners, HSA IV			
PROVIDER (HOSPITAL SYSTEM)	CITY	COUNTY	# OF FIXED PET SCANNERS
Duke Raleigh Hospital	Raleigh	Wake	1
Duke University Hospital	Durham	Durham	3
Rex Hospital	Raleigh	Wake	2
UNC Hospitals	Chapel Hill	Orange	1*
Wake PET Services	Cary	Wake	1
<b>HSA IV Total Fixed PET Scanners</b>			<b>8</b>

\*As noted within these Findings, the 2025 SMFP incorrectly includes an additional fixed PET scanner that was approved pursuant to Policy AC-3, which should have been excluded from the inventory.

The Duke University Health System currently owns and operates four fixed PET scanners in HSA IV. The UNC Health System currently owns and operates three fixed PET scanners in HSA IV; one at UNC Medical Center and two at Rex Hospital. WakeMed is a majority owner of Wake PET Services. Therefore, UNC Medical Center, WR Imaging-Garner, Duke Cary Hospital, Duke University Hospital and Raleigh PET are existing providers of fixed PET services in HSA IV.

The proposals submitted by **DDI** and **AUNC** would be new providers of fixed PET services in HSA IV. Therefore, regarding patient access to a new provider of fixed PET services, the applications submitted by **DDI** and **AUNC** are more effective alternatives.

### **Access by Underserved Groups**

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

*“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”*

For access by underserved groups, applications are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is evaluated as a separate factor.

### **Projected Number of Medicare Patients**

The following table compares the total number of Medicare patients projected to utilize the applicant's fixed PET services in the third full fiscal year of operation for each application in this review. Generally, the application proposing to serve the highest number of Medicare patients is the more effective alternative with regard to this comparative factor.

PROJECTED NUMBER OF MEDICARE PATIENTS TO BE SERVED IN PROJECT YEAR 3			
APPLICANT	a TOTAL PTS.	b % MEDICARE	c # OF MEDICARE PTS
DDI	2,875	42.9%	1,233
UNC Medical Center	5,890	55.1%	3,245
AUNC	2,646	29.4%	778
WR Imaging-Garner	2,761	63.0%	1,739
Duke Cary Hospital	2,150	58.9%	1,266
Duke University Hospital	9,519	56.0%	5,331
Raleigh PET	2,222	47.6%	1,058

Source: Section C.3 and Section L.3 for each application.  
Formula:  $a \times b = c$

As shown in the table above, **Duke University Hospital** projects to serve the highest number of Medicare patients in the third full fiscal year of operation. Therefore, with regard to this comparative factor, the application submitted by **Duke University Hospital** is the more effective alternative; the applications submitted by the remaining applicants are less effective alternatives.

### **Projected Number of Medicaid Patients**

The following table compares the total number of Medicaid patients projected to utilize the applicant's fixed PET services in the third full fiscal year of operation for each application in this review. Generally, the application proposing to serve the highest number of Medicaid patients is the more effective alternative with regard to this comparative factor.

PROJECTED NUMBER OF MEDICAID PATIENTS TO BE SERVED IN PROJECT YEAR 3			
APPLICANT	a TOTAL PTS.	b % MEDICAID	c # OF MEDICAID PTS
DDI	2,875	5.5%	158
UNC Medical Center	5,890	8.1%	477
AUNC	2,646	2.1%	56
WR Imaging	2,761	7.0%	193
Duke Cary Hospital	2,150	3.5%	75
Duke University Hospital	9,519	3.9%	371
Raleigh PET	2,222	7.4%	164

Source: Section C.3 and Section L.3 for each application.  
Formula:  $a \times b = c$

As shown in the table above, **UNC Medical Center** projects to serve the highest number of Medicaid patients in the third full fiscal year of operation. Therefore, with regard to this comparative factor, the application submitted by **UNC Medical Center** is the more effective alternative, and the remaining applications are less effective alternatives.

### **Projected Percentage of Services to Medicare Patients**

The following table shows each applicant's percentage of total services projected to be provided to Medicare patients for fixed PET services in each applicant's third full operating year following project completion based on the information provided in Section L.3 of each application. Generally, the application proposing to provide a higher percentage of services to Medicare patients is the more effective alternative regarding this comparative factor.

**Projected Percentage of Services to Medicare Patients, PY 3**

<b>APPLICANT</b>	<b>% Medicare</b>
DDI	42.9%
UNC Medical Center	55.1%
AUNC	29.4%
WR Imaging-Garner	63.0%
Duke Cary Hospital	58.9%
Duke University Hospital	56.0%
Raleigh PET	47.6%

Source: Section L.3 in each application.

As shown in the table above, **WR Imaging-Garner** projects the highest percentage of fixed PET scanner services that will be provided to Medicare patients in the third year of operation. Therefore, with regard to this comparative factor, the application submitted by **WR Imaging-Garner** is the more effective alternative, and the remaining applications are less effective alternatives.

### **Projected Percentage of Services to Medicaid Patients**

The following table shows each applicant's percentage of total services projected to be provided to Medicaid patients for fixed PET services in each applicant's third full year of operation following project completion, based on the information provided in Section L.3 of each application. Generally, the application proposing to provide a higher percentage of services to Medicaid patients is the more effective alternative regarding this comparative factor.

**Projected Percentage of Services to Medicaid Patients, PY 3**

APPLICANT	% Medicaid
DDI	5.5%
UNC Medical Center	8.1%
AUNC*	2.1%
WR Imaging	7.0%
Duke Cary Hospital	3.5%
Duke University Hospital	3.9%
Raleigh PET, LLC	7.4%

Source: Section L.3 in each application.

As shown in the table above, **UNC Medical Center** projects the highest percentage of fixed PET scanner services to be provided to Medicaid patients in the third year of operation. Therefore, with regard to this comparative factor, the application submitted by **UNC Medical Center** is the more effective alternative, and the remaining applications are less effective alternatives.

**Projected Average Net Revenue per PET Procedure**

The following table compares projected average net revenue per PET procedure in the third full operating year following project completion for each project, based on the information provided in each application's pro forma financial statements in Section Q. Generally, the application proposing the lowest average net revenue per procedure is the more effective alternative regarding this comparative factor since a lower average net revenue per procedure may indicate a lower cost to the patient or third-party payor.

AVERAGE NET REVENUE PER PET PROCEDURE PROJECT YEAR 3			
	TOTAL # OF PROCEDURES	TOTAL NET REVENUE	AVERAGE NET REVENUE /PET PROCEDURE
DDI	2,875	\$6,538,298	\$2,274
UNC Medical Center	5,890	\$18,828,320	\$3,197
AUNC	2,646	\$16,671,122	\$6,300
WR Imaging	2,761	\$4,034,179	\$1,461
Duke Cary Hospital	2,150	\$8,635,601	\$4,017
Duke University Hospital	9,519	\$33,642,562	\$3,534
Raleigh PET	2,222	\$10,864,390	\$4,889

Source: Section Q, Forms C.2b and F.2.b for each application.

**Note:** DDI, WR Imaging-Garner and Raleigh PET propose to "global bill" for services, which means their projected net revenues are based on charges for both the technical and professional components. AUNC propose to global bill for only for non-Medicare patients, and UNC Medical Center, Duke Cary Hospital and Duke University Hospital propose to bill separately for the professional and technical components, which means their projected net revenues exclude professional fees and would be higher than those shown in the table above.

As shown in the table above, **WR Imaging-Garner** projects the lowest average net revenue per PET procedure in the third full fiscal year following project completion. Therefore, with regard to this comparative factor, the application submitted by **WR Imaging-Garner** is the more effective alternative, and the remaining applications are less effective alternatives.

**Projected Average Operating Expense per PET Procedure**

The following table compares projected average operating expense per PET procedure in the third full operating year following project completion for each facility, based on the information provided in each application's pro forma financial statements in Section Q. Generally, regarding this factor, the application proposing the lowest average operating expense per procedure is the more effective alternative, since a lower average operating cost per procedure may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

AVERAGE OPERATING COST PER PET PROCEDURE PROJECT YEAR 3			
	TOTAL # OF PROCEDURES	TOTAL OPERATING COST	AVERAGE OPERATING COST PET PROCEDURE
DDI	2,875	\$4,199,934	\$1,461
UNC Medical Center	5,890	\$14,014,596	\$2,379
AUNC	2,646	\$14,767,800	\$5,581
WR Imaging	2,761	\$2,545,335	\$922
Duke Cary Hospital	2,150	\$5,720,308	\$2,661
Duke University Hospital	9,519	\$27,416,693	\$2,880
Raleigh PET, LLC	2,222	\$8,430,460	\$3,794

Source: Section Q, Forms C.2b and F.2.b for each application.

**Note:** DDI, WR Imaging-Garner and Raleigh PET propose to “global bill” for services, which means their projected operating costs are based on costs for both the technical and professional components. AUNC propose to global bill for only for non-Medicare patients, and UNC Medical Center, Duke Cary Hospital and Duke University Hospital propose to bill separately for the professional and technical components, which means their projected operating costs exclude professional fees and would be higher than those shown in the table above.

As shown in the table above, **WR Imaging-Garner** projects the lowest average operating cost per PET procedure in the third full fiscal year following project completion. Therefore, with regard to this comparative factor, the application submitted by **WR Imaging-Garner** is the more effective alternative and the remaining applications are less effective alternatives.



## SUMMARY

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance:

COMPARATIVE FACTOR	DDI	UNC MEDICAL CENTER	AUNC	WR IMAGING-GARNER
Conformity with Statutory and regulatory Review Criteria	Yes	Yes	Yes	Yes
Scope of Services	Equally Effective	Equally Effective	Equally Effective	Equally Effective
Geographic Accessibility (Location within the Service Area)	Less Effective	Less Effective	Less Effective	<b>More Effective</b>
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Competition (Patient Access to a New or Alternate Provider)	<b>More Effective</b>	Less Effective	<b>More Effective</b>	Less Effective
Projected Number of Medicare Patients	Less Effective	Less Effective	Less Effective	Less Effective
Projected Number of Medicaid Patients	Less Effective	<b>More Effective</b>	Less Effective	Less Effective
Projected Percentage of Services to Medicare Patients	Less Effective	Less Effective	Less Effective	<b>More Effective</b>
Projected Percentage of Services to Medicaid Patients	Less Effective	<b>More Effective</b>	Less Effective	Less Effective
Projected Average Net Revenue per Procedure	Less Effective	Less Effective	Less Effective	<b>More Effective</b>
Projected Average Operating Cost per Procedure	Less Effective	Less Effective	Less Effective	<b>More Effective</b>

COMPARATIVE FACTOR	DUKE CARY HOSPITAL	DUKE UNIVERSITY HOSPITAL	RALEIGH PET
Conformity with Statutory and regulatory Review Criteria	Yes	Yes	Yes
Scope of Services	Equally Effective	Equally Effective	Equally Effective
Geographic Accessibility (Location within the Service Area)	Less Effective	Less Effective	Less Effective
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive
Competition (Patient Access to a New or Alternate Provider)	Less Effective	Less Effective	Less Effective
Projected Number of Medicare Patients	Less Effective	<b>More Effective</b>	Less Effective
Projected Number of Medicaid Patients	Less Effective	Less Effective	Less Effective
Projected Percentage of Services to Medicare Patients	Less Effective	Less Effective	Less Effective
Projected Percentage of Services to Medicaid Patients	Less Effective	Less Effective	Less Effective
Projected Average Net Revenue per Procedure	Less Effective	Less Effective	Less Effective
Projected Average Operating Cost per Procedure	Less Effective	Less Effective	Less Effective

As shown in the tables above, the application submitted by **WR Imaging-Garner** was determined to be the more effective alternative regarding the following factors:

- Geographic Accessibility
- Projected percentage of services to Medicare patients, PY 3
- Projected average net revenue per PET procedure, PY 3
- Projected average operating costs per PET procedure, PY 3

The application submitted by **UNC Medical Center** was determined to be the more effective alternative regarding the following factors:

- Projected number of Medicaid patients, PY 3
- Projected percentage of services to Medicaid patients, PY 3

The five remaining applications were found to be less effective alternatives in this Comparative Analysis. Therefore, based upon the independent review of each application and the Comparative Analysis, the following applications are approved as submitted:

- Project ID #J-12602-25 **Wake Radiology UNC REX Healthcare-Garner and WR Imaging, LLC**/Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.
- Project ID #J-12595-25 **University of North Carolina Hospitals at Chapel Hill**/Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

The following applications are denied:

- Project ID #J-12593-25 **Durham Diagnostic Imaging, LLC, Novant Health, Inc. and Novant Health Norfolk, LLC**/Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.
- Project ID #J-12598-25 **Associated Urologists of North Carolina, P.A. and Associated Urologists of NC Properties, LLC**/Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.
- Project ID #J-12607-25 **Duke University Health System, Inc.**/Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.
- Project ID #J-12610-25 **Duke University Health System, Inc.**/Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.
- Project ID #J-12611-25 **Raleigh PET, LLC**/Acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP.

## DECISION

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the applications submitted by **Wake Radiology UNC REX Healthcare-Garner and WR Imaging, LLC** and **University of North Carolina Hospitals at Chapel Hill** are the most effective alternatives proposed in this review for the development of a total of two fixed PET scanner in HSA IV pursuant to the need determination in the 2025 SMFP.

**Wake Radiology UNC REX Healthcare-Garner and WR Imaging, LLC** proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP and the application is approved subject to the following conditions:

1. **Wake Radiology UNC REX Healthcare-Garner and WR Imaging, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

- 2. The certificate holder shall acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.**
- 3. The certificate holder shall develop and implement strategies to provide culturally competent services to members of its defined medically underserved community that are consistent with representations made in the certificate of need application.**
- 4. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. The first progress report shall be due on November 1, 2025.**
- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

**University of North Carolina Hospitals at Chapel Hill** proposes to acquire one fixed PET scanner pursuant to the need determination in the 2025 SMFP and the application is approved subject to the following conditions:

- 1. University of North Carolina Hospitals at Chapel Hill (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire no more than one fixed PET scanner pursuant to the need determination in the 2025 SMFP.**
- 3. The certificate holder shall develop and implement strategies to provide culturally competent services to members of its defined medically underserved community that are consistent with representations made in the certificate of need application.**
- 4. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable**

**and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**

- b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. The first progress report shall be due on November 1, 2025.**
- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**