

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 2, 2015

Findings Date: September 2, 2015

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Team Leader: Fatimah Wilson

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Project ID #: G-11051-15

Facility: Novant Health Forsyth Medical Center

FID #: 923174

County: Forsyth

Applicant: Forsyth Memorial Hospital, Inc.

Project: Replace and convert an existing PET/CT scanner to a mobile PET/CT scanner pursuant to Policy TE-1 in the 2015 SMFP

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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

The applicant, Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center (NHFMC), proposes to replace and convert one of its two fixed PET/CT scanners currently in use at NHFMC to a mobile PET/CT scanner, pursuant to Policy TE-1 in the 2015 State Medical Facilities Plan (SMFP), to serve multiple host site hospitals in North Carolina.

NHFMC states that it will remove one of its two existing fixed PET/CT scanners from service in North Carolina once the proposed mobile scanner becomes operational; thus, there will be no increase in the total inventory of fixed and mobile PET/CT scanners in North Carolina.

Need Determination

The applicant does not propose to develop beds, add new health services or acquire medical equipment for which there is a need determination in the 2015 SMFP. Therefore, there are no need determinations in the 2015 SMFP that are applicable to this review.

Policies

There is one policy in the 2015 SMFP that is applicable to this review.

POLICY TE-1: CONVERSION OF FIXED PET SCANNERS TO MOBILE PET SCANNERS states:

“Facilities with an existing or approved fixed PET scanner may apply for a Certificate of Need (CON) to convert the existing or approved fixed PET scanner to a mobile PET scanner if the applicant(s) demonstrates in the CON application that the converted mobile PET scanner:

- 1. Shall continue to operate as a mobile PET scanner at the facility, including satellite campuses, where the fixed PET scanner is located or was approved to be located.*
- 2. Shall be moved at least weekly to provide services at two or more host facilities.¹*
- 3. Shall not serve any mobile host site that is not owned by the PET certificate holder or an entity related to the PET certificate holder such as a parent or subsidiary that is located in the county where any existing or approved fixed PET scanner is located, except as required by subpart (1).*

There will be one certificate of need application filing opportunity each calendar year.

¹The council recommended the revision of the current East and West service areas to a statewide service area to allow flexibility in servicing mobile PET sites.”

In Section III.2, page 70, the applicant states that NHFMC meets each requirement of the above policy, specifically:

- “1. The fixed PET scanner to be converted is located in Forsyth County. NHFMC will operate the mobile PET scanner in Forsyth County at its satellite campus in Kernersville (NHKMC).*
- 2. The mobile PET scanner will serve 7 host sites, including NHKMC, NHMMC, NHHMC, NHMC, NHRMC, Lenoir Memorial Hospital and Morehead Memorial Hospital. As such the mobile PET unit will move at least weekly among the sites.*

3. *Forsyth and Mecklenburg Counties are the only counties involved in this proposal that have fixed PET service; in those counties NHFMC is not serving entities that are not related to the PET certificate holder.”*

The information provided by the applicant is reasonable and meets the requirements stated in POLICY TE-1; therefore, the application is consistent with POLICY TE-1.

Conclusion

In summary, the applicant adequately demonstrates that its proposal is consistent with POLICY TE-1. Therefore, the application is conforming to this criterion.

- (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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to replace and convert one of its two fixed PET/CT scanners currently in use at NHFMC to a mobile PET/CT scanner, pursuant to Policy TE-1 in the 2015 SMFP.

The most recent data, published in the Proposed 2016 SMFP, shows a slight decline (a compound annual growth rate (CAGR) of -2% over the last three years) in the total number of fixed PET procedures performed in North Carolina, with some facilities showing a small increase in procedures and others showing a small decrease. The data shows a slight increase in the number of mobile PET procedures over the same period (CAGR of 1%), even though the only two mobile PET scanners in the State have been operating above capacity for several years. The data also indicates that while the mobile PET scanners are operating above capacity, the fixed PET scanners all have excess capacity.

The applicant states that one of NHFMC's existing fixed PET scanners will be removed from service at project completion; therefore, there will be no increase in the total inventory of fixed and mobile PET scanners in North Carolina. The proposed project would eliminate some excess fixed PET capacity and provide additional mobile PET capacity.

In Section I, pages 5-8, the applicant describes NHFMC and its health services, and states that NHFMC will utilize the combined experience of Novant Health, Inc. (Novant Health) and MedQuest Associates, Inc. (MedQuest) to provide mobile PET/CT services in North Carolina.

Novant Health, the non-profit parent company of NHFMC, owns other legal entities that in turn operate the following hospitals in North Carolina:

- Novant Health Charlotte Orthopaedic Hospital, Charlotte, Mecklenburg County,
- Novant Health Presbyterian Hospital, Charlotte, Mecklenburg County,
- Novant Health Matthews Medical Center, Matthews, Mecklenburg County,
- Novant Health Huntersville Medical Center, Huntersville, Mecklenburg County,
- Novant Health Rowan Medical Center, Salisbury, Rowan County,
- Novant Health Thomasville Medical Center, Thomasville, Davidson County,
- Novant Health Forsyth Medical Center, Winston-Salem, Forsyth County,
- Novant Health Kernersville Medical Center¹, Kernersville, Forsyth County,
- Novant Health Clemmons Medical Center², Clemmons, Forsyth County,
- Novant Health Medical Park Hospital, Winston-Salem, Forsyth County,
- Novant Health Franklin Medical Center, Louisburg, Franklin County, and
- Novant Health Brunswick Medical Center, Bolivia, Brunswick County.

Novant Health has been CON-approved to construct Novant Health Mint Hill Medical Center in Charlotte, Mecklenburg County.

Novant Health has shared services agreements with the following hospitals inside North Carolina:

- Ashe Memorial Hospital, Jefferson, Ashe County,
- Cape Fear Valley Medical Center, Fayetteville, Cumberland County,
- Hugh Chatham Memorial Hospital, Elkin, Surry County,
- Morehead Memorial Hospital, Eden, Rockingham County,
- Lenoir Memorial Hospital, Kinston, Lenoir County, and
- Halifax Regional Medical Center, Roanoke Rapids, Halifax County.

Novant Health owns other legal entities that in turn, operate the following outpatient providers located in the Novant Greater Winston-Salem market and in the Triangle/Coastal market:

- Novant Health Hawthorne Outpatient Surgery, Winston-Salem, Forsyth County,
- Novant Health Outpatient Orthopedic Surgery, Winston-Salem, Forsyth County,
- NHRMC's Julian Rd. Imaging Center, Salisbury, Rowan County,
- Novant Health Julian Rd. Outpatient Surgery, Salisbury, Rowan County,
- Novant Health Rehabilitation Center, Winston-Salem, Forsyth County,

¹ Novant Health Kernersville Medical Center is licensed under the existing Novant Health Forsyth Medical Center hospital license.

² Novant Health Clemmons Medical Center is licensed under the existing Novant Health Forsyth Medical Center hospital license.

- Novant Health Today's Woman Health and Wellness Center, Winston-Salem, Forsyth County, and
- Numerous Novant Health Medical Group physician practices and urgent care centers located in Forsyth, Davie, Davidson, Yadkin, Iredell, Surry, Wilkes, Guilford, Rowan, Wake, Durham, Orange, Franklin and Brunswick counties.

Novant Health owns and operates three fixed PET/CT scanners at the following locations:

- Novant Health Forsyth Medical Center, Winston-Salem, Forsyth County (2), and
- Novant Health Presbyterian Medical Center, Charlotte, Mecklenburg County (1).

Novant Health does not own or operate any mobile PET/CT scanners in North Carolina or any other state at this time.

The applicant states that MedQuest will manage the applicant's proposed mobile PET/CT scanner program. MedQuest operates the following imaging centers in North Carolina:

- Open MRI & Imaging of Asheville, Asheville, Buncombe County,
- Novant Health Imaging Cabarrus, Concord, Mecklenburg County,
- Carolina Imaging of Fayetteville, Fayetteville, Cumberland County,
- Chapel Hill Diagnostic Imaging, Chapel Hill, Orange County,
- Coastal Diagnostic Imaging, Jacksonville, Onslow County,
- Durham Diagnostic Imaging-Independence Park, Durham, Durham County,
- Durham Diagnostic Imaging-Southpoint/Triangle, Durham, Durham County,
- Durham Diagnostic Imaging-Henderson, Henderson, Vance County,
- Novant Health Imaging Maplewood, Winston-Salem, Forsyth County,
- Novant Health Breast Center, Winston-Salem, Forsyth County,
- Novant Health Imaging Kernersville, Kernersville, Forsyth County,
- Novant Health Gastonia Imaging, Gastonia, Gaston County,
- Novant Health Imaging Southpark, Charlotte, Mecklenburg County,
- Novant Health Imaging Mooresville, Mooresville, Iredell County,
- North Carolina Diagnostic Imaging-Cary, Cary, Wake County,
- Novant Health Imaging Piedmont, Winston-Salem, Forsyth County,
- Novant Health Imaging Monroe, Monroe, Union County,
- Novant Health Imaging Museum, Charlotte, Mecklenburg County,
- Novant Health Imaging University, Charlotte, Mecklenburg County,
- Novant Health Imaging Ballantyne, Charlotte, Mecklenburg County,
- Novant Health Imaging Steele Creek, Charlotte, Mecklenburg County,
- Novant Health Breast Center, Charlotte, Mecklenburg County,
- Novant Health Breast Center-Huntersville, Huntersville, Mecklenburg County,
- Novant Health Imaging-Julian Rd., Salisbury, Rowan County,
- Southern Pines Diagnostic Imaging, Southern Pines, Moore County, and
- Novant Health Imaging Triad, Greensboro, Guilford County.

Population to be Served

On page 138, the 2015 SMFP defines the service area for mobile PET scanners as statewide. Thus, the service area for this facility's mobile PET service is statewide.

In Section III.5(a), page 73, the applicant states:

“For purposes of the Application, NHFMC has identified the Primary Service Area Counties as the home counties for each mobile host site (Forsyth, Mecklenburg, Rowan, Davidson, Lenoir and Rockingham Counties) that will contract for mobile PET/CT service with NHFMC.”

In Section III.1, page 42, the applicant states that it will initially serve the following PET host sites:

- Novant Health Kernersville Medical Center, Forsyth County, HSA II,
- Novant Health Rowan Medical Center, Rowan County, HSA III,
- Novant Health Huntersville Medical Center, Mecklenburg County, HSA III,
- Novant Health Matthews Medical Center, Mecklenburg County, HSA III,
- Novant Health Thomasville Medical Center, Davidson County, HSA II,
- Lenoir Memorial Hospital, Lenoir County, HSA VI, and
- Morehead Memorial Hospital, Rockingham County, HSA II.

The applicant provides a mobile PET host site map on page 43 of the application. Letters of intent from the Presidents on behalf of each medical center above are included in Exhibit 4.

On page 60 of the application, the applicant states that five of the seven proposed mobile PET/CT host sites currently offer mobile PET/CT services through a service agreement with Alliance Imaging: Novant Health Huntersville Medical Center (NHHMC), Novant Health Rowan Medical Center (NHRMC), Novant Health Matthews Medical Center (NHMMC), Novant Health Thomasville Medical Center (NHTMC), and Lenoir Memorial Hospital (LMH). Novant Health Kernersville Medical Center (NHKMC) and Morehead Memorial Hospital (MMH) have not had access to mobile PET scan services in the past.

In Section III.4(b), pages 72-73, the applicant provides the federal fiscal year (FFY) 2013-14 patient origin for mobile PET services at the proposed five mobile PET host sites which currently have mobile PET services, as summarized in the following table.

Proposed Mobile PET Sites Currently Providing Mobile PET Services Current Patient Origin by County FFY 2013-14					
County	Percent Patient Origin				
	NHHMC	NHMMC	NHRMC	NHTMC	LMH
Mecklenburg	53.6%	48.7%	0.0%	0.0%	0.0%
Iredell	23.4%	0.0%	0.0%	0.0%	0.0%
Lincoln	11.0%	0.0%	0.0%	0.0%	0.0%
Catawba	5.0%	0.0%	0.0%	0.0%	0.0%
Union	0.0%	36.1%	0.0%	0.0%	0.0%
Rowan	0.0%	0.0%	84.1%	0.0%	0.0%
Davidson	0.0%	0.0%	5.4%	88.2%	0.0%
Davie	0.0%	0.0%	2.9%	0.0%	0.0%
Stanly	0.0%	0.0%	1.7%	0.0%	0.0%
Forsyth	0.0%	0.0%	0.0%	3.5%	0.0%
Guilford	0.0%	0.0%	0.0%	3.5%	0.0%
Lenoir	0.0%	0.0%	0.0%	0.0%	60.4%
Duplin	0.0%	0.0%	0.0%	0.0%	14.9%
Onslow	0.0%	0.0%	0.0%	0.0%	7.1%
Greene	0.0%	0.0%	0.0%	0.0%	5.8%
Other	7.0%	15.2%	5.9%	4.8%	11.8%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

Applicant's Source: 2015 License Renewal Applications
 Other: NHHMC: Alamance, Cabarrus, Rowan, Wake counties and South Carolina
 NHMMC: Anson Cabarrus, Lincoln, Stanly counties and South Carolina
 NHRMC: Ashe, Cabarrus, Catawba, Cleveland, Forsyth, Gaston, Guilford, Iredell, Stokes counties and Virginia
 NHTMC: Moore, Randolph, Stanly, and Wake counties
 LMH: Pitt, Sampson, Carteret, Wayne and Craven counties

In Section III.5(c), page 75-77, the applicant provides the projected patient origin for PET services at each of the seven proposed PET host sites for the first two years following project completion, as illustrated in the following tables.

NHHMC Projected Patient Origin by County				
County	Year 1 FFY 2016-17		Year 2 FFY 2017-18	
	Patients	Percent	Patients	Percent
Mecklenburg	243	53.6%	243	53.6%
Iredell	106	23.4%	106	23.4%
Lincoln	50	11.0%	50	11.0%
Catawba	23	5.0%	23	5.0%
Other	32	7.0%	32	7.0%
Total	454	100.0%	454	100.0%

Other: Alamance, Cabarrus, Rowan Wake counties and South Carolina

NHHMC Projected Patient Origin by County				
County	Year 1 FFY 2016-17		Year 2 FFY 2017-18	
	Patients	Percent	Patients	Percent
Mecklenburg	115	48.7%	231	48.7%
Union	86	36.1%	171	36.1%
Other	36	15.2%	72	15.2%
Total	237	100.0%	474	100.0%

Other: Anson, Cabarrus, Lincoln, and Stanly counties

NHRMC Projected Patient Origin by County				
County	Year 1 FFY 2016-17		Year 2 FFY 2017-18	
	Patients	Percent	Patients	Percent
Rowan	266	84.1%	266	84.1%
Davidson	17	5.4%	17	5.4%
Davie	9	2.9%	9	2.9%
Stanly	5	1.7%	5	1.7%
Other	19	5.9%	19	5.9%
Total	316	100.0%	316	100.0%

Other: Ashe, Cabarrus, Catawba, Cleveland, Forsyth, Gaston, Guilford, Iredell, Stokes counties and Virginia

NHTMC Projected Patient Origin by County				
County	Year 1 FFY 2016-17		Year 2 FFY 2017-18	
	Patients	Percent	Patients	Percent
Davidson	119	88.2%	119	88.2%
Forsyth	5	3.5%	5	3.5%
Guilford	5	3.5%	5	3.5%
Other	6	4.8%	6	4.8%
Total	135	100.0%	135	100.0%

Other: Moore, Randolph, Stanly and Wake counties

LMH Projected Patient Origin by County				
County	Year 1 FFY 2016-17		Year 2 FFY 2017-18	
	Patients	Percent	Patients	Percent
Lenoir	98	60.4%	98	60.4%
Duplin	24	15.0%	24	15.0%
Onslow	12	7.1%	12	7.1%
Greene	9	5.8%	9	5.8%
Jones	7	4.0%	7	4.0%
Other	13	7.7%	13	7.7%
Total	163	100.0%	163	100.0%

Other: Pitt, Sampson, Carteret, Wayne and Craven counties

NHKMC Projected Patient Origin by County				
County	Year 1 FFY 2016-17		Year 2 FFY 2017-18	
	Patients	Percent	Patients	Percent
Forsyth	367	66.0%	374	66.0%
Stokes	72	13.0%	73	13.0%
Davidson	39	7.0%	40	7.0%
Guilford	28	5.0%	28	5.0%
Other	50	9.0%	51	9.0%
Total	556	100.0%	566	100.0%

Other: Davie, Yadkin, Surry, Rowan and other NC counties

MMH Projected Patient Origin by County				
County	Year 1 FFY 2016-17		Year 2 FFY 2017-18	
	Patients	Percent	Patients	Percent
Rockingham	57	74.4%	76	74.4%
Caswell	3	3.5%	4	3.5%
Stokes	1	1.1%	1	1.1%
Other	16	21.0%	21	21.0%
Total	77	100.0%	102	100.0%

Other: Virginia

Total NHFMC Projected Patient Origin by County*				
County	Year 1 FFY 2016-17		Year 2 FFY 2017-18	
	Patients	Percent	Patients	Percent
Forsyth	372	19.2%	379	17.1%
Rowan	266	13.7%	266	12.0%
Mecklenburg	358	18.5%	474	21.4%
Davidson	175	9.0%	176	8.0%
Iredell	106	5.5%	106	4.8%
Lenoir	98	5.1%	98	4.4%
Union	86	4.4%	171	7.7%
Stokes	73	3.8%	74	3.3%
Rockingham	57	2.9%	76	3.4%
Lincoln	50	2.6%	50	2.3%
Guilford	33	1.7%	33	1.5%
Duplin	24	1.2%	24	1.1%
Catawba	23	1.2%	23	1.0%
Onslow	12	0.6%	12	0.5%
Greene	9	0.5%	9	0.4%
Davie	9	0.5%	9	0.4%
Jones	7	0.4%	7	0.3%
Stanly	5	0.3%	5	0.2%
Caswell	3	0.2%	4	0.2%
Other	172	8.9%	214	9.7%
Total	1,938	100.0%	2,210	100.0%

*Includes Winston-Salem and Kernersville campuses combined

Other: Alamance, Anson, Cabarrus, Carteret, Craven, Moore, Pitt, Randolph, Sampson, Surry, Wayne, Wake, Yadkin and other NC counties, South Carolina and Virginia

In Section III.5(d), page 77, the applicant states that the following assumptions and methodologies were used to project patient origin:

“NHFMC assumes that the projected PET patient origin for each mobile host site will continue to reflect each facility’s historical operating experience. New sites that will be offering mobile PET services utilized patient origin estimates based on existing cancer care programs at each facility.”

The applicant adequately identified the population to be served.

Analysis of Need

In Section III.1(a), pages 40-59, the applicant discusses the need to replace its existing fixed PET/CT scanner and the need for an additional mobile PET/CT scanner in North Carolina, stating the need is based on the following factors:

- the age of the existing fixed PET/CT unit at NHFMC and the need to replace it with state-of-the-art PET/CT technology,
- the lack of availability of mobile PET capacity,
- expanding need for PET scanning capabilities and applications at the proposed host sites,
- historical cancer incidence rates, and
- growth in the population 65 years of age and older.

The applicant states that the existing fixed PET/CT unit being replaced is over 10 years old, has reached the end of its useful life and will be removed from service in North Carolina. NHFMC’s second fixed PET/CT scanner began operation on the NHFMC campus in November 2014, has advanced technology and the capacity to adequately meet the facility’s need for PET/CT services at this time.

The applicant states (page 41) that the proposed mobile PET/CT unit represents state-of-the-art technology in mobile PET/CT imaging. The unit will have all the functionality of the new fixed PET/CT scanner at NHFMC, including cardiac imaging capabilities and the “MedRad Intego PET Infusion System”.

In Section III.1(a), pages 37-40, the applicant discusses the lack of mobile PET/CT capacity in North Carolina. Currently, there are only two mobile PET/CT scanners in North Carolina. They are owned and operated by Alliance Imaging and serve a combined 29 host sites across the State.³ The applicant states that due to the overwhelming number of mobile PET host sites per scanner, it is practically impossible to obtain additional days of service from Alliance or to add a new mobile PET host site, unless an existing Alliance Imaging host site reduces its existing days or hours of service. The applicant provides tables demonstrating Alliance Imaging’s historical mobile PET utilization on page 38 of the application, as summarized below.

³ Alliance Imaging’s January 2015 Registration and Inventory of Medical Equipment

SMFP	Data Year	Eastern Region			Western Region		
		# of Host Sites	PET Volume	Percent Change	# of Host Sites	PET Volume	Percent Change
2006	FFY 2004	8	1,094		7	1,154	
2007	FFY 2005	8	2,175	98.8%	8	1,446	25.3%
2008	FFY 2006	7	1,543	-29.0%	13	1,885	30.3%
2009	FFY 2007	7	2,036	32.0%	14	2,826	49.9%
2010	FFY 2008	8	2,619	28.6%	15	3,196	13.1%
2011	FFY 2009	9	2,437	-6.9%	14	2,821	-11.7%
2012	FFY 2010	10	2,550	4.6%	18	2,861	1.4%
2013	FFY 2011	11	2,650	3.9%	18	3,066	7.2%
2014	FFY 2012	11	2,811	6.1%	19	3,066	0.0%
2015	FFY 2013	11	2,858	1.7%	18	2,933	-4.3%
Draft 2016	FFY 2014	12	2,837	-0.7%	17	3,033	3.4%

Source: # of host sites – sites reported in the SMFP that performed 1 or more scans; FFY 2014 data- Alliance Imaging’s 2015 Registration and Inventory of Medical Equipment submitted to DHSR.

The applicant states that the percent reduction in volume for the Western Region in 2015 was due to CMC-Union operating a fixed PET scanner and Valdese General Hospital closing. On page 38, the applicant states:

“The total number of mobile PET host sites being served by Alliance Imaging makes it logistically impossible to accommodate additional capacity requests, particularly for host sites that need service on a weekly basis. As indicated in the charts above, the two existing mobile PET units have exceeded 2,600 procedures for several years. In fact, the western mobile PET unit has exceeded that threshold since FFY 2007, or nearly eight years while the eastern unit has surpassed the threshold since FFY 2011.”

On page 39, the applicant discusses the State Health Coordinating Council (SHCC) and its Adoption of SMFP Policy TE-1 to create an opportunity for existing healthcare providers to convert an existing previously CON-approved fixed PET/CT scanner to a mobile PET/CT scanner to improve accessibility to PET services for smaller community hospitals without increasing the overall PET/CT scanner inventory. The applicant states:

“As the SHCC has recognized, it is no longer feasible for two mobile PET/CT units to provide adequate mobile PET coverage to the number of hospitals that are requesting this vital healthcare service.”

In Section III, pages 43-44, the applicant states that over the last several years Novant Health’s mobile PET host sites have repeatedly requested additional time but the vendor has been unable to fully meet the requests, further stating:

“Over the past several years, Alliance representatives have told Novant that additional days of service are not available due to the number of sites being serviced.”

The applicant discusses the expanding need for PET/CT services at its proposed host sites on pages 44-48, citing comprehensive cancer programs and well-established oncology specialty groups as factors impacting the growing need for PET/CT services at those sites. On page 47, the applicant states that the most frequent use of PET/CT scanner diagnostic imaging studies is for diagnosis, treatment, and follow-up of cancer patients. The applicant also identifies the use of PET for cardiac imaging as an evolving application for PET imaging.

Beginning on page 55, the applicant discusses the cancer incidence rates in its proposed primary service area of Davidson, Forsyth, Mecklenburg, Rowan, Rockingham and Lenoir counties, stating that five of the six counties have significantly higher cancer incidence rates than the State average. The applicant further states (page 56) that the primary service area as a whole has experienced an increase of 12.5% in new cancer cases from 2010 to 2015. On page 58, the applicant states that according to a study published in the Journal of Clinical Oncology, researchers predict a 67 percent increase in the number of adults age 65 or older diagnosed with cancer.

Though the applicant’s proposed primary service area is projected to have modest growth in overall population from 2015-2019, the applicant provides data (pages 58-59) showing that the population for aged 65+ residents in the primary service area is expected to increase from 7.7% to 21.6%, depending upon county, becoming anywhere from 11.58% to 20.21% of each respective county’s total population. The applicant states that from a healthcare perspective, this represents a pressing concern as the elderly population increases in a community where their support systems (younger family members) may be unavailable to participate in their care on a daily basis. The applicant further states:

“The combination of these factors make it even more important to offer services, such as mobile PET/CT imaging, locally in order to better serve patients within communities.”

Based on the factors above, NHFMC anticipates continued demand for PET/CT services; thus, the applicant states that it is proposing to replace and convert a fixed dedicated PET/CT scanner at NHFMC to a mobile PET/CT scanner, pursuant to Policy TE-1, to better serve the existing mobile PET host sites, as well as offer mobile PET services to sites that do not currently offer such service. Though it is possible for physicians at the proposed host sites to refer their PET patients out to existing underutilized fixed PET providers, the applicant states on page 44 of the application:

“The ability to offer consistent, weekly mobile PET/CT service at these facilities will reduce travel burdens for patients and provide access to critical imaging tools for their physicians.”

Projected Utilization

In Section III.1, beginning on page 59, the applicant provides the projected utilization for its fixed PET/CT scanner at NHFMC and for its proposed mobile PET/CT scanner. The applicant states that the methodology for the mobile PET/CT scanner incorporates multiple factors based on the individual facility needs for each proposed mobile PET host site. The applicant states that the methodology consolidates these factors based on the following:

- the anticipated PET/CT volume demands at NHFMC and NHKMC in Forsyth County,
- the individual facility needs for mobile PET/CT imaging at the existing mobile PET host sites (NHTMC, NHRMC, NHHMC, NHMMC, and LMH), and
- the projected demand for mobile PET/CT imaging as a new service at MMH.

The applicant further describes the methodology in pages 60-68, as discussed below.

Step 1: Historical PET/CT Usage at Novant Health Forsyth Medical Center in Forsyth County (pages 60-61).

The applicant states that with the second PET/CT scanner becoming operational in late 2014, NHFMC has primarily operated only one fixed PET/CT scanner. The applicant provides NHFMC historical PET volume data on page 61, reflecting a compound annual growth rate of 1.7% from 2012 through annualized 2015. The applicant states that the new scanner benefits from improved technology, faster scanning capabilities and fewer maintenance issues and therefore will not have any difficulty performing the total projected NHFMC scan volume on the single newer scanner.

Step 2: Determine the projected volume of PET scans at NHFMC through the end of Project Year 3 (pages 61-62). The applicant applies the CAGR for fixed PET volume at NHFMC from CY 2012 through annualized CY 2015 (1.7%) to the annualized CY 2015 volume. The applicant bases the annualized CY 2015 on four months of data: January 1 through April 30, 2015. The applicant projects the fixed PET scan volume at NHFMC (page 61), as shown below.

Projected NHFMC Fixed PET Scan Volume

	CY 2014	Annualized CY 2015*	CY 2016	CY 2017	CY 2018	CY 2019
PET/CT Volume	2,502	2,700	2,746	2,793	2,840	2,888
% Growth		7.90%	1.70%	1.70%	1.70%	1.70%

*Annualized based on 1/1/15-4/30/15 data

The applicant states that the projection is reasonable, using a 1.7% growth rate, which it states is conservative considering the 7.9% increase in PET/CT volume from CY 2014 to annualized CY 2015. In the applicant’s response to comments, the applicant

provides more current data based on six months of data (January 1, 2015 through June 30, 2015) showing that NHFMC's Annualized data for CY2015 PET volume is 2,804 scans, which exceeds its projected CY2017 projection of 2,793 scans, supporting its premise that the projection is reasonable, if not conservative.

However, it is not necessary for the applicant to project growth in its NHFMC PET service to demonstrate the need to replace and convert one of its existing fixed PET scanners to a mobile PET scanner pursuant to Policy TE-1. The PET scanner already exists; the proposed project does not increase the total inventory of fixed and mobile PET scanners; therefore, there are no applicable performance standards required to be met.

Step 3: Determine the projected volume of PET scans at NHKMC through the end of Project Year 3 (page 62-63).

NHKMC, an acute care facility in Kernersville, is licensed as part of NHFMC, thus is a satellite campus of NHFMC. The applicant proposes to provide mobile PET/CT imaging services at NHKMC two days per week.

The applicant states that with the availability of mobile PET/CT services at NHKMC, NHFMC reasonably anticipates a shift in volume to the NHKMC location, especially since NHKMC has developed a satellite comprehensive cancer center in Kernersville and PET/CT services represents a natural extension of the full-range of cancer care provided there.

The applicant states that it estimates that 20% of NHFMC's existing fixed PET/CT patient population would be served at NHKMC during the first three project years based on:

- 1) patient origin data for current NHFMC fixed PET/CT services,
- 2) the patient origin of radiation oncology cases at NHKMC,
- 3) the overall growth in the cancer program at NHKMC, and
- 4) the enhanced capacity to provide PET services at NHFMC and NHKMC.

Based on the above facts, the applicant projects the following PET volume for NHFMC and NHKMC. The applicant converts the calendar year volume to federal fiscal year (FFY) for the first three project years, as shown in the following table.

	Project Year 1	Project Year 2	Project Year 3
	FFY 2016-17	FFY 2017-18	FFY 2018-19
Total NHFMC PET/CT Projected Volume	2,782	2,828	2,876
Percentage of Patients to be Served at NHKMC	20%	20%	20%
Projected Mobile PET/CT Volume at NHKMC	556	566	575
Projected Fixed PET/CT Volume for NHFMC	2,226	2,262	2,301

As stated in Step 2 above, it is not necessary for the applicant to project growth in its NHFMC PET service to demonstrate the need to replace and convert one of its

existing fixed PET scanners to a mobile PET scanner pursuant to Policy TE-1. Therefore the applicant could propose to serve a lesser percentage of its historical 2014 NHFMC volume at NHKMC, with no projected increase, and still demonstrate the need to replace and convert the existing fixed PET scanner to a mobile scanner.

Step 4: Estimate the average PET/CT volume per day of service for the existing mobile PET host sites based on historical data (pages 63-64).

The applicant states that it reviewed the mobile PET volume data for fiscal year October 1, 2014 through March 31, 2015 to determine the annualized volume for each existing mobile PET host site and the average number of PET scans performed per day of service, as illustrated below.

Average Scan Per Day of Service (Existing Host Sites)				
	Annualized Volume 10/1/14-3/31/15	Current Service Days/Wk	Annual Service Days	PET Scans /Day of Service
NHRMC	236	0.75	38.25	6.2
NHHMC	226	0.50	25.50	8.9
NHTMC	68	0.25	12.75	5.3
NHMMC	118	0.25	12.75	9.3
LMH	163	0.50	25.50	6.4

The applicant states that it then determined the proposed days of service for each site and project year, based on input from Novant Health team members currently overseeing mobile PET programs at existing host site facilities and representatives from each hospital. The following table shows the proposed days of service per week at each proposed mobile host site.

	Proposed Days of Service Per Week		
	PY 1	PY 2	PY 3
Existing Host Sites			
NHRMC	1.00	1.00	1.00
NHHMC	1.00	1.00	1.50
NHTMC	0.50	0.50	0.50
NHMMC	0.50	1.00	1.00
LMH	0.50	0.50	0.50
Subtotal	3.50	4.00	4.00
Proposed New Host Sites			
NHKMC	2.00	2.00	2.00
MMH	0.25	0.25	0.25
Total	5.75	6.25	6.75

On page 64, the applicant states:

“The proposed schedule in Project Year 1 reflects increases in capacity at NHRMC, NHHMC, NHTMC and NHMMC as requested by the facilities. The schedule for Lenoir and Morehead in Project Years 1-3 reflect the requested availability for those sites from the NHFMC mobile PET unit. In project Years 2 and 3, NHFMC reasonably anticipates a staggered increase in capacity for NHHMC and NHMMC due to the high demand at those facilities.”

Steps 5, 6 and 8: Determine Project Years 1-3 volume using the average scans per day of service and the proposed days of service for each existing mobile PET/CT host site (pages 64-67). The applicant assumes the additional time requested for each host facility already providing service will be utilized at the same rate as the existing mobile service.

There is no Step 7 in the application methodology; however, it does not appear that any steps were omitted from the methodology, just that the numbering is off.

The applicant states that it applied the average scans per day of service to the projected number of days of service per week for each existing host site to determine the projected number of scans for Project Years 1-3 as shown in the following table. The average scans per day of service remains the same for each existing host site through the first three years of operation. Likewise, the projected number of days of service per week remains the same each year for each existing host site, except NHMMC which increases from 0.5 days per week in Project Year 1 to 1.0 day per week in Project Years 2 and 3; and NHHMC which increases from 1.0 day per week in Project Years 1 and 2 to 1.5 days per week in Project Year 3. The following table summarizes the applicant’s projected PET scan volume (pages 65-66) for each of the five existing host sites in Project Years 1-3.

Existing Host Sites	Projected PET Scan Volume		
	PY 1	PY 2	PY 3
NHRMC	316	316	316
NHHMC	454	454	681
NHTMC	135	135	135
NHMMC	237	474	474
LMH	163	163	163

Step 9: Determine Project Years 1-3 volume for Morehead Memorial Hospital in Rockingham County (page 67).

The applicant states that the following projected PET scan volume at MMH is based on the existing number of cancer patients at MMH combined with the number of patients traveling out of county for PET/CT scans.

MMH Projected PET Scan Volume

	PY 1	PY 2	PY 3
Scans per 0.5 Day of Service	3.0	4.0	5.0
Half Days of Service/Year*	25.5	25.5	25.5
Scans/Year	77.0	102.0	128.0

*Step 4: 0.5 day every other week (0.25 day per week), 51 weeks per year = 25.5 half days of service annually

The applicant states that the above projection is conservative and equates to 21% of the cancer patients that were provided care at MMH during FY 2013-12 and less than 19% of the patients that traveled out of county to obtain fixed PET services during the same time period.

Step 10: Combine projected mobile PET volumes for NHKMC, the existing mobile PET sites (NHRMC, NHTMC, NHMMC, NHHMC and LMH) and projected volume for MMH to determine the total projected volume of mobile PET scans for the NHFMC mobile PET/CT scanner for Project Years 1-3 (page 68).

Projected Mobile PET/CT Volume

	Projected PET Scan Volume		
	PY 1	PY 2	PY 3
NHKMC (Step 3)	556	566	575
NHRMC (Steps 5-8)	316	316	316
NHHMC (Steps 5-8)	454	454	681
NHTMC (Steps 5-8)	135	135	135
NHMMC (Steps 5-8)	237	474	474
LMH (Steps 5-8)	163	163	163
MMH (Step 9)	77	102	128
Total	1,938	2,210	2,472

On page 68, the applicant states:

“The methodology for the NHFMC mobile PET/CT scanner is reasonable based on numerous factors, including:

- *The demand for additional mobile PET/CT imaging capacity in North Carolina as acknowledged by the State Health Coordinating Council;*
- *The individual need at each mobile PET/CT host site for mobile PET/CT imaging based on comprehensive cancer programs and/or historical provision of mobile PET/CT imaging;*
- *The overall growth in the population of the primary service area counties;*

- *The aging of the population of the primary service area counties, which is outpacing overall population growth in each county;*
- *The cancer incidence rates in the primary service area counties, which are higher than the state average in most of the primary service area counties; and*
- *The increasing medical applications for mobile PET/CT imaging.”*

The applicant adequately demonstrates projected utilization is based on reasonable and adequately supported assumptions. Thus, the applicant adequately identifies the population to be served and adequately demonstrates the need that population has for the proposed service.

Access

In Section VI.2, page 89, the applicant states:

“It is the policy of all the Novant Health facilities and programs, including NHFMC, to provide necessary services to all individuals without regard to race, age, sex, creed, color, insurance status, or handicap. Novant Health facilities and programs do not discriminate against the above listed persons, or other medically underserved person, regardless of their ability to pay.”

In Section VI.15, pages 100-103, the applicant provides the projected payor mix for each proposed mobile site for the second operating year following project completion. In the applicant’s response to comments, the applicant pointed out and corrected two typographical errors in the projected NHKMC payor mix. The corrected payor mix percentages are reflected in the table below.

**NHFMC Mobile PET/CT Host Site Projected Payor Mix
 Project Year 2**

Payors	Percent of Total PET Procedures						
	NHKMC	NHTMC	NHRMC	NHMMC	NHHMC	LMH	MMH
Self-Pay/Indigent/Charity	3.31%	9.21%	3.49%	2.79%	1.78%	1.00%	5.73%
Medicare / Mdcr Managed Care	50.28%	60.53%	63.95%	62.38%	54.22%	69.00%	50.70%
Medicaid	1.10%	9.21%	3.88%	3.96%	1.78%	11.00%	3.30%
Commercial Insurance	0.00%	0.00%	0.39%	0.99%	0.00%	1.00%	37.23%
Managed Care	44.75%	21.05%	25.58%	27.72%	40.00%	17.00%	0.00%
Other Gov’t & Workers Comp	0.55%	0.00%	2.71%	1.98%	2.22%	1.00%	3.03%
Total	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Totals may not sum due to rounding.

Each host site’s payor mix is projected based on that facility’s existing mobile PET service payor mix or radiation therapy payor mix. The applicant projects that between 51% and 80% of the patients who receive services at the seven proposed mobile host sites will have their services paid for by Medicare or Medicaid.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

Conclusion

In summary, the applicant adequately identified the population to be served; adequately demonstrates the need that the population projected to be served has for the proposed mobile PET/CT services; and adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed mobile PET services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

NHFMC proposes to replace and convert one of its two existing fixed PET/CT units to a mobile PET/CT. On page 13, the applicant states that it has determined that replacing one of its existing fixed PET/CT scanners with a mobile unit will not adversely impact patients served by NHFMC. From 2005 through November 2014, NHFMC operated a single fixed scanner to satisfactorily meet the demand for inpatient and outpatient PET/CT scans at the facility. On page 14, the applicant provides a table showing NHFMC's annual PET scans and percent of capacity utilization. The applicant states that NHFMC PET/CT scanner staff and radiologists have developed and maintained an efficient and reliable model for ensuring smooth PET patient flow and accessibility that will allow the remaining fixed PET scanner to adequately meet the demand at NHFMC.

Furthermore, the applicant states that the proposed NHFMC mobile PET/CT scanner will provide mobile PET services at NHKMC, a satellite of NHFMC. The applicant estimates that 20% of the fixed PET volume at NHFMC will be served by the NHKMC mobile PET/CT scanner in the future.

On page 79, the applicant states:

“The patients who will continue to utilize fixed PET/CT services at NHFMC will have more than adequate access to PET/CT imaging and services based on the availability of the newly installed state-of-the-art PET/CT scanner at NHFMC. This fixed PET/CT scanner benefits from advanced technology and faster scanning times than the older fixed PET/CT unit that will be converted to a mobile PET/CT unit. NHFMC has the ability to increase operational hours for the fixed PET/CT scanner in order to meet any fluctuations in demand for this service. Furthermore, NHKMC’s patients that have traveled from Kernersville to Winston-Salem for PET/CT imaging will be more efficiently served by the local mobile PET/CT service that will be onsite at NHKMC two days per week.”

The applicant adequately demonstrates that the needs of the population presently served at NHFMC will be adequately met by the remaining fixed PET/CT scanner and the proposed mobile PET/CT scanner and the proposed project will not negatively impact the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care; therefore the application is conforming with this criterion.

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

CA

In Section III.3, pages 70-71, the applicant discusses the alternatives considered prior to the submission of this application, which include: 1) maintain the status quo; and 2) seek approval to convert one existing PET/CT scanner at Forsyth Medical Center to a mobile PET/CT scanner.

- 1) Maintain the status quo – the applicant states that this would not be an effective alternative because the existing provider of mobile PET services does not have additional capacity available on the only two mobile PET/CT units operating in North Carolina.
- 2) Convert an existing PET/CT scanner to a mobile PET/CT scanner – the applicant states:

“As illustrated in Section II, III, and IV of this Application, the replacement and conversion of NHFMC’s existing fixed PET/CT scanner to a mobile PET/CT scanner will provide necessary and locally accessible diagnostic imaging support for community hospitals allowing their patients to remain in-county for these services.”

The applicant states that four Novant Health sites currently offering mobile PET services require additional time, which is unavailable from the vendor. In addition, NHKMC has an extensive cancer program and needs to offer mobile PET/CT services. The applicant

further states that obtaining CON approval to convert an existing resource, in need of replacement, to a mobile unit capable of serving the above discussed sites, is the most cost-effective option.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the need for additional access to mobile PET/CT services. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center shall materially comply with all representations made in the certificate of need application.**
- 2. Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center shall replace an existing fixed PET scanner with a mobile PET/CT scanner with transporting equipment to initially serve seven host sites, as designated in the CON application. The mobile PET/CT scanner shall be moved each week to provide PET/CT services to host sites and shall not, at any time, serve less than two host sites each week.**
- 3. Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center shall not change or add host sites unless it first obtains a determination from the Healthcare Planning and Certificate of Need Section authorizing the change in location of the equipment.**
- 4. Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center shall not convert the mobile PET/CT scanner to a fixed PET/CT scanner unless it first obtains a determination from the Healthcare Planning and Certificate of Need Section authorizing the conversion. If converted to fixed, the fixed PET/CT must be located in Forsyth County.**
- 5. The acquisition of the mobile PET/CT scanner shall constitute development of one mobile diagnostic program. The acquisition of the mobile PET/CT scanner shall not result in the creation of a diagnostic center located at any of the host sites or any other facility owned, operated or otherwise affiliated with Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center.**
- 6. Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center shall not acquire, as part of the project, any equipment that is not included in the proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

7. **Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (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.

C

In Section VIII.1, page 113, the applicant projects that the total capital cost of the project will be \$2,548,643 as shown in the table below.

Movable Equipment	\$ 2,503,643
Consultant Fees	\$ 21,500
Contingency	\$ 23,500
Total Capital Cost	\$ 2,548,643

In Section VIII.1, page 112, the applicant states:

“The capital costs are based on a turnkey quote from an established global imaging equipment vendor where the quote includes: a new fixed PET/CT scanner, a trailer, a hot lab and control room in the trailer, and an injector. In addition, the vendor’s quote includes the cost to remove the existing NHFMC fixed PET/CT scanner which is to be replaced by the proposed mobile PET/CT scanner.”

In Section IX.1-3, page 122, the applicant states start-up and initial operating expenses required for the project will total \$118,042. The applicant states that Novant Health accumulated reserves will finance all the capital and working capital needs for the proposed project.

In Exhibit 9, the applicant provides a copy of the equipment quote for the proposed PET/CT scanner and trailer. Exhibit 10 contains copies of the letters documenting availability/commitment of funding and Novant Health’s audited financial statements for the calendar years ending December 31, 2014 and 2013. As of December 31, 2014, Novant Health had Cash and cash equivalents of \$353,797,000, Total current assets of \$1,308,931,000 and Total net assets of \$2,665,164,000 (total assets – total liabilities).

The applicant provides proforma financial statements for the first three years of the project. The applicant projects mobile PET/CT revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

Mobile PET/CT Service	Project Year 1	Project Year 2	Project Year 3
Projected # of Scans	1,938	2,210	2,472
Projected Average Charge (Patient Revenue / Projected # of Scans)	\$ 957	\$ 957	\$ 957
Patient Revenue	\$ 1,854,666	\$ 2,114,970	\$ 2,365,704
Total Expenses	\$ 1,339,448	\$ 1,522,832	\$ 1,585,924
Net Income	\$ 515,218	\$ 592,138	\$ 779,780

The applicant also projects a positive net income for the entire facility of more than \$133 million in each of the first three operating years of the project. In the event that the mobile PET service was not profitable, the facility has more than adequate financial capacity to support the proposed mobile PET service. The assumptions used by the applicant in preparation of the proforma financial statements are reasonable, including projected utilization, costs and charges. See the Proforma Section of the application, pages 146-150, for the assumptions regarding costs and charges. See the discussions regarding projected utilization and staffing in Criteria (3) and (7), respectively, which are incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

NHFMC proposes to replace and convert one of its two existing fixed PET/CT scanners currently in use at NHFMC to a mobile PET/CT scanner, pursuant to Policy TE-1 in the 2015 SMFP, to provide better access to patients at multiple host site hospitals in North Carolina.

On page 138, the 2015 SMFP defines the service area for mobile PET scanners as statewide. Thus, the service area for this facility’s mobile PET service is statewide. The applicant describes its primary service area as the home counties of its proposed host sites: Forsyth, Mecklenburg, Rowan, Davidson, Lenoir and Rockingham counties.

The most recent data, published in the Proposed 2016 SMFP shows a slight decline (a compound annual growth rate (CAGR) of -2% over the last three years) in the total number of fixed PET procedures performed in North Carolina, with some facilities showing a small increase in procedures and others showing a small decrease. The data shows a slight increase in the total number of mobile PET procedures over the same period (CAGR of 1%), even though the only two mobile PET scanners in the State have been operating above capacity for several years. The data also indicates that while the mobile PET scanners are operating above capacity, each of the fixed PET scanners have excess capacity.

The applicant states that one of its existing fixed PET scanners will be removed from service; therefore, there will be no increase in the total inventory of fixed and mobile PET scanners in North Carolina. The proposed project would eliminate some excess fixed PET capacity while providing additional mobile PET capacity.

Alliance Imaging owns and operates the only two mobile PET/CT scanners in North Carolina. Those two mobile PET/CT scanners provide service to 29 mobile PET host sites across the State. The applicant states that due to the overwhelming number of mobile PET host sites per scanner, it is practically impossible to obtain additional days of service from the current vendor or to add a new mobile PET/CT scanner host site unless an existing Alliance Imaging mobile PET site reduces its existing days/hours of service. Both mobile scanners exceeded the 2,600 procedure utilization threshold years ago.

In Section III, pages 43-44, the applicant states that over the last several years Novant Health's mobile PET host sites have repeatedly requested additional mobile PET service time but the vendor has been unable to fully meet the requests, further stating:

“Over the past several years, Alliance representatives have told Novant that additional days of service are not available due to the number of sites being serviced.”

The applicant discusses the expanding need for PET/CT services at its proposed host sites on pages 44-48.

In Section III.1, page 39, the applicant provides an excerpt from the Agency Report for the Technology & Equipment Committee from April 2014 regarding the petitions filed by Novant Health, Inc. Randolph Hospital and Alliance Imaging regarding the need for additional mobile PET/CT capacity. The report reads, in part:

“The two existing mobile PET scanners are over-capacity and patient access is impacted as a result. Beginning in 2009, one unit (West) has been over capacity, which is defined as 2,600 PET scans, every subsequent year. The second unit was over capacity in 2010, but has been consistently over capacity beginning in the 2013 SMFP...”

As a result, the council recommended changing the East and West service areas to a statewide service area to allow flexibility in servicing mobile PET sites. The SHCC also ultimately adopted SMFP Policy TE-1, allowing the conversion of an existing fixed PET scanner to a mobile PET scanner under certain conditions, as stated in the policy.

In Section III, pages 40 and 78-80, the applicant discusses the impact of the proposed project on competition in the service area as it relates to existing or approved health service capabilities. The applicant states:

“Accessibility will increase on a local level and thereby reducing unnecessary travel burdens and costs for patients. It also opens the possibility for patients for which out-of-county travel was not an option, the ability to obtain this critical imaging service locally. ... NHFMC will offer the mobile PET/CT service at a reasonable rate that is anticipated to be less than the current contracted rate of the existing mobile PET/CT provider for these services.”

The 2015 SMFP (page 141) shows that NHFMC operated its two existing fixed PET scanners at 42.67% of capacity in 2013. The most recent data, published in the Proposed 2016 SMFP, shows that NHFMC’s PET service operated at 41.97% of capacity in 2014. Based upon the historical CAGR for PET services at NHFMC, the applicant projects the volume of PET procedures to increase by 1.7% annually. This would result in a total NHFMC fixed PET/CT volume of 2,876 procedures on the two fixed PET scanners (page 62) in FFY2018-19, which is a utilization rate of only 47.9% on the two scanners (2,876 / (3000 x 2)). With the proposed project to replace and convert one fixed PET scanner to a mobile PET scanner, the applicant projects a utilization in Project Year 3 (FFY2018-19) on the one existing fixed PET scanner remaining at NHFMC of 2,301 procedures or 76.7% (2,301 / 3,000) capacity, and a utilization of 2,472 procedures or 95.0% on the proposed mobile PET scanner, based on mobile PET capacity of 2,600 procedures. The mobile utilization would be 82.4%, if measured by the same 3,000 procedure capacity threshold of a fixed PET scanner. As shown by the projected utilization figures presented above, conversion of one NHFMC’s fixed PET scanner to a mobile PET scanner serving the proposed seven host sites results in better utilization for the two NHFMC PET scanners.

Furthermore, the proposed mobile PET service will increase the number of days of service at each of the five proposed host sites which already provide mobile PET services, but have been unsuccessful in obtaining additional days of service. The proposed mobile PET will also provide access to mobile PET services to two additional host sites which do not currently provide mobile PET services, providing better access to PET/CT services to patients on a local community level. See the discussions regarding analysis of need and projected utilization in Criterion (3) which are incorporated herein by reference.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on health service capabilities in the service area.

The information provided by the applicant in those sections is reasonable and adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming to this criterion.

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

C

In Section VII.1(b), page 104, the applicant provides projected staffing for the proposed PET/CT services for the second full fiscal year following completion of the project. In its response to comments, the applicant explains a typographical error in the driver FTE position (0.10 should be 1.00) and the double counting of the managerial supervisory FTE positions. The following table shows the FTE positions and salary totals as presented on page 104 of the application and the FTE positions and salary totals as presented in NHFMC’s response to comments.

**NHFMC Mobile PET/CT Services
 Project Year 2 (10/1/2017 – 9/30/2018)**

Position	Total FTE Positions (Pg 104)	Projected Salary per Position (pg 104)	Total FTE Positions (Response to Comments)	Projected Salary per Position (Response)
Nuclear Medicine/PET Technologist	2.50	\$182,795	2.50	\$182,795
Nuclear Medicine Supervisor	0.25	\$25,512	*	*
Manager Radiology	0.10	\$10,784	*	*
Senior Director Radiology	0.05	\$8,385	*	*
Radiation Safety Officer	0.20	\$40,453	0.20	\$40,453
Clinical Equipment Mgmt Staff	0.25	\$14,205	0.25	\$14,205
Tractor/Cab Driver	0.10	\$7,955	1.00	\$52,331
Total	3.45	\$289,785	3.95	\$289,784

*Included in the management fee per MedQuest Management Agreement in Exhibit 3.

As the above table reflects, the total projected salary expense for the second operating year is \$289,784, which corresponds with the total salaries on the proforma Form C-1 on page 138 of the application.

The applicant states that all of the clinical positions already exist within Novant Health and the current Nuclear Medicine/PET staff will rotate time providing coverage on the mobile and fixed scanners. The applicant states that MedQuest will supply a mobile truck driver, as needed, under the management agreement.

The proforma financial statements indicate adequate mobile PET/CT net income (\$592,138 in Project Year 2) to cover additional driver FTE positions, if needed. Furthermore, NHFMC projects a net income of over \$133 million in each of the first three project years, which is more than adequate to cover any potentially understated staffing costs related to the mobile PET/CT project.

The applicant further states that Novant Health recruits needed personnel through a variety of means, including advertisements in local newspapers, trade journals, and on its web site. Regional newspapers also run ads where Novant has facilities. In Section V.3(c), page 85, the applicant states that Liston Orr, MD will serve as Medical Director of the NHFMC mobile PET/CT program. Dr. Orr is the Medical Director of Nuclear Medicine and PET at NHFMC.

Exhibit 5 contains a letter signed by Dr. Orr indicating his commitment to serve as Medical Director along with a copy of his curriculum vitae. Physician letters of support are provided in Exhibit 15. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section II.1(b), page 15, the applicant provides a table showing ancillary and support services and whether the service will be provided by facility staff or facility paid contractors. Exhibit 3 contains the proposed MedQuest management agreement. Exhibits 5, 6, 7 and 8 contain letters from appropriate officials confirming the availability of support and ancillary services for the proposed PET/CT scanner services. The applicant discusses how the proposed services will be coordinated with the existing health care system through transfer agreements with other hospitals; through its network of physicians in Novant Medical Group, independent physicians, and other health care clinicians practicing in various medical and surgical specialties; and through its relationships with other local healthcare providers such as the Forsyth County Health Department and the Forsyth County EMS program. Exhibit 20 contains a list of Novant Health's patient transfer agreements; Exhibit 15 contains support letters from primary care physicians, specialty physicians and surgeons, and referral physicians. The applicant adequately demonstrates the availability of the necessary ancillary and support services for the proposed services and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

- (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

- (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

- (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 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 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

In Section VI.12 and VI.13, page 99, the applicant provides the payor mix during CY 2014 for the entire facility and the Nuclear Medicine and Fixed PET program, as illustrated in the table below:

NHFMC
CY 2014 (1/1/14-12/31/14)
Patient Days/Procedures as a % of Total Utilization

	Entire Facility	Nuclear Med/PET Service
Self-Pay / Indigent / Charity	11.35%	1.84 %
Medicare/Medicare Managed Care	38.02%	62.51%
Medicaid	16.14%	5.40%
Commercial Insurance	0.62%	0.24%
Managed Care	32.15%	28.94%
Other (Work comp and Other Gov't)	5.8%	1.07%
Total	100.0%	100.0%

Totals may not sum due to rounding.

In Section VI.2, page 89, the applicant states:

“It is the policy of all the Novant Health facilities and programs, including NHFMC, to provide necessary services to all individuals without regard to race, age, sex, creed, color, insurance status, or handicap. Novant Health facilities and programs do not discriminate against the above-listed persons, or other medically underserved person, regardless of their ability to pay.”

Exhibit 13 contains the Novant Health Charity Care policies, which the applicant states apply to NHFMC, its programs, and the surgeons and physicians who will support the mobile PET/CT program. Novant also offers financial counseling and financial assistance to patients in need. On page 90, the applicant states:

“The mobile PET hospital host sites at Morehead Memorial Hospital and Lenoir Memorial Hospital are managed by Novant Health and will apply their hospital specific policies regarding charity care, since it is the host site hospitals that assess each PET patient’s eligibility for charity care or bill the patient’s insurance company, as appropriate.”

The applicant states that NHFMC will work with each host site hospital to ensure that its mobile PET trailer is accessible to handicapped PET patients, make interpreter and sign language services available and will continue to conform to all requirements of North Carolina and the Americans with Disabilities Act.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available. The following counties comprise the projected counties of residence for the patients to be served by the proposed mobile PET service.

	2010 Total # of Medicaid Eligibles as % of Total Population	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population	2009 % Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Caswell	21.4%	10.8%	20.0%
Catawba	16.6%	6.2%	19.1%
Davidson	17.2%	6.9%	18.4%
Davie	13.5%	5.1%	17.3%
Duplin	20.3%	7.6%	24.6%
Forsyth	16.1%	5.7%	19.5%
Greene	21.1%	7.6%	24.6%
Guilford	15.3%	5.9%	19.5%
Iredell	14.0%	5.5%	18.3%
Jones	20.5%	9.8%	20.9%
Lenoir	24.6%	11.0%	21.1%
Lincoln	15.0%	6.2%	19.0%
Mecklenburg	14.7%	5.1%	20.1%
Onslow	10.7%	4.2%	23.4%
Rockingham	19.9%	9.3%	19.0%
Rowan	18.7%	7.6%	18.9%
Stanly	17.4%	7.6%	18.3%
Stokes	14.3%	6.3%	16.6%
Union	10.9%	3.4%	18.0%
Average for SA Counties	17.0%	6.9%	19.8%
Statewide	16.5%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the imaging services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to

the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the services offered at NHFMC and the existing mobile PET host sites. Therefore, the application is conforming to this criterion.

- (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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, pages 97-98, the applicant states:

“Novant Health’s tertiary hospitals (NHFMC and NHPMC) fulfilled their Hill-Burton obligations many years ago in 1991. ... Novant Health continues to comply with the community service obligation and there is no denial, restriction, or limitation of access to minorities or handicapped persons.”

The applicant further states that Novant's Charity Care Policies (Exhibit 13) are among the most generous in this state. Novant Health Forsyth Medical Center, Winston-Salem, NC provided \$98,276,780 in Charity Care in CY 2014. This amounts to 13.89% of net revenue for CY2014. The applicant projects 14.12% of net revenue in charity care for the proposed mobile PET service. Exhibit 13 contains the applicant's Admissions Policy which states,

“It is the policy of Novant Health to admit patients and to provide services only at the direction of a member of the Medical/Dental staff. Patients whose physicians have classified their need as emergency or urgent will be given first priority for admission and services. Persons shall be admitted and receive services without regard to race, color, religion, sex, age, national origin, handicap or ability to pay (if emergency or urgent) and the facility will maintain compliance with federal guidelines such as EMTALA and HIPAA.”

In Section VI.10 (a), page 97, the applicant states that it is not aware of any civil rights equal access complaints being filed against Novant Health facilities or

programs in North Carolina within the past five years. Therefore, 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

In Section VI.15, pages 100-103, the applicant provides the payor mix for the proposed mobile PET/CT service for the second full fiscal year of operation following completion of the project. The applicant's response to comments revealed two typographical errors in the NHKMC payor mix. The following table reflects the correct percentages, as shown in the applicant's response to comments.

**NHFMC Mobile PET/CT Host Site Projected Payor Mix
 Project Year 2**

Payors	Percent of Total PET Procedures						
	NHKMC	NHTMC	NHRMC	NHMMC	NHHMC	LMH	MMH
Self-Pay/Indigent/Charity	3.31%	9.21%	3.49%	2.79%	1.78%	1.00%	5.73%
Medicare / Mdcr Managed Care	50.28%	60.53%	63.95%	62.38%	54.22%	69.00%	50.70%
Medicaid	1.10%	9.21%	3.88%	3.96%	1.78%	11.00%	3.30%
Commercial Insurance	0.00%	0.00%	0.39%	0.99%	0.00%	1.00%	37.23%
Managed Care	44.75%	21.05%	25.58%	27.72%	40.00%	17.00%	0.00%
Other Gov't & Workers Comp	0.55%	0.00%	2.71%	1.98%	2.22%	1.00%	3.03%
Total	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Totals may not sum due to rounding. The applicant states it used NHKMC radiation therapy treatments as a proxy for NHKMC's projected PET/CT payor mix.

The applicant states that its projected payor mix for the proposed PET/CT service is based on available information for each host site: mobile PET services for hospitals currently providing mobile PET services and reasonable proxies for the other host sites.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (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

In Section VI.9(a), page 96, the applicant states that patients will have access to the proposed mobile PET/CT services through referral and written order from a physician

on the medical staff at the host site hospital. Furthermore, in Section VI.9(b), pages 96-97, the applicant states:

“All of the host site hospitals identified as the initial host sites for the proposed NHFMC mobile PET/CT scanner are full-service community hospitals and historically accept patients from numerous sources such as other area hospitals, primary care physicians, emergency room physicians, hospitalist/inpatient care physicians, home health agencies [sic] hospice facilities/programs, nursing homes and other healthcare providers.

Patients at the hospital host sites that require a PET/CT scan will be accepted by the NHFMC mobile PET/CT scanner by physician referral only as discussed above. The typical referral path is from the patient’s primary care physician to a medical oncologist and then to the radiation oncologist. Usually, the cancer physicians are the primary sources for PET scan patient referrals. These physicians will typically refer the patient for PET imaging before, during, and after a course of treatment. Also, a patient’s specialty physician such as a cardiologist, neurologist, urologist, oncologic surgeon, gastroenterologist, or pulmonologist may refer a patient for a PET scan. The NHFMC Mobile PET/CT Scanner Program will accept referrals from throughout each host hospital’s service area.”

The information provided in Section VI.9 is reasonable and supports a finding of conformity with 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.

C

In Section V.1(a), page 83, the applicant states:

“Novant Health Greater Winston-Salem (GWS) Market has many established clinical education agreements with area health education programs in the service area and these agreements will encompass the NHFMC mobile PET/CT scanner once it is operational. See Exhibit 20 for a list of Novant Health’s clinical education agreements and a sample clinical education agreement.”

In Exhibit 20, the applicant provides a list of existing clinical education agreements which NHFMC and Novant Health have with health professional training programs in Forsyth and surrounding counties.

The applicant demonstrates that the facility will continue to accommodate the clinical needs of health professional training programs in the area. The information provided is reasonable and supports a finding of conformity 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

The applicant proposes to replace and convert one of its two fixed PET/CT scanners currently in use at NHFMC to a mobile PET/CT scanner, pursuant to Policy TE-1 in the 2015 SMFP.

On page 138, the 2015 SMFP defines the service area for mobile PET scanners as statewide. Thus, the service area for this facility's mobile PET service is statewide. The applicant identifies its primary service area as the home counties (Forsyth, Mecklenburg, Rowan, Davidson, Lenoir and Rockingham counties) for each mobile host site expected to contract for mobile PET services with NHFMC.

In Section III.1, page 39, the applicant provides an excerpt from the Agency Report for the Technology & Equipment Committee from April 2014 regarding the petitions filed by Novant Health, Inc. Randolph Hospital and Alliance Imaging regarding the need for additional mobile PET/CT capacity. The report reads, in part:

“The two existing mobile PET scanners are over-capacity and patient access is impacted as a result. Beginning in 2009, one unit (West) has been over capacity, which is defined as 2,600 PET scans, every subsequent year. The second unit was over capacity in 2010, but has been consistently over capacity beginning in the 2013 SMFP...”

In Section III, pages 43-44, the applicant states that over the last several years Novant Health's mobile PET host sites have repeatedly requested additional time but the vendor has been unable to fully meet the requests, further stating:

“Over the past several years, Alliance representatives have told Novant that additional days of service are not available due to the number of sites being serviced.”

The applicant discusses the growing need for PET/CT services at its proposed host sites on pages 44-48.

In Section V.7, pages 87-88, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“The proposed project will promote cost-effective approaches, expand health care services to the medically underserved, and encourage quality health care services by improving access to mobile PET/CT scanner diagnostic imaging to the patient population served by the proposed and existing PET Scanner in the NHFMC mobile PET Service Area as defined previously in this Application. ... As the data for the Alliance Imaging mobile PET scanners show, it is simply not possibly [sic] for the existing mobile PET scanners to provide more days/times to existing sites or expand coverage to sites that do not currently have contracts with Alliance Imaging. This in turn means access to PET scanner services is hindered, and cost increases because patients are having to travel out of county. ... For more than a decade, hospitals seeking mobile PET service have had no choice in the vendor selection, as Alliance is the sole provider in North Carolina. This is highly unusual because for most goods and services consumed by hospitals there are multiple vendors. Thus, on its face, this proposal would offer competition that currently does not exist. As amply illustrated throughout this application, the proposed NHFMC scanner will be well utilized, and will be operated in a safe and cost-effective manner.”

In Section III, pages 40 and 78-80, the applicant discusses the impact of the proposed project on competition in the service area as it relates to existing or approved health service capabilities. The applicant states:

“Accessibility will increase on a local level and thereby reducing unnecessary travel burdens and costs for patients. It also opens the possibility for patients for which out-of-county travel was not an option, the ability to obtain this critical imaging service locally. ... NHFMC will offer the mobile PET/CT service at a reasonable rate that is anticipated to be less than the current contracted rate of the existing mobile PET/CT provider for these services.”

The 2015 SMFP (page 141) shows that NHFMC operated its two existing fixed PET scanners at 42.67% of capacity in 2013. The most recent data, published in the Proposed 2016 SMFP, shows that NHFMC’s PET service operated at 41.97% of capacity in 2014. Based upon the historical CAGR for PET services at NHFMC, the applicant projects the volume of PET procedures to increase by 1.7% annually. This would result in a total NHFMC fixed PET/CT volume of 2,876 procedures on the two existing fixed PET scanners (page 62) in FFY2018-19, which is a utilization rate of only 47.9% (2,876 / (3000 x 2)). With the proposed project to replace and convert one fixed PET scanner to a mobile PET scanner, the applicant projects a utilization in Project Year 3 (FFY2018-19) on the one existing fixed PET scanner remaining at NHFMC of 2,301 procedures or 76.7% (2,301 / 3,000) capacity, and a utilization of 2,472

procedures or 95.0% on the proposed mobile PET scanner, based on mobile PET capacity of 2,600 procedures. The mobile utilization would be 82.4%, if measured by the same 3,000 procedure capacity threshold of a fixed PET scanner. As shown by the projected utilization figures presented above, conversion of one NHFMC's fixed PET scanner to a mobile PET scanner serving the proposed seven host sites results in better utilization for the two NHFMC PET scanners.

Furthermore, the applicant states that the proposed mobile PET service will increase the number of days of service at each of the five proposed host sites which already provide mobile PET services, but have been unsuccessful in obtaining additional days of service. The proposed mobile PET will also provide access to mobile PET services to two additional host sites which do not currently provide mobile PET services. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to replace and convert the existing fixed PET/CT scanner to a mobile PET/CT scanner and that the proposal is cost effective. The discussions regarding analysis of need and alternatives found in Criterion (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that NHFMC has and will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that NHFMC has and will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

The application is conforming to this criterion.

- (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.

C

In Section I.12, pages 5-6, the applicant states that it currently owns, leases, or manages 12 hospitals in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of

the application through the date of this decision no facilities were found to be out of compliance with one or more Medicare conditions of participation. At this time, all 12 facilities are in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 12 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.
- (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.

NA

The applicant proposes to replace an existing PET/CT scanner and convert it to a mobile PET/CT scanner; the total licensed inventory of fixed and mobile PET/CT scanners will remain the same. Therefore the Criteria and Standards for Positron Emission Tomography Scanner, promulgated in 10A NCAC 14C .3700, are not applicable to this review.