

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 28, 2013
PROJECT ANALYST: Gloria C. Hale
TEAM LEADER: Lisa Pittman
ASSISTANT CHIEF: Martha J. Frisone
PROJECT I.D. NUMBERS: **G-10127-13** / Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center d/b/a Novant Health Kernersville Medical Center (**Kernersville**)/ Acquire a PET scanner/ Forsyth County

G-10133-13 / North Carolina Baptist Hospital (**Baptist**)/ Convert research only PET scanner to clinical use pursuant to the need determination in the 2013 SMFP/ Forsyth County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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.

NC
Kernersville
Baptist

The 2013 State Medical Facilities Plan (SMFP) identifies a need for one additional fixed dedicated positron emission tomography (PET) scanner in HSA II. Thus, the 2013 SMFP establishes a limit of one fixed dedicated PET scanner that may be approved in HSA II, which includes Alamance, Caswell, Guilford, Randolph, Rockingham, Davidson, Davie, Forsyth, Stokes, Surry, and Yadkin counties. Two applications were submitted to the Certificate of Need Section, one proposing to acquire a fixed dedicated PET scanner, and one proposing to convert a research only PET scanner to clinical use, both to be located in Forsyth County in HSA II. Although the

applications propose to develop a total of two fixed dedicated PET scanners for HSA II, only one may be approved. Each proposal is briefly described below.

Kernersville. Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center d/b/a Novant Health Kernersville Medical Center (Kernersville) proposes to acquire a PET/CT scanner and locate it on Kernersville campus on a mobile pad in a trailer, proximate and connected to the hospital via a covered walkway. Novant Health, Inc. is the parent company of Forsyth Memorial Hospital d/b/a Novant Health Forsyth Medical Center d/b/a Novant Health Kernersville Medical Center (Kernersville). Kernersville operates under the license of Novant Health Forsyth Medical Center (Forsyth Medical Center) and is located in Kernersville, Forsyth County, east of Winston-Salem. Forsyth Medical Center is located in Winston-Salem, Forsyth County. Forsyth Medical Center has one fixed dedicated PET scanner located in its Radiology Department and has been approved for one additional fixed dedicated PET scanner (Project I.D. #G-8129-08). Note: the authorized location for the approved PET scanner is Forsyth Medical Center. The applicant proposes to develop no more than one additional fixed dedicated PET scanner in HSA II, which is conforming to the applicable need determination in the 2013 SMFP.

Baptist. North Carolina Baptist Hospital (Baptist) proposes to convert one research only PET scanner currently owned by Wake Forest University Health Sciences to clinical use to allow it to provide both clinical and research PET/CT scans. The research PET scanner is a General Electric Discovery VCT PET/CT scanner and is two years old. It is proposed to be used for oncology, cardiology, neurology, Alzheimer's and dementia procedures, the latter two being an expansion of the use of Amyvid, an FDA approved positron emission tomography tracer. Baptist owns and operates one fixed clinical PET/CT scanner and one AC-3 PET scanner which is authorized to be used for simulation or treatment planning only. The research only PET scanner currently owned by Wake Forest University Health Sciences is not authorized to perform clinical PET scans. The applicant proposes to convert no more than one research only fixed dedicated PET scanner to clinical use in HSA II, which is conforming to the applicable need determination in the 2013 SMFP.

In addition, Policy GEN-3 in the 2013 SMFP is applicable to the review of these proposals. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer 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 promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in

meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Kernersville. In Section V.7, pages 70-71, the applicant describes how the proposed project will promote safety and quality. In 2011, Novant Health won the VHA Leadership Award for Clinical Excellence for three of its hospitals, including Forsyth. In addition, several of Novant Health’s medical centers, including Forsyth, are certified Nursing Magnet Programs as designated by the American Nurses Credentialing Center. The applicant states, *“NHKMC, as part of Novant Health, benefits from these recognitions and experiences of NH Forsyth Medical Center and other Novant Hospitals in improving and maintaining quality healthcare services for its patients.”* In addition, Novant Health has a systemwide quality program entitled, *‘First Do No Harm: Leadership Methods in a Safe Culture’* which uses proven management techniques to improve patient safety. The applicant states that the goal of the program is to educate leaders on *“basic human performance factors and how they affect patient safety and to provide leadership strategies which will encourage employees to identify, question and correct behaviors to improve patient care.”* Moreover, Novant Health is implementing a program entitled, *“Safety F.I.R.S.T. Methods for Leaders”*, which employs evidence-based practice methods to reduce errors resulting in patient harm, to identify and fix system problems, and to build accountability. See Exhibits 9 and 14 for Novant Health’s Patient Safety materials.

The applicant discusses how the proposed project will promote equitable access in Section V.7, pages 71-72. The applicant states that Novant Health provides healthcare coverage for patients with annual household incomes up to 300% of the Federal Poverty Level as part of its charity care policies. See Exhibit 6 for copies of all of these policies. In Section VI.2, page 75, the applicant states,

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

In addition, in Section X.1, page 114, the applicant discusses how utilizing an existing mobile equipment pad will be beneficial in comparison to implementing the proposed project inside the Kernersville facility. The applicant states the proposed project will be less expensive, less time consuming and will be less disruptive to the existing medical center. On page 114, the applicant states Kernersville will save *“approximately \$1 million dollars in capital costs versus renovating space inside the medical center for the scanner. Also, it has the potential to save construction time and will minimize unnecessary disruptions to the day-to-day operations of the medical center.”*

Further, the applicant states in Section II.5, pages 12-13, that the proposed PET/CT scanner would operate in the context of a satellite cancer center that is being developed

on the campus of Kernersville. A new medical office building is under construction on the Kernersville campus which is expected to be utilized as satellite offices for established Hematology/Oncology, Radiation Oncology, and Surgical Oncology physician groups who currently practice at the Cancer Center at Forsyth Medical Center.

In addition, an approved linear accelerator will be placed at the physician office building and *“the assets and specialty physicians described above will greatly expand the capabilities of the cancer service line on the HNKMC [sic] campus.”*

The applicant adequately demonstrates plans for promoting safety and quality in the delivery of health care services while promoting equitable access. However, the applicant does not demonstrate how its projected volumes incorporate these concepts in meeting the need identified in the SMFP and, therefore, does not demonstrate how it maximizes healthcare value for resources expended. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein. Therefore, the application is not consistent with Policy GEN-3 and is not conforming to this criterion.

Baptist. The applicant states, in Section II.7(a), page 24, that it will continue to monitor and evaluate the quality and appropriateness of patient care, and will continue to resolve identified patient care problems and performance. Exhibit 7 contains copies of Baptist’s Quality Improvement Plan, and Risk Management and Safety Management Plans. In addition, Baptist participates in a national program, through the Institute for Health Care Improvement, to improve care and reduce costs. Moreover, the applicant states on pages 24-25,

“PET services at NCBH are continuously and rigorously monitored for quality, meeting or exceeding standards promulgated by the American College of Radiology accreditation programs. The quality maintenance process is multifactorial, including certification and CME requirements for technologists and radiologists; regular quantitative assessments of image contrast and resolution; regular qualitative assessments of image quality by an MD Radiologist; double readings of a subset of scans each month to assure interpretive error rates are minimized.”

The applicant discusses how the proposed project will address equitable access in Section VI.2, pages 88 – 90. The applicant states on page 88,

“NCBH does not discriminate based on age, race, national or ethnic origin, disability, sex, income, or ability to pay. Patients are admitted and services are rendered in compliance with:

- 1. Title VI of Civil Rights Act of 1963*
- 2. Section 504 of Rehabilitation Act of 1973*
- 3. The Age Discrimination Act of 1975*
- 4. Americans with Disabilities Act”*

Exhibit 20 contains Baptist's Admission and Financial Collection policies.

In regard to maximizing healthcare value, the applicant states in Section III, page 64, that the clinical research and studies conducted at Baptist contribute to improved diagnosis and treatment of diseases which, in turn, reduce costs to patients, families, and the insurance carriers. Moreover, in Section II.1, page 15, the applicant states that efficiency will be improved by converting a research PET scanner that is only being used at 25% capacity to clinical use rather than purchasing a new one, "*which allows for maximum flexibility, economy and utilization.*"

The applicant adequately demonstrates plans for promoting safety and quality in the delivery of health care services while promoting equitable access. However, the applicant does not demonstrate how its projected volumes incorporate these concepts in meeting the need identified in the 2013 SMFP and, consequently, how it maximizes healthcare value for resources expended. See Criterion (3) for discussion regarding projected utilization, which is incorporated hereby as if set forth fully herein. Therefore, the application is not consistent with Policy GEN-3 and not conforming to this criterion.

Summary

Neither of the two applications is consistent with Policy GEN-3. Both applications are conforming to the need determination in the 2013 SMFP for one additional fixed dedicated positron emission tomography (PET) scanner in HSA II. However, the limit on the number of PET scanners that may be approved in this review is one. Therefore, both applications cannot be approved even if they were consistent with Policy GEN-3. See the Summary following the Comparative Analysis for the decision.

- (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.

NC
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Kernersville. Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center d/b/a Novant Health Kernersville Medical Center (**Kernersville**) proposes to acquire a fixed, dedicated PET/CT scanner and locate it on the campus of Kernersville on a mobile pad in a trailer, proximate and connected to the hospital via a covered walkway. Kernersville operates under the license of Forsyth Medical Center. The applicant will continue to acquire radioisotopes from PETNet Pharmaceuticals, Inc., a

radioisotope production facility that is located within two hours transport time to Kernersville.

Population to be Served

In Section III.5(a), page 55, the applicant states that Novant Health's service area consists of Davidson, Davie, Forsyth, Stokes, Surry, Wilkes and Yadkin counties, which account for 92% of Forsyth's FFY 2011-2012 PET patient origin. The applicant anticipates that this service area will remain the same for Kernersville, however it expects to serve more patients in the eastern portion of the service area, specifically Forsyth, Stokes and Davidson counties, due to its location in the eastern part of Forsyth County. In Section III.4(a), page 54, the applicant provides the current patient origin by county of residence for the entire Kernersville facility, followed by Forsyth Medical Center's current patient origin by county for its PET/CT service, as illustrated below:

**Novant Health Kernersville Medical Center's
Patient Origin
General Acute Care Services CY2012**

County	CY 2012
	% of Total
Forsyth	79.2%
Guilford	10.9%
Stokes	4.0%
Davidson	1.2%
Rockingham	1.1%
All Other*	3.6%
Total	100.0%

**"Other includes Alamance, Alleghany, Ashe, Avery, Beaufort, Bladen, Brunswick, Buncombe, Burke, Cabarrus, Caldwell, Carteret, Caswell, Catawba, Chatham, Cherokee, Cleveland, Columbus, Craven, Cumberland, Davie, Durham, Edgecombe, Franklin, Gaston, Graham, Harnett, Iredell, Mecklenburg, Onslow, New Hanover, Rowan, Stanly, Surry, Union, Wake, Wilkes and Yadkin Counties, VA, SC, PA, TX and other states."*

**Forsyth Medical Center’s PET/CT Services
Patient Origin
FFY 2012**

County	% of Total
Forsyth	47.7%
Davidson	11.0%
Stokes	7.8%
Surry	6.8%
Davie	6.5%
Wilkes	6.3%
Yadkin	5.9%
All Other*	8.0%
Total	100.0%

**“Other includes – Alamance, Alexander, Alleghany, Anson, Ashe, Avery, Catawba, Columbus, Guilford, Iredell, Lincoln, Mecklenburg, Randolph, Rockingham, Rowan, Stanly, Wake, Watauga, Wayne,[sic] Counties, Georgia, South Carolina, Virginia.”*

In Section III.5(a), page 56, the applicant provides the projected patient origin for PET services at Kernersville for the first two years following project completion, illustrated in the following table:

Projected Patient Origin, Kernersville PET services, CY2017 – CY2018

County	Year One (CY 2017)		Year Two (CY 2018)	
	# of patients	% of Total	# of patients	% of Total
Forsyth	587	80.0%	741	80.0%
Davidson	29	4.0%	37	4.0%
Stokes	7	1.0%	9	1.0%
All Other*	111	15.0%	139	15.0%
Total	734	100.00%	926	100.00%

**“Other includes Davie, Surry, Wilkes, Yadkin, Randolph, Rockingham, Guilford, Alamance, and other NC Counties and other states.”*

In Section III.5(d), page 56, the applicant states that the following assumptions and methodologies were used to project patient origin:

“NHKMC is an existing acute care community hospital with an established service area. However, NHKMC does not currently offer PET/CT services. The NHKMC

PET Service Area encompasses the same counties as the Novant Health PET Service Area, while utilizing its acute care patient origin as a benchmark for PET/CT services. NHKMC anticipates serving more patients in the eastern portion of the defined Novant PET Service Area.”

The applicant adequately identified the population to be served.

Need Analysis

In Section III.1(a), pages 27-37, the applicant discusses the need for a fixed dedicated PET/CT scanner at Kernersville. Kernersville is proposing to acquire a fixed dedicated PET/CT scanner in response to the need determination in the 2013 SMFP for one fixed dedicated PET scanner in HSA II. The proposed PET/CT scanner would be located on a mobile pad next to Kernersville and adjacent to the Emergency Department, Radiology Department, and Kernersville’s surgical suite. It would be available 24 hours per day, 7 days a week.

The applicant states the proposed PET/CT scanner would “*expand the capabilities of the cancer service line on the HNKMC [sic] campus.*” The applicant states, on page 27, that three specialty physician groups who currently practice at the Cancer Center at Forsyth Medical Center, namely Novant Health Oncology Specialists (NHOS), Novant Health Salem Surgical Associates (NHSSA), and Piedmont Radiation Oncology (PRO), plan to establish satellite offices in the medical office building currently being built on the Kernersville campus. One of the specialty practices, NHOS, has been practicing in Kernersville in satellite offices for nearly 20 years. In addition, Kernersville has approval to place a linear accelerator at the new medical office building to provide radiation therapy locally. The applicant further states that the three specialty physician groups, NHOS, NHSSA, and PRO have been working together “*in a coordinated and interdisciplinary manner*” for many years to care for cancer patients. Moreover, the addition of the proposed PET/CT scanner would be a “*well-utilized and necessary asset in the cancer services continuum of care offered by NHKMC and the associated cancer physicians and surgeons.*”

In addition, the applicant discusses the expanding PET scanning capabilities as a factor contributing to its need for this technology. Unlike MRI or CT scans which primarily provide images of organ anatomy, the applicant states PET scans “*quantitatively measure metabolic, biochemical, and functional activity in living tissue by electronic detection of short-lived positron emitting radiopharmaceuticals.*” This capability allows for earlier diagnosis of disease than on diagnostic MRI or CT images and, when combined with CT scan data, can yield an “*anatomical map*” with a metabolic image, and correct for excess radiation which may distort the image. Further, on pages 33-34, the applicant discusses the results of a National Oncologic PET Registry (NOPR) study which sought “*to measure the impact of PET findings on patient management*”, concluded that PET use was beneficial “*for many uncovered indications*”, and that “*oncologists and other clinicians may have access to the valuable information PET affords for ensuring the best patient care.*” As a result of this study’s findings, NOPR recommended to the Centers for Medicare and Medicaid Services that it provide

expanded coverage for PET scans for diagnosis, staging, and re-staging of all cancers. The applicant states that *“NOPR’s recommendation is quite likely to result in an increased access to the technology and utilization, in clinically appropriate ways...”* In addition, the applicant discusses the increasing support for the use of PET scanning to aid in diagnosing coronary artery disease and other non-cancer applications, and suggests the technology will be used more often.

Lastly, the applicant states in Section III.1, pages 36-37, that cancer incidence rates in the primary service area and an aging population will contribute to continued demand for PET/CT services. The applicant states four out of seven counties in Novant’s PET service area, Davidson, Forsyth, Surry, and Yadkin counties, had higher cancer incidence rates than the state as a whole from 2006-2010, citing data from the North Carolina Cancer Registry, January 2013. The applicant demonstrates that the population over 65 years of age in each of the counties in its primary service area is expected to increase over time. Based on projections obtained from the North Carolina Office of State Budget and Management, the percentage of persons aged 65 and older in the primary service area is anticipated to increase by nearly 17% from July 2013 to July 2019. However, despite population growth in Novant’s PET service area, the number of PET scans performed at Forsyth Medical Center has decreased each year since FFY 2009 (3,762) through FFY 2012 (2,615), a 30.5% decrease ($3,762 - 2,615 = 1,147$; $1,147/3,762 = 0.305$). The compound annual rate of decrease is 11.4% per year.

Projected Utilization

In Section III.1, pages 38-44, the applicant provides the projected utilization for its two existing and approved, fixed dedicated PET/CT scanners at Forsyth Medical Center and for its proposed fixed dedicated PET/CT scanner at Kernersville. The applicant describes the methodology as follows:

“Step 1: Determine County Incidence Data to Project New Cancer Cases in the Novant PET Service Area”

The applicant used 2006-2010 cancer incidence data from the North Carolina Cancer Registry to calculate cancer incidence rates for each of the counties in the primary service area.

“Step 2: Estimate the Projected Number of New Cancer Cases in the Novant PET Service Area in 2016 through 2019”

The applicant then multiplied the projected population for each county by each county’s cancer incidence rate to obtain the number of new cancer cases. This is illustrated in the following table:

Projected New Cancer Cases in Novant PET Service Area

	2017	2018	2019
Davidson County Population	166,995	167,630	168,438
Cancer Incidence Rate	0.0051	0.0051	0.0051
Projected Cases	854	857	861
Davie County Population	41,616	41,657	41,698
Cancer Incidence Rate	0.0049	0.0049	0.0049
Projected Cases	203	203	203
Forsyth County Population	376,474	379,930	383,289
Cancer Incidence Rate	0.0051	0.0051	0.0051
Projected Cases	1,907	1,924	1,941
Stokes County Population	45,866	45,665	45,481
Cancer Incidence Rate	0.0047	0.0047	0.0047
Projected Cases	214	213	212
Surry County Population	74,609	74,787	74,964
Cancer Incidence Rate	0.0051	0.0051	0.0051
Projected Cases	378	379	380
Wilkes County Population	71,351	71,669	71,987
Cancer Incidence Rate	0.0049	0.0049	0.0049
Projected Cases	349	351	353
Yadkin County Population	37,732	37,644	37,566
Cancer Incidence Rate	0.0050	0.0050	0.0051
Projected Cases	190	190	190
Total Cases*	7,620 [4,095]	7,679 [4,117]	7,739 [4,140]

*On page 39, the applicant provided incorrect totals. Corrected totals are represented in brackets. Totals may not foot due to rounding.

“Step 3: Estimate the Novant Market Share in the Proposed PET Service Area”

The applicant states, on page 39,

“NHKMC reviewed the PET/CT patient origin data from each mobile and fixed PET provider in North Carolina from the 2013 Acute Care License Renewal Applications to determine Novant’s market share percentage for each proposed service area county.”

The applicant lists the following market share results for each county:

County	Davidson	Davie	Forsyth	Stokes	Surry	Wilkes	Yadkin
Forsyth Medical Center Market Share	0.377	0.690	0.700	0.785	0.449	0.580	0.720

“Step 4: Estimate the Number of Projected Cancer Cases from each Service Area County using Novant Market Share Percentage from 2017 through 2019”

The percent market share for each county was multiplied by the projected number of cancer cases in each county to determine projected Novant cancer PET patients. This resulted in the following numbers of projected Novant cancer PET patients:

Novant Projected Cancer PET Patients

	2017	2018	2019
Davidson	322	323	325
Davie	140	140	140
Forsyth	1,333	1,345	1,357
Stokes	168	167	166
Surry	170	170	171
Wilkes	203	204	204
Yadkin	137	137	136
Totals*	2,472	2,486	2,500

*Totals may not foot due to rounding.

“Step 5: Estimate the Number of Projected Cancer-Related PET Scans for In-Migration from 2017 through 2019”

The applicant states, on page 42,

“The Novant PET Service Area consisting of Davidson, Davie, Forsyth, Surry, Stokes, Wilkes and Yadkin Counties represents 92% of Novant’s PET patient origin for FFY 2011-12. Based on historical data, Novant projects 8% immigration from other counties in North Carolina consistent with its historical operating experience.”

The applicant multiplied the projected number of cancer PET patients in the Novant PET Service Area by 8% to obtain the estimated number of in-migration cancer PET cases. However, the applicant incorrectly calculated the 8% in-migration data. First, 100% of the projected cancer PET patients to be served by Novant must be calculated by dividing the projected number of cancer PET patients in the Novant PET Service Area by 92%. Next, the dividend would be multiplied by 8% to get the projected number of in-migration patients. For example, in 2017 the applicant projects there will be 2,485 cancer PET patients in the Novant PET Service Area. To estimate 100% of the cancer PET patients, divide 2,485 by .92 (92%) to get 2,687. Multiply 2,687 by .08 (8%) to get 215 cancer PET patients from counties outside the Novant PET Service Area (i.e. in-migration).

The applicant then multiplied the total projected cancer PET patients (Novant Service Area patients plus in-migration patients) by two to reflect that each cancer patient would receive two scans for diagnosis, treatment and follow up evaluations. The applicant bases its assumption of the need for two PET scans per cancer PET patient on a PETNet Solutions, Inc. article, provided in Exhibit 18, that states, “...a follow-up whole-body PET/CT scan can provide information to assess if the treatment was successful and if areas that were previously abnormally metabolically active have responded.” PETNet Solutions, Inc. is a vendor of Forsyth Medical Center, providing Forsyth Medical Center’s PET services program with radiopharmaceuticals used in PET scanning. In addition, the applicant provides documentation in Exhibit 18 from the Centers for Medicare and Medicaid Services (CMS) that indicates that a follow up PET scan is covered by Medicare in ten types of cancer and that follow up PET scans for other types of cancer are only covered if the treating physicians and patients are participating in CMS clinical studies. The applicant states, in Section III, page 32, that Forsyth Medical Center’s PET/CT Imaging program participates in the CMS clinical studies being implemented by NOPR. However, the applicant does not provide information on its treatment of the ten types of cancer covered by Medicare or whether other payers would cover follow up scans. Moreover, no historical data is provided showing that on average two scans per patient are performed at Forsyth Medical Center. Therefore, the applicant does not adequately demonstrate that its assumption that two scans are needed for each cancer PET patient is reasonable, credible or supported.

The applicant provides the total projected number of cancer PET scans, as illustrated in the following table:

	CY 2017	CY 2018	CY 2019
New Cancer PET Patients from Novant PET Service Area	2,472	2,486	2,500
8% in-migration**	198 [215]	199 [216]	200 [217]
Novant Cancer PET Patients from Service Area plus In-migration Cancer PET Patients	2,669 [2,687]	2,684 [2,702]	2,699 [2,717]
X 2 Scans Each	X 2	X 2	X 2
Total PET Scans for Cancer Related Cases*	5,339 [5,374]	5,369 [5,404]	5,399 [5,434]

* Totals may not foot due to rounding.

** Adjusted to reflect correct calculation. Corrected totals reflected in brackets.

“Step 6: Estimate the Number of Projected Non-Cancer Related PET Scans for the Novant PET scanners from 2017 through 2019”

The applicant states that in CY 2012 approximately 2% of PET scans at Forsyth Medical Center were for non-cancer patients, specifically for cardiology and neurology cases. Based on documentation included in Exhibit 18, the applicant assumes that PET scans in non-cancer patients at Kernersville and Forsyth Medical Center will increase to 10% of the total in CY 2017, 15% in CY 2018, and 20% in CY 2019. Exhibit 18 includes a HealthImaging article which states that PET studies for cardiology and neurology “...are likely to become a larger proportion of PET studies, as other radiopharmaceutical tracers, ...become approved for clinical use.” However, the applicant does not adequately demonstrate how it determined that PET scans in non-cancer PET patients would increase from only 2% of the total in CY 2012 to 20% in CY 2019, an increase of 18 percentage points in seven years (20% - 2% = 18%). The applicant calculated the projected number of non-cancer related PET scan procedures for each of these years by multiplying the sum of the projected number of Novant cancer PET service area and in-migration patients by 10%, 15%, and 20% for CY 2017, CY 2018, and CY 2019, respectively. These results were then multiplied by two, representing two scans per patient, to obtain the total projected cardiac and neurology PET scans, as illustrated in the table below:

Projected Non-Cancer PET Scans

	2017	2018	2019
Projected Cancer Cases	2,687	2,702	2,717
%	10%	15%	20%
Neurology & Cardiac Patients	269	405	543
X 2 Scans per Patient	x 2	x 2	x 2
Total Neurology & Cardiac PET Procedures*	538	810	1,086

* Totals may not foot due to rounding.

The applicant cites an article, in Exhibit 18, from PETNet Solutions, Inc. that discusses the benefits of follow up scans. However, PETNet Solutions, Inc. is a vendor of Forsyth Medical Center, providing Forsyth Medical Center's PET services program with radiopharmaceuticals used in PET scanning. Moreover, additional documentation provided in Exhibit 18, from the Centers for Medicare and Medicaid Services, 2010, (CMS 2010), does not demonstrate that there is Medicare or other payer coverage for follow up PET scans for non-cancer PET patients. In fact, the CMS 2010 document describes limitations for using "the PET scan" for various non-cancer cases and does not mention follow-up scans. (Note: in 2008 Forsyth Medical Center assumed 1.4 PET scans for each cancer PET patient and 1.5 PET scans for each non-cancer PET patient. See the Required State Agency Findings for Project I.D. #G-8129-08.) The applicant does not adequately demonstrate that its assumption of two scans for each non-cancer PET patient is reasonable, credible or supported.

The applicant provides the total combined number of projected cancer and non-cancer PET scans in Step 7.

"Step 7: Estimate the Total Number of Projected Cancer & Non-Cancer Related PET Scans for the Novant PET scanners from 2017 to 2019"

Novant Health PET Scans	2017	2018	2019
Cancer-Related PET Scans**	5,339 [5,374]	5,369 [5,404]	5,399 [5,434]
Neurology & Cardiac Related PET Scans	534 [538]	805 [810]	1,080 [1,086]
Totals*	5,873 [5,912]	6,174 [6,214]	6,479 [6,520]

*Totals may not foot due to rounding.

**Adjusted to reflect corrected calculation in Step 5.

The applicant states, on page 43, that the volume of PET/CT procedures was then distributed among Novant Health’s two existing and approved PET/CT scanners at Forsyth Medical Center using the assumption that the majority of scans will occur at Forsyth Medical Center due to the availability of two scanners and that “*NHKMC will experience a conservative ramp-up period during Project Years 1-3.*” The applicant further states, on page 44, “...as the second fixed PET/CT scanner becomes operational at NHFMC it will gradually take on more volume to reduce the existing burden on the first fixed PET/CT scanner at NHMC [sic].” The distribution of PET/CT scans among Novant’s three existing, approved and proposed PET scanners for the first three years after project completion is illustrated in the following table:

Forsyth Medical Center	CY 2017 (Project Year 1)	CY 2018 (Project Year 2)	CY 2019 (Project Year 3)
PET scans – currently operational PET scanner**	2,643 [2,660]	2,377 [2,393]	2,170 [2,184]
PET scans – approved PET scanner	1,762 [1,774]	1,957 [1,957]	2,170 [2,184]
Forsyth Medical Center’s Total PET scans	4,405 [4,434]	4,322 [4,350]	4,341 [4,368]
Average number of scans per Forsyth Medical Center’s PET/CT scanner	2,202.5 [2,217]	2,161 [2,125]	2,170.5 [2,184]
Kernersville’s proposed PET scans	1,468 [1,498]	1,852 [1,864]	2,138 [2,152]
Total Novant PET scans*	5,873 [5,912]	6,174 [6,214]	6,479 [6,520]

*Totals may not foot due to rounding.

**Adjusted to reflect corrected calculation in Step 5.

As the table above depicts, the proposed PET/CT scanner at Kernersville would perform 2,152 PET procedures in the third full year of the project in CY 2019. This exceeds the performance standard of 2,080 PET procedures required by 10A NCAC 14C .3703(a)(1).

However, Forsyth Medical Center’s License Renewal Applications for Federal Fiscal Years 2009 – 2012 show a downward trend in PET scanner utilization, as illustrated in the following table:

**Forsyth Medical Center's PET Scanner Utilization
2009 - 2012**

	2009	2010	2011	2012
Number of PET procedures	3,762	3,346	2,875	2,615
Percent change		- 11.1%	- 14.1%	- 9.0%
Compound Annual Rate of Decrease				- 11.4%

In addition, Forsyth Medical Center is currently providing PET services to its patients on one fixed dedicated PET/CT scanner. Forsyth Medical Center was issued a certificate of need on November 13, 2008, (Project I.D. #G-8129-08) to develop one fixed dedicated PET scanner in Forsyth County in response to a need determination in the 2008 SMFP for one fixed dedicated PET scanner in HSA II. The PET scanner will be placed in the Radiology Department at Forsyth Medical Center. Therefore, Forsyth Medical Center has approval for two fixed dedicated PET scanners, however there have been a number of delays in the development of the second PET scanner. In its project status report for Project I.D. #G-8129-08, dated April 1, 2011, Novant Health, Inc. cited delays in implementation due to other priorities, namely the opening of Kernersville Medical Center and the opening of Brunswick Novant Medical Center, formerly Brunswick Community Hospital, in 2011, in addition to other utilization of needed resources.

On August 12, 2011, the Division of Health Service Regulation (DHSR) received a request for a declaratory ruling from Forsyth Medical Center to allow the acquisition of a mobile PET/CT scanner, in place of the approved fixed dedicated PET scanner, to be operated at Forsyth Medical Center, Thomasville Medical Center, Rowan Regional Medical Center, and Kernersville Medical Center. The DHSR denied this request on October 24, 2011, citing a material change in the physical location and scope of the proposed project, in addition to “no need identified” in the 2008 SMFP for additional mobile dedicated PET scanners anywhere in the state. On March 6, 2013, the Division of Health Service Regulation received a petition from MedQuest Associates, Inc. and Novant Health, Inc. requesting the establishment of a ‘methodology for mobile PET scanners that generates a need determination for a new mobile PET scanner when an existing mobile PET/CT scanner in the defined service area exceeds the 2,600 annual procedure capacity.’¹ The State Health Coordinating Council Technology and Equipment Committee responded to this petition at its committee meeting on April 14, 2013. The petition was denied, citing decreases in statewide mobile PET scanner and fixed PET scanner utilization and concluding that there was “sufficient availability of PET scanning services to meet demand.”²

¹ Petition to the State Health Coordinating Council Related to Mobile PET Services for The 2014 State Medical Facilities Plan, received by the Division of Health Service Regulation, Medical Facilities Planning Branch, on March 6, 2013.

² Technology and Equipment Committee Agency Report Petition Related to Mobile PET Services for the 2014 State Medical Facilities Plan, provided at the Technology and Equipment Committee meeting held on April 24, 2013.

As of Novant Health, Inc.'s most recent progress report on this project, dated October 21, 2013, the scanner has not been ordered, renovations have not been started, and architectural drawings are not complete. In short, no real progress has been made in the five years since the certificate was issued.

The PET scanner utilization rate for Forsyth Medical Center for its two fixed dedicated PET scanners for 2010-2011, as stated in the 2013 SMFP, is only 47.92%. Forsyth Medical Center's PET scanner utilization rate for 2011-2012 has decreased to 43.58%, based on 2,615 PET procedures reported in Forsyth Medical Center's 2012 License Renewal Application. The applicant projects there will be a total of 4,405 PET procedures in 2017, which represents an increase in utilization of 68.45% from 2012 to 2017. The applicant does not adequately demonstrate the need to acquire the proposed PET scanner because it has not acquired the PET scanner it has been approved for since November 2008 and the applicant did not adequately demonstrate that its utilization projections are based on reasonable, credible, or supported assumptions.

In summary, the applicant adequately identified the population to be served and the extent to which all residents of the Novant PET service area, including underserved populations, would have adequate access to PET services at Kernersville. However, the applicant did not adequately demonstrate the need that the population projected to be served has for the proposed third fixed PET/CT scanner. Therefore, the application is not conforming to this criterion.

Baptist. North Carolina Baptist Hospital (Baptist) proposes to convert the research PET/CT scanner currently owned by Wake Forest University Health Sciences to clinical use. The applicant contracts with PETNet to provide the clinical doses of radioisotopes needed. However, the applicant may also use an existing cyclotron currently used for research PET scans.

Population to be Served

In Section III.1, pages 37-39 and page 41, Baptist defines its PET/CT service area as a 21-county area that includes all 11 counties in HSA II, eight counties in HSA I, and two counties in HSA III. These counties are: Alamance, Alexander, Alleghany, Ashe, Burke, Caldwell, Caswell, Catawba, Davidson, Davie, Forsyth, Guilford, Iredell, Randolph, Rockingham, Rowan, Stokes, Surry, Watauga, Wilkes, and Yadkin. As stated in Section III.5(a), page 74, this service area has "*remained constant for several years and NCBH does not anticipate any changes as a result of this project.*" The applicant provides the historical patient origin for all inpatient discharges from Baptist in FFY 2012 in Section III.4(a), page 67, illustrated as follows:

**Baptist Patient Origin, Entire Facility
FFY 2012 (July 1, 2011 – June 30, 2012)**

Davidson	7.4%
Davie	3.1%
Forsyth	34.2%
Guilford	6.7%
Randolph	3.1%
Stokes	3.6%
Surry	5.1%
Wilkes	4.1%
Virginia	7.0%
All Others*	25.8%
Total	100.0%

*All Others includes the remaining 74 counties of North Carolina and "All Others", unspecified by the applicant, pages 67-70.

In addition, in Section III.4(b), pages 70-74, the applicant provides the current patient origin for Baptist's PET/CT service for FFY 2012, illustrated as follows:

Davidson	9.8%
Forsyth	22.4%
Guilford	7.2%
Randolph	3.7%
Surry	6.7%
Wilkes	4.0%
Virginia	9.8%
All Others*	36.4%
Total	100.0%

*All Others include 82 counties in North Carolina plus "zAll Others" [sic] unspecified by the applicant, pages 70-74.

In Section III.5(c), pages 75-77, the applicant provides the projected patient origin for PET services at Baptist for the first two years following project completion, illustrated in the following table:

Davidson	9.8%
Forsyth	22.4%
Guilford	7.2%
Randolph	3.7%
Surry	6.7%
Wilkes	4.0%
Virginia	9.8%
All Others*	36.4%
Total	100.0%

*All Others include 54 counties in North Carolina plus “zAll Others” [sic] unspecified by the applicant, pages 75-77.

In Section III.5(d), page 78, the applicant states that the assumptions and methodologies used to project patient origin were based on historical patient origin and input from Radiology Department leadership. Baptist does not expect any significant changes to its patient origin in the future.

The applicant adequately identified the population to be served.

Need Analysis

In Section III.1(a), pages 35-47, the applicant discusses the need for converting a research PET/CT scanner to clinical use at Baptist in response to the need determination in the 2013 SMFP for one fixed dedicated PET/CT scanner in HSA II. The proposed, converted PET/CT scanner is already located on the ground floor of Baptist’s MRI building and it would remain right where it is. The applicant discusses the need for the PET/CT scanner based on the service area’s population growth, increases in cancer incidence, the expansion of Baptist’s Cancer Center, increases in the prevalence of Alzheimer’s Disease, expanded coverage due to the Affordable Care Act, and the Advisory Board’s projections for increased PET/CT utilization.

Baptist’s service area population is projected to grow at a rate of 0.59% per year through 2018 and is expected to increase even faster for the 55+ and 65+ populations at 2.29% and 3.02%, respectively. The applicant provides a table illustrating population projections for each county in its 21-county service area, from 2010-2019, in Section III, pages 37-39. In addition, the applicant demonstrates that cancer incidence rates and cancer deaths in most of the counties in its service area exceed the respective statewide rates. In Section III, page 41, the applicant provides a table that shows that 16 of the 21 counties in its service area, or 76.2%, have higher cancer incidence rates than for the state as a whole. The applicant states, on page 42,

“As more emphasis is placed on early detection, the value of PET services is even more pronounced and it is even more likely that the rate of cancer incidence will increase while the rate of cancer deaths decrease if more cancer can be identified early through the use of PET as a diagnostic tool.”

In addition, Baptist expects its inpatient volumes and its hematology/oncology clinic visits to increase over time in conjunction with the increase in the number of cancer patients it serves due to the aging population and increasing cancer incidence, as stated on page 43. Baptist expects to open an expanded Cancer Center (CON Project I.D. #G-8280-09) in December 2013, to address, in part, current demand and projected growth of patients in need of cancer care. Baptist states expanded PET services are also needed for projected increases in Alzheimer's Disease. The applicant states, in Section III, page 43, that the prevalence of Alzheimer's Disease is expected to grow by approximately 30% from 2010 to 2025 according to the 2013 Alzheimer's Disease Facts and Figures report.

Moreover, in Section III, pages 46-47, the applicant discusses the expected impact of recent payment changes by the Centers for Medicare and Medicaid (CMS), stating that coverage has been expanded for FDG-PET, which accounts for 90-95% of all PET studies. In addition, the federal Patient Protection and Affordable Care Act will allow for more people to receive federal subsidy support for health care and, therefore, health insurance. This, in turn, is likely to lead to a greater number of people seeking medical care. The applicant states, on page 47, *"Therefore, previously undiagnosed cancer cases may be diagnosed which would also lead to an increase in PET scanner use over the next five years."*

Lastly, as a member of the Advisory Board, a global research, technology, and consulting firm partnering with leaders in over 3,700 healthcare and higher education organizations, Baptist states, on page 45, that the Advisory Board's Technology Insights program *"has projected that PET/CT utilization will grow 22% over the next five years and 55% over the next ten years in northwest North Carolina. Technological advances, demographic trends, decreasing price points, and reimbursement changes are driving this projected growth."*

Projected Utilization

In Section III.1(b), pages 48-63, the applicant discusses its assumptions and methodology used to project utilization for the proposed fixed dedicated PET/CT scanner at Baptist. The methodology used to project utilization is described in the following steps:

"Step 1 – Determine County Incidence Data to Project New Cancer Cases in the NCBH PET Service Area"

The applicant states, on page 48,

"...the North Carolina Central Cancer Registry projects annual new cancer cases for all 100 North Carolina counties using actual historical new cancer case data collected from cancer centers throughout the State. Projections through project years 2013-2018 are provided below"

for HSA II and the NCBH service area. The 2013 incidence rate was held constant and applied to the NC Demographer's Office population projections by county (Table 2) to determine the number of Cancer cases through 2018."

The projected new cancer cases for project years 2013-2018 for Baptist's PET service area are illustrated in the following table:

Projected New Cancer Patients in Baptist's Service Area

Service Area: 21 counties	2013 Incidence Rate*	2013	2014	2015	2016	2017	2018
Alamance	0.006	923	928	934	939	945	950
Alexander	0.007	248	249	251	252	253	254
Alleghany	0.008	87	87	86	86	85	85
Ashe	0.008	216	218	219	221	223	224
Burke	0.007	597	597	597	597	597	597
Caldwell	0.007	544	545	545	545	546	546
Caswell	0.007	166	166	166	166	167	167
Catawba	0.006	953	957	960	964	968	971
Davidson	0.006	1,028	1,034	1,040	1,046	1,051	1,057
Davie	0.007	290	292	294	296	297	299
Forsyth	0.006	2,030	2,047	2,063	2,079	2,095	2,110
Guilford	0.005	2,758	2,789	2,819	2,850	2,881	2,911
Iredell	0.006	950	960	970	979	989	999
Randolph	0.006	880	886	892	897	903	909
Rockingham	0.007	625	625	624	624	623	623
Rowan	0.006	837	837	836	836	835	835
Stokes	0.007	327	328	329	330	331	332
Surry	0.007	484	484	483	483	483	482
Watauga	0.005	280	284	288	292	295	299
Wilkes	0.007	485	487	489	490	492	494
Yadkin	0.007	254	254	255	255	256	256
Service Area Total	0.006	14,962	15,056	15,148	15,240	15,332	15,423

*Incidence rates rounded to the nearest thousandth by Project Analyst.

"Step 2 – Estimate the number of projected PET patients for cancer cases in the NCBH PET service area from 2013-2018"

The applicant assumed that approximately 95% of cancer patients would be appropriate for receiving PET scans based on the report, 'FDG Indications

CANCERS AND INDICATIONS ELIGIBLE FOR ENTRY IN THE NOPR'. The number of projected patients appropriate for receiving PET scanning for cancer in the Baptist service area for 2013-2018 is illustrated in the following table:

**Baptist's PET Service Area
Projected Number of Cancer PET Patients**

County	2013*	2014	2015	2016	2017	2018
Alamance	877	882	887	892	898	903
Alexander	236	237	238	239	240	241
Alleghany	83	83	82	82	81	81
Ashe	205	207	208	210	212	213
Burke	567	567	567	567	567	567
Caldwell	517	518	518	518	519	519
Caswell	158	158	158	158	159	159
Catawba	905	909	912	916	920	922
Davidson	977	982	988	994	998	1,004
Davie	276	277	279	281	282	284
Forsyth	1,929	1,945	1,960	1,975	1,990	2,005
Guilford	2,620	2,650	2,678	2,708	2,737	2,765
Iredell	903	912	922	930	940	949
Randolph	836	842	847	852	858	864
Rockingham	594	594	593	593	592	592
Rowan	795	795	794	794	793	793
Stokes	311	312	313	314	314	315
Surry	460	460	459	459	459	458
Watauga	266	270	274	277	280	284
Wilkes	461	463	465	466	467	469
Yadkin	241	241	242	242	243	243
Totals**	14,214	16,315 [14,304]	16,398 [14,384]	16,482 [14,467]	16,566 [14,549]	16,648 [14,630]

*2013 data calculated by Project Analyst from the number of new cancer patients provided by applicant for 2013 in Step 1.

**Corrected totals are in brackets.

For the table above, the applicant did not provide projected PET patients from cancer cases for 2013, therefore the Project Analyst multiplied the projected number of cancer patients for each county in Baptist's service area for 2013 by 95%, and then summed them to get the total. In addition, the applicant did not provide the correct totals for the projected PET patients from cancer cases for the years 2014 – 2018, therefore the Project Analyst calculated these by summing the data in each column. The totals provided by the applicant appear to be typographical errors since the correct totals are used in subsequent tables.

“Step 3 – Estimate the number of projected PET patients for non-cancer cases in the NCBH Service Area and HSA II from 2013-2018”

Based on a review of its utilization in FY 2012, the applicant determined that 2% of PET scans were for non-cancer patients which equated to approximately 75 patients. However, Baptist does not clearly state if “FY 2012” is Baptist’s Fiscal Year (7/1 – 6/30) or the Federal Fiscal Year (10/1 – 9/30). According to Baptist’s 2013 hospital license renewal application, Baptist served 2,009 PET patients in FFY 2012. Two percent of 2,009 PET patients is equal to 40, not 75. Based on its review of the literature, discussion with staff of Baptist’s Department of Radiology PET/CT imaging program, and expected increases in the number of insured due to enrollment in the Affordable Health Care Act – Marketplace/Health Exchange, the applicant applied an increase in non-cancer PET patients of 10% a year for project years 1, 2 and 3. The applicant projects the following non-cancer PET patient totals for 10 months of 2013 annualized through 2018, as follows:

**Baptist
Projected Non-Cancer PET Patients**

County	Baptist's FY 2013 - 10 months annualized	2014	2015	Project Year 1 2016	Project Year 2 2017	Project Year 3 2018
Alamance	0	0	0	0	0	0
Alexander	0	0	0	0	0	0
Alleghany	0	0	0	0	0	0
Ashe	0	0	0	0	0	0
Burke	0	0	0	0	0	0
Caldwell	0	0	0	0	0	0
Caswell	0	0	0	0	0	0
Catawba	0	0	0	0	0	0
Davidson	9	10	11	12	13	14
Davie	5	5	6	7	7	8
Forsyth	53	58	63	69	76	84
Guilford	4	4	5	5	6	6
Iredell	0	0	0	0	0	0
Randolph	0	0	0	0	0	0
Rockingham	0	0	0	0	0	0
Rowan	0	0	0	0	0	0
Stokes	5	5	6	7	7	8
Surry	7	8	8	9	10	11
Watauga	7	8	8	8	10	11
Wilkes	6	7	7	8	9	9
Yadkin	2	2	2	3	3	3
Total	98	107	116	128	141	155
% Change		9%	9%	10%	10%	10%

The applicant states, on page 53, that approximately 75 patients in FY 2012 were non-cancer PET patients. The projected number of non-cancer PET patients is shown to increase by 9% from 2013 (10 months annualized) to 2014, by 9% from 2014 to 2015, and by 10% annually for 2016-2018. Although the applicant explains that it calculated 98 patients in 2013 by annualizing 10 months of data, it did not explain the 30% one year increase from 75 to 98 non-cancer PET patients when total PET scanner volume decreased 22% between FFY 2011 and FFY 2012. For 98 to be approximately 2% of PET patients, the

total number of PET patients would need to be 4,900. In FFY 2012, Baptist served only 2,009 PET patients, not 4,900.

The applicant did not adequately demonstrate that its projected number of non-cancer PET patients from 2013 – 2018 is based on reasonable, credible and supported assumptions.

Next, the applicant estimates its market share of non-cancer PET patient volume, on page 54, stating it, “*reviewed the past six years of license renewal application data by its 19 county service area for all of HSA I, II, and III and calculated its three year market average – 17.5%.*” Baptist states it looked at six years of data and provides six years of data, but then calculated only a three year average. The applicant does not provide sufficient explanation in its application.

However, the Project Analyst reviewed the past three years of data provided by the applicant in Exhibit 15 and in DHSR Patient Origin Reports³, determining that Baptist’s three year market share average was only 15.2%, not 17.5%. Therefore, the applicant actually underestimates the total number of non-cancer PET patients (all providers). The applicant estimates the total number of non-cancer PET patients in the service area by dividing the projected number of non-cancer PET patients to be served at Baptist in each of its service area counties by its three-year market share average. Revised estimates, using a 15.2% three year market share average were calculated by the Project Analyst using the following formula (Davidson County is used as an example):

Baptist’s projected 2014 Davidson County non-cancer PET patients/ three-year market share average = total non-cancer PET patients (all providers) 10/ 0.152 = 65.8.

Data for CY 2018 was calculated by the Project Analyst using the applicant’s data from pages 53-54 because the applicant mislabeled Table 11 on page 54 and does not provide projections for CY 2018. The annual estimated totals provided by the applicant, along with the revised estimated totals provided by the Project Analyst shown in brackets, are illustrated in the following table:

³ DHSR 2013, 2012 and 2011 Patient Origin Reports for PET Scanner (summary data from hospitals’ License Renewal Applications)

**Estimated Total Number of Non-Cancer PET Patients in Baptist's Service Area
(All Providers)***

County	2013 - 10 months annualized	2014	2015	Project Year 1 2016	Project Year 2 2017	Project Year 3 2018**
Alamance	0	0	0	0	0	0
Alexander	0	0	0	0	0	0
Alleghany	0	0	0	0	0	0
Ashe	0	0	0	0	0	0
Burke	0	0	0	0	0	0
Caldwell	0	0	0	0	0	0
Caswell	0	0	0	0	0	0
Catawba	0	0	0	0	0	0
Davidson	51 [59]	56 [66]	61 [72]	67 [79]	74 [86]	80 [92]
Davie	29 [33]	31 [33]	34 [39]	37 [46]	41 [46]	46 [53]
Forsyth	303 [349]	330 [382]	360 [414]	396 [454]	435 [500]	480 [553]
Guilford	23 [26]	25 [26]	27 [33]	30 [33]	33 [39]	34 [39]
Iredell	0	0	0	0	0	0
Randolph	0	0	0	0	0	0
Rockingham	0	0	0	0	0	0
Rowan	0	0	0	0	0	0
Stokes	29 [33]	31 [33]	34 [39]	37 [46]	41 [46]	46 [53]
Surry	40 [46]	44 [53]	48 [53]	52 [59]	58 [66]	63 [72]
Watauga	40 [46]	44 [53]	48 [53]	52 [53]	58 [66]	63 [66]
Wilkes	34 [39]	37 [46]	41 [46]	45 [53]	49 [59]	51 [59]
Yadkin	11 [13]	12 [13]	14 [13]	15 [20]	16 [20]	17 [20]
Total Number of Non-Cancer PET Patients (All Providers)	560 [644]	610 [705]	665 [762]	732 [843]	805 [928]	886 [1,007]

*Project Analyst calculated revised data using 15.2% market share. Results are in brackets.

**Project Analyst calculated Project Year 2018 using totals provided by applicant in Step 3.

“Step 4 – Estimate the Number of Projected PET Patients for Cancer and Non-Cancer cases in the FMC [sic] PET service area from 2013-2018”

The applicant then combined the projected number of cancer and non-cancer PET patients in the service area to obtain the total market share, as illustrated in the table below:

**Projected Total Number of Cancer and Non-Cancer PET Patients in
Baptist's Service Area (All Providers)***

County	2013 - 10 months annualized**	2014	2015	Project Year 1 2016	Project Year 2 2017	Project Year 3 2018
Alamance	877	882	887	892	898	903
Alexander	236	237	238	239	240	241
Alleghany	83	83	82	82	81	81
Ashe	205	207	208	210	212	213
Burke	567	567	567	567	567	567
Caldwell	517	518	518	518	519	519
Caswell	158	158	158	158	159	159
Catawba	905	909	912	916	920	922
Davidson	1,036	1,048	1,060	,1073	1,084	1,096
Davie	309	310	318	327	328	337
Forsyth	2,278	2,327	2,374	2,429	2,490	2,558
Guilford	2,646	2,676	2,711	2,741	2,776	2,804
Iredell	903	912	922	930	940	949
Randolph	836	842	847	852	858	864
Rockingham	594	594	593	593	592	592
Rowan	795	795	794	794	793	793
Stokes	344	345	352	360	360	368
Surry	506	513	512	518	525	530
Watauga	312	323	327	330	346	350
Wilkes	500	509	511	519	526	528
Yadkin	254	254	255	262	263	263
Total Number of Cancer and Non-Cancer PET Patients (All Providers)	14,861	15,509	15,146	15,310	15,477	15,637

*Table calculated by Project Analyst due to errors in cell counts and totals. Project Analyst's revised data for non-cancer PET patients from previous table were utilized in calculations.

**Project Analyst calculated 2013 data due to applicant's omission.

“Step 5 – Apply NCBH’s 3 Year average market share to the projected number of PET Patients receiving a scan for Cancer and Non-Cancer cases by County in the NCBH Service area and HSA II.”

The applicant stated, on page 57, it reviewed its PET service market share based on patient origin data contained in license renewal applications for FFY 2008 through FFY 2013 for HSAs I, II, and III. Exhibit 15 was then referenced which contains six years of patient origin data from license renewal applications for all PET service providers in Baptist’s service area with the exception of Alamance and Caswell counties. The applicant stated, on page 57, that it calculated its three year average market share by county, and then multiplied the average by each county’s projected number of cancer and non-cancer PET patients to project the total number of PET patients at Baptist for “FY2013 – 2018.” The applicant indicated, in Table 13 on page 57, that Alamance and Caswell counties are “*Not in 19 county service area*” and that a 1% three year average market share was used “*to be conservative.*” However, the applicant’s three year market share averages were not correct. Therefore, the Project Analyst calculated Baptist’s three year average market shares based on patient origin data contained in license renewal applications for Baptist’s service area, including Alamance and Caswell counties, for FFY 2010 through FFY 2012, and then calculated the projected number of PET patients to be served at Baptist. The applicant omitted data for FFY 2013 in Table 13 on page 57, therefore only FFY’s 2014 – FFY 2018 are provided in the table below.

Projected Number of PET Patients to be Served at Baptist*

County	3-Year Average Market Share	FFY2014	FFY2015	FFY2016	FFY2017	FFY2018
Alamance	1%	9	9	9	9	9
Alexander	9.9% [10.7%]	25	25	26	26	26
Alleghany	52.7% [49.2%]	41	40	40	40	40
Ashe	42.3% [26.3%]	54	55	55	56	56
Burke	25.3% [13.9%]	79	79	79	79	79
Caldwell	13.3% [8.0%]	41	41	41	42	42
Catawba	4.3% [4.8%]	44	44	44	44	44
Caswell	1% [6.1%]	10	10	10	10	10
Davidson	25.3% [21.2%]	222	225	227	230	232
Davie	21.3% [20.5%]	64	65	67	67	69
Forsyth	21.8% [21.2%]	493	503	515	528	542
Guilford	8.3% [7.9%]	211	214	217	219	222
Iredell	12.5% [9.3%]	85	86	86	87	88
Randolph	16.1% [13.0%]	109	110	111	112	112
Rockingham	8.1% [8.0%]	48	47	47	47	47
Rowan	17.6% [8.3%]	66	66	66	63	63
Stokes	19.3% [19.1%]	66	67	69	69	70
Surry	41.2% [29.8%]	153	153	154	156	158
Watauga	42.9% [22.5%]	73	74	74	79	79

Wilkes	34.2% [32.1%]	163	164	167	169	169
Yadkin	23.9% [23.4%]	59	60	61	62	62
		2,115	2,137	2,165	2,194	2,219

*Table calculated by Project Analyst using total projected number of cancer and non-cancer PET patients (all providers) calculated in Step 4. Revised three year average market share percentages are in brackets.

“Step 6 – Project the Total Number of PET Patients at NCBH for FY 2013-2018”

The applicant states that it treats patients from outside its service area and HSA II. The applicant states, on page 59, that “NCBH’s historical patient origin for PET services outside of its service area is 18% which consists largely of out-of-state patients...” and that it expects in-migration to be constant based on its experience. However, the applicant incorrectly calculated the 18% in-migration. To correctly calculate it, 100% of the projected PET patients to be served at Baptist must be calculated by dividing the projected number of Baptist service area/HSA II patients by 82%. The result of that step would be multiplied by 18% to get the projected number of in-migration patients. The applicant provides the projected number of in-migration PET patients for FY 2014-2018, illustrated in the following table:

Projected Total Number of PET Patients to be Served at Baptist (including in-migration)*

	FY2014	FY2015	FY2016	FY2017	FY2018
Baptist’s Service Area/HSA II	2,115	2,137	2,165	2,194	2,219
In-Migration (18%)**	455 [464]	459 [469]	464 [475]	469 [482]	475 [487]
Total Projected Patients Receiving a PET Scan at Baptist	2,983 [2,579]	3,012 [2,606]	3,043 [2,640]	3,076 [2,676]	3,112 [2,706]

*Table calculated by Project Analyst using projected number of cancer and non-cancer PET patients to be served at Baptist as calculated in Step 5.

**Adjusted to reflect correct calculation. Corrected numbers are reflected in brackets.

“Step 7 – Project the Total Number of PET scans at NCBH for FY 2013-2018”

The applicant then reviewed the last three years of Baptist’s internal Radiology Information Systems repository to calculate the patient to scan ratio, illustrated in the following table:

	Patient/Scan Ratio
FY 2010	1.27
FY 2011	1.28
FY 2012	1.27
3 year average	1.2793

The applicant states, on page 60, “*NCBH performs more than one PET/CT scan per patient for both staging and monitoring of treatment per the CMS guidelines for many cancers.*” The applicant states, on page 60, “*NCBH chose to apply the three year average of 1.2793 PET scans per patient as a fixed rate to only the cancer patient projections to calculate the number of PET scans...*” However, the applicant did not apply the scan rate to the cancer patient projections only, rather the applicant applied the 1.2793 PET scan rate to the total number of projected cancer and non-cancer PET patients and to the total number of projected in-migration patients, assumed to represent both cancer and non-cancer patients. If the 1.2793 PET scan rate was to be applied to only the cancer patient projections, as stated by the applicant, then Baptist’s projected number of PET procedures is overestimated. The applicant provides its results in the following table:

Baptist’s Projected PET Volume*

	2014	2015	2016	2017	2018
Baptist’s Service Area/HSA II patients times 1.2793 scans	3,234 [2,706]	3,265 [2,734]	3,299 [2,770]	3,335 [2,807]	3,374 [2,839]
In-Migration (18%) patients times 1.2793	582 [594]	588 [600]	594 [608]	600 [617]	607 [623]
Total Projected PET Scans	3,816 [3,300]	3,853 [3,334]	3,893 [3,378]	3,935 [3,424]	3,982 [3,462]
Baptist Expected Volume (i.e. ramp up)	68%	75%	100%	100%	100%
Projected Baptist Volume	2,605 [2,244]	2,890 [2,501]	3,893 [3,378]	3,935 [3,424]	3,982 [3,462]

*Table calculated by Project Analyst using data calculated in Step 6. Corrected numbers are reflected in brackets.

The applicant states, on page 60, that a ramp up period is expected during the interim project years and that “*realistically NCBH would meet 68% of the volume targets in interim year FY 14 and 75% in interim year FY 215 [sic] rather than 100% given that only one clinical PET/CT scanner would be operational in that time period.*”

“*Step 7 [sic] – Calculate the Total Number of PET Amyvid/Amyloid scans for Alzheimer’s Patients at NCBH for FY 2013-2018*”

The applicant states, on page 60, that Baptist performs approximately 10 clinical Amyvid/amyloid PET scans per year, however Amyvid is FDA approved and “*is*

expected to receive CMS approval by FY 2015 as supported in the attached literature. (See Exhibit 14)."

In addition, the applicant states, on page 61,

"Through the development of an 'Alzheimer's Center' NCBH will begin to increase the number of clinical PET scans for amyloid imaging for 65+ who meet the appropriateness criteria outlined below regardless of CMS funding:"

The applicant then presents *"the appropriateness criteria."* Baptist states, on page 61, that it reviewed its internal data using ICD-9 codes to determine the number of patients aged 65 and older treated in the clinic in FY 2012 who would have been eligible for the clinical Alzheimer's program if it were fully operational. The applicant states that these numbers would have equated to *"approximately 387 unique patients."* In addition, the applicant states it received input on the number of patients expected to be eligible for Amyvid PET scans from Dr. Suzanne Craft of Baptist, who will lead the development and expansion of the use of Amyvid PET use for both clinical and research patients through the planned Alzheimer's Institute. The applicant states, *"Based on conversations with Dr. Craft, she has estimated that of the total clinic population approximately 25% would be eligible for the Amyvid scan, which would have equated to approximately 178 PET/CT scans today."* Next, the applicant projects future Alzheimer's clinic volume *"based on the aging of the population and increasing Alzheimer's prevalence coupled with historical volume of Alzheimer's patients treated at NCBH."* In addition, the applicant states, on page 62, that *"Volumes have been ramped up based on direction from Dr. Craft, up to full capacity by 2018."* Projections for this population of PET patients are provided in the following table:

	FY2014	FY2015	FY2016	FY2017	FY2018
Total Alzheimer's/Dementia Patients Treated at Clinic	100	200	400	600	800
25% Patient Ratio for Amyvid PET/CT Scan	25	50	100	150	200
Total Projected Amyvid PET Patients	25	50	100	150	200

However, the applicant did not adequately demonstrate that its estimates of the total number of Alzheimer's/Dementia patients to be treated at the clinic for project years 2014 - 2018 were based on reasonable, credible and supported assumptions. Therefore, the estimates for the total number of Amyvid PET patients are also not based on reasonable, credible and supported assumptions. In fact, the information provided to substantiate the estimates in the table above is conflicting and does not support the data provided in the table. The applicant states that approximately 10 Amyvid PET scans are provided per year and that CMS

approval is expected in 2015. The applicant does not explain how it determined that the number of Amyvid PET scans would increase to 25 in 2014, representing an increase of 150% in a two-year period. Moreover, the applicant projects a 100% increase in Alzheimer's/Dementia patients from 2014 to 2015, 100% from 2015 to 2016, 50% from 2016 to 2017, and 33% from 2017 to 2018 without providing adequate supporting documentation. Therefore, Baptist did not adequately demonstrate that the projected number of Amyvid PET patients for years 2014 – 2018 was based on reasonable, credible and supported assumptions.

“Step 8 – Combine Step 6 & 7 to determine the total number of PET Scans for the NCBH Service Area/HSA II for FY 2013-2018”

The applicant states that based on conversations with Dr. Craft, each Alzheimer's/Dementia patient would receive one PET scan each. The applicant provides its total projected PET scans for all patients, including Alzheimer's/Dementia patients for FY2014 – FY2018, illustrated in the following table:

Baptist's Total Projected PET Scans

	2014	2015	2016	2017	2018
Total Projected Cancer and Non-Cancer PET Scans, excluding Amyvid PET Scans*	2,605 [2,244]	2,890 [2,501]	3,893 [3,378]	3,935 [3,424]	3,982 [3,462]
Total Projected Amyvid PET Scans	25	50	100	150	200
Total Projected PET Scans	2,630 [2,269]	2,940 [2,551]	3,993 [3,478]	4,085 [3,574]	4,182 [3,662]

*Calculated by Project Analyst using data calculated in Step 7. Corrected numbers are reflected in brackets.

The corrected number of projected PET scans per PET scanner for 2018, the third year after the project is completed, is 1,831 [$3,662/2 = 1,831$], which is less than the 2,080 required by 10A NCAC 14C .3703(a)(1).

In addition, the projected utilization is not based on reasonable, credible and supported assumptions as summarized below.

- The applicant overestimated the projected number of non-cancer PET patients for FY 2013 through FY 2018 based on an error calculating the approximate number of non-cancer PET patients in FY 2012 and did not adequately explain the 30% increase in non-cancer PET patients from FY 2012 to FY 2013.

- The applicant stated it would apply a 1.2793 PET scan rate to its projected cancer patients only, however it applied the rate to cancer and non-cancer patients, resulting in an overestimation of PET procedures.
- The applicant did not adequately demonstrate that the projected number of Amyvid PET patients was reasonable and supported.

Therefore, the applicant did not adequately demonstrate the need the population it proposes to serve has for a fixed PET scanner, and the application is not 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.

NA – Both Applications

- (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.

NC
Kernersville
Baptist

Kernersville. In Section III.3, pages 52-53, the applicant discusses the alternatives considered prior to the submission of this application, which include: 1) maintaining the status quo; 2) utilizing mobile PET/CT services; or 3) converting an existing fixed PET/CT scanner to a mobile PET/CT scanner; and, 4) relocating an existing PET/CT scanner from Forsyth Medical Center to Kernersville.

- 1) Maintaining the Status Quo – the applicant states that this would not be an effective alternative since it would not meet the need. The applicant states acquiring “*a fixed PET/CT scanner at NHKMC will provide necessary and locally accessible diagnostic imaging support for NHKMC’s growing cancer treatment program.*”
- 2) Utilizing Mobile PET/CT Services – the western region of the state has only one mobile PET/CT scanner and does not have the additional capacity needed to offer services to Kernersville. In addition, there has been no need determination in the SMFP for additional mobile PET/CT scanners in the state over the last several years. Therefore, this is not an effective alternative.
- 3) Converting an Existing PET/CT Scanner to a Mobile PET/CT Scanner – the applicant states that its request for a Declaratory Ruling to convert its existing,

approved fixed PET/CT scanner at Forsyth Medical Center to a mobile PET/CT scanner was denied in 2011. Therefore, this is not an effective alternative.

- 4) Relocating an Existing PET/CT Scanner from Forsyth Medical Center to Kernersville – the applicant states that it considered this option, however due to the deadline of May 15, 2013 for this application, it decided to apply for a new fixed PET/CT scanner to be located at Kernersville in order to *“keep open as many options as possible to get a PET/CT scanner on the NHKMC campus within a reasonable timeframe.”*

The applicant states that acquiring a fixed PET/CT scanner for its cancer program at Kernersville is the most effective alternative to benefit service area residents. However, the application is not conforming to all other statutory and regulatory review criteria, and thus, is not approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant did not adequately demonstrate that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion.

Baptist. In Section III.3, pages 65-66, the applicant discusses two alternatives it considered prior to the submission of this application. One alternative is to maintain the status quo and the other is to locate a PET/CT scanner at another hospital in HSA II.

- 1) Maintain the Status Quo – the applicant states that it is performing above the state defined performance standard and is serving a much higher acuity level of patients due to its status as an academic medical center. Higher acuity translates into longer scan times, more patient preparation time, and more time to perform the PET/CT scans. In addition, expected population increases for those 55 and older, increases in cancer cases and newly insured persons, in addition to increases in patients needing Amyvid scans are expected to increase the number of PET/CT scans performed by Baptist by FY 2018. Therefore, maintaining the status quo is not an effective alternative.
- 2) Locate a PET/CT Scanner at Another Hospital in HSA II – the applicant states that there is at least one PET/CT scanner at each of the established cancer treatment programs in HSA II and that *“it is the PET/CT volume at NCBH that generated the need for the new PET scanner...”* The second PET/CT scanner will support ensuring access to PET diagnostics and will support the development of Baptist’s Alzheimer’s Institute. For these reasons, the applicant states that this is not an effective alternative.

The applicant states that converting an existing research only PET/CT scanner to clinical use will meet the needs of its Cancer Center expansion and the development of its Alzheimer’s Institute and allow for cost economy and greater efficiency of both of its PET/CT scanners. However, the application is not conforming to all other statutory

and regulatory review criteria, and thus, is not approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant does not adequately demonstrate that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion.

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

NC
Kernersville
Baptist

Kernersville. In Exhibit 11, the applicant provides a copy of the equipment quote for the proposed PET/CT scanner and trailer. The total capital cost for the project, listed in Section VIII, page 103, will be \$1,621,447, comprised as follows:

Fixed and Movable Equipment Purchase	\$1,480,147
Construction Contract	\$ 47,000
Miscellaneous Project Costs, including Architect/ Engineering Fees	\$ 19,300
Other: Project Contingency	<u>\$ 75,000</u>
Total	\$1,621,447

In Section VIII.3, page 104, the applicant indicates that the capital cost will be financed with the accumulated reserves of Novant Health, Inc. In Section IX, page 113, the applicant indicates there will be both start up expenses of \$20,939 and initial operating expenses of \$297,715, for a total working capital requirement of \$318,654, which will be funded with the accumulated reserves of Novant Health.

Exhibit 8 of the application contains a letter dated May 8, 2013 from the Senior Vice President Operational Finance, Novant Health, Inc. that states,

“This letter will serve to confirm that Novant Health will be funding the capital cost of \$1,621,447 for the proposed new PET/CT Scanner at NHKMC. The start-up and working capital needs are defined in CON Application Section IX. In addition, Novant also reserves the right to seek tax exempt funding for all or part of this project as discussed in Section VIII of our CON Application. I have*

considered Novant Health's current and anticipated future capital needs and in my opinion Novant will be able to fund this project.

...

**318,654"*

Exhibit 8 contains audited financial statements for the years ending December 31, 2012 and December 31, 2011 for Novant Health, Inc. As of December 31, 2012, the applicant had cash and cash equivalents of \$276,637,000 and total net assets of \$2,163,123,000. The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project. The applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below:

Kernersville PET/CT Services	Project Year 1 (1/01/2017 – 12/31/2017)	Project Year 2 (1/01/2018 – 12/31/2018)	Project Year 3 (1/01/2019 – 12/31/2019)
Projected # of Scans	1,468	1,852	2,139
Projected Average Charge (Gross Patient Revenue / Projected # of Scans)	\$6,563	\$6,760	\$6,962
Gross Patient Revenue	\$9,634,198	\$12,518,945	\$14,892,745
Deductions from Gross Patient Revenue	\$6,097,610	\$7,923,404	\$9,425,813
Net Patient Revenue	\$3,536,589	\$4,595,541	\$5,466,932
Total Expenses	\$1,339,326	\$1,438,502	\$1,524,505
Net Income	\$2,197,262	\$3,157,039	\$3,942,427

The applicant also projects a positive net income for the entire facility in each of the first three operating years of the project. However, the applicant's utilization projections are unsupported and unreliable. Consequently, operating expenses and revenues that are based on the applicant's projected utilization are also unreliable. See Criterion (3) for discussion of utilization projections which is incorporated hereby as if fully set forth herein. Therefore, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, the application is not conforming to this criterion.

Baptist. In Section VIII, page 106, the applicant provides a table showing the capital cost of the proposed project. The total capital cost for the project will be \$1,585,505.62, comprised as follows:

Fixed Equipment Purchase/Lease	\$1,565,505.62
Miscellaneous Project Costs (CON/Other Agency)	\$ 20,000.00
	<hr/>
Total	\$1,585,505.62

Note: there is a typographical error on page 106 where miscellaneous project costs shows \$50,000, but it should show \$20,000. In Section VIII.3, page 107, the applicant states that the total capital cost will be \$1,585,505.62 and indicates that \$20,000 of the capital cost will be financed with accumulated reserves and \$1,565,505.62 (the value of the equipment) will be an intercompany transfer. In its response to the written comments, Baptist confirmed that the \$50,000 on page 106 should have been \$20,000, consistent with page 107.

Exhibit 23 of the application contains a letter dated May 15, 2013 from the Associate Vice President for Financial Planning for North Carolina Baptist Hospital, documenting the availability of accumulated reserves which states,

“North Carolina Baptist Hospital agrees to make available from its accumulated reserves a total of \$20,000 for the fees incurred in the development of the aforementioned project. As Associate Vice President for Financial Planning for North Carolina Baptist Hospital, I can attest to the availability of funds for this purpose.”

In addition, the applicant provides a letter in Exhibit 23, dated May 15, 2013, from the President and COO of the Health System of Wake Forest University Baptist Medical Center, authorizing the intercompany transfer of the PET/CT equipment from Wake Forest Health Sciences to North Carolina Baptist Hospital. The letter states,

“This letter confirms the intent to complete the intercompany transfer of the ownership of PET/CT equipment from Wake Forest Health Sciences to North Carolina Baptist Hospital upon the receipt by North Carolina Baptist Hospital of CON approval for the incremental PET/CT scanner.”

Exhibit 24 contains the audited financial statements for the years ending June 30, 2011 and June 30, 2010 for Baptist which show that, as of June 30, 2011, the applicant had cash and cash equivalents of \$20,648,000 and total net assets of \$987,132,000. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project. The applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the following table:

Baptist PET/CT Services	Project Year 1 (7/01/2015 – 6/30/2016)	Project Year 2 (7/01/2016 – 6/30/2017)	Project Year 3 (7/01/2017 – 6/30/2018)
Projected # of Scans	3,993	4,085	4,182
Projected Average Charge (Gross Patient Revenue / Projected # of Scans)	\$8,040	\$8,364	\$8,698
Gross Patient Revenue	\$32,103,525	\$34,165,713	\$36,376,071
Deductions from Gross Patient Revenue	\$23,952,662	\$25,906,597	\$27,850,858
Net Patient Revenue	\$8,150,863	\$8,259,115	\$8,525,213
Total Expenses	\$5,508,015	\$5,740,246	\$5,987,778
Net Income	\$2,642,848	\$2,518,869	\$2,537,435

The applicant also projects a positive net income for the entire facility in each of the first three operating years of the project. In Section XII, page 123, the applicant indicates in its proposed schedule for developing the project that the project will become operational on 7/01/2017. The applicant states that this is a typographical error. However, the applicant's utilization projections are unsupported and unreliable. Consequently, operating expenses and revenues that are based on the applicant's projected utilization are also not reliable. See Criterion (3) for discussion of utilization projections which is incorporated hereby as if fully set forth herein. Therefore, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, the application is not 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.

NC
Kernersville
Baptist

Kernersville does not adequately demonstrate that the proposed project would not result in unnecessary duplication of existing or approved PET services in HSA II based on the following analysis:

- 1) The State Health Coordinating Council and Governor determined a need for one additional fixed dedicated PET scanner in HSA II. See Table 9N of the 2013 SMFP. Kernersville submitted its application in response to the need determination in the 2013 SMFP.
- 2) However, Kernersville did not adequately demonstrate in its application that the fixed dedicated PET scanner it proposes to develop in Forsyth County in HSA II is needed in addition to the existing and approved fixed dedicated PET scanners in HSA II. In particular, the applicant has been authorized since 2008 to acquire a second PET scanner which still has not been acquired five years later. The

proposed PET scanner would be the hospital's third PET scanner. Moreover, PET scanner volume at Forsyth Medical Center has declined 11.4% per year (compounded) since FFY 2009.

Consequently, the application is not conforming to this criterion.

Baptist does not adequately demonstrate that the proposed project would not result in unnecessary duplication of existing or approved PET services in HSA II based on the following analysis:

- 1) The State Health Coordinating Council and Governor determined a need for one additional fixed dedicated PET scanner in HSA II. See Table 9N of the 2013 SMFP. Kernersville submitted its application in response to the need determination in the 2013 SMFP.
- 2) However, Baptist did not adequately demonstrate in its application that the fixed dedicated PET scanner it proposes to develop in Forsyth County in HSA II is needed in addition to the existing fixed dedicated PET scanners in HSA II. In particular, Baptist does not meet the 2,080 scans per PET scanner required by 10A NCAC 14C .3703(a)(1) and does not adequately demonstrate that projected utilization is based on reasonable, credible and supported assumptions.

Consequently, the application is not 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
Kernersville
Baptist

Kernersville. In Section VII.1(b), page 93, the applicant provides projected staffing for the proposed PET/CT services for the second full fiscal year following completion of the project, illustrated in the following table:

**Kernersville PET Imaging Services
Project Year 2 (1/01/2018 – 12/31/2018)**

Position	Total # of FTE Positions to be Employed
Diagnostic Operations Assistant	1.0
Nuclear Medicine/PET Technologist	3.0
Supervisor, Radiology	0.5
Manager, Radiology	0.2
Director, Radiology	0.1
Radiation Safety Officer	0.2
Total	5.0

As shown in the above table, Kernersville proposes to add Nuclear Medicine/PET Technologist positions and a Diagnostic Operations Assistant position at Kernersville, however these positions already exist within Novant Health facilities. In Section VII.3(b), page 93, the applicant states that ancillary and support services, including, but not limited to, pharmacy, laboratory, administration, and central supply will be provided by the employees of Kernersville and Novant Health. Housekeeping, Laundry, and Dietary/Nutrition Services are provided by contractors utilized corporate-wide in Novant Health facilities. Novant Health will recruit 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 64, the applicant states that Dr. Listen Orr will continue as Medical Director of Nuclear Medicine at Kernersville. Dr. Orr also provides medical direction for the Nuclear Imaging and PET/CT program at Forsyth Medical Center. Exhibit 5 contains a letter signed by the Medical Director and includes a copy of his resume. In addition, the applicant states that additional board-certified radiologists in Triad Radiology Associates, including nuclear medicine/PET radiologists, are credentialed to provide coverage and interpretation of images for the Kernersville imaging program. 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.

Baptist. In Section VII.1(b), page 99, the applicant provides projected staffing for the proposed PET/CT services for the second full fiscal year following completion of the project. For FFY 2017, July 1, 2016 – June 30, 2017, the applicant proposes to add one full-time PET/CT technician to the three existing full-time PET/CT technicians to staff the proposed PET/CT services. In addition, in Section V.3(c), page 85, the applicant states that the proposed project involves existing services and that *“The Department of Radiology is staffed with a specialized and highly skilled group of Physicians, Fellows, Residents, Radiologic Technologists, and Nurses.”* In Section V.3(c), page 85, the applicant states that the Department of Radiology Chair is Dr. King Li and that none of the medical directors or department chairs will change as a result of the proposed project since the project involves existing services. Dr. Li’s curriculum vitae is provided in Exhibit 2.

In addition, the applicant states, in Section II, page 33, that Dr. Anita Thomas is the Medical Director for Nuclear Medicine. Her curriculum vitae is provided in Exhibit 2. The Chief Medical Officer of Baptist is Dr. Thomas Sibert, MD, MBA. His curriculum vitae is provided in Exhibit 22. If Baptist deems it necessary to recruit externally, it will do so through Forsyth Technical Community College's Nuclear Medicine program with which it already has an established relationship. Secondly, Baptist will utilize a professional recruiting firm. 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

Kernersville

Baptist

Kernersville. In Section II.2, page 11, the applicant states that as part of the Kernersville campus and part of its diagnostic imaging services, the Kernersville PET/CT scanner will have access to the same clinical and non-clinical support services that the other diagnostic imaging modalities and nuclear medicine have. Exhibit 4 contains a letter from the President of Kernersville confirming the availability of many support and ancillary services for the proposed PET/CT scanner services. The applicant discusses how the proposed service 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 12 contains a list of Novant Health's patient transfer agreements and Exhibit 4 contains support letters from primary care physicians, specialty physicians, and surgeons who practice in Kernersville and surrounding counties. The applicant adequately demonstrates the availability of the necessary ancillary and support services for the proposed service and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

Baptist. In Section II.2(a), page 18, the applicant states that while the services provided in the Radiology Department are not dependent on other ancillary services of the hospital, some patients may utilize other services during their stay such as surgical services, pharmacy, labs, and others. The applicant states, on page 18, that "*The Radiology Department is supported by the Engineering, Housekeeping, Medical Records, Infection Control, and all other general administrative and support areas of NCBH as needed.*" In addition, the applicant states that ancillary, administrative, and support services will continue to be provided for the Radiology Department.

The applicant discusses how Baptist and its PET/CT services are coordinated with the existing healthcare system in Section V, pages 84-85. Baptist routinely accepts referrals from hospitals throughout the state and has many transfer agreements in place with other hospitals. Exhibit 18 contains a list of providers with whom Baptist has transfer agreements in place. In addition, Baptist has developed strong referral relationships with the medical community over its 90-year history as an acute care facility, including with physicians. Letters of support for the project are provided in Exhibit 19. Moreover, the applicant states that Baptist has relationships with other healthcare providers in the local community as well as the broader service area. Services are coordinated with many community and social agencies. The applicant adequately demonstrates the availability of the necessary ancillary and support services for the proposed service 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 – Both Applicants

- (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

NA – Both Applicants

- (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 – Both Applicants

- (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 – Both Applicants

Kernersville. An existing exterior mobile pad on the campus of Kernersville will be renovated to be used as the site of the new PET/CT scanner. The applicant states that it will use modern energy controls and energy-effective materials when developing the project. Further, as stated in Section XI.7, page 120, it “*will be designed in compliance with all applicable local, state, and federal requirements for energy efficiency and consumption.*”

Baptist. The applicant proposes to convert a research only PET/CT scanner to clinical use which will enable it to utilize existing space, administration, and staff resources. Baptist adequately demonstrates that no construction or renovation is necessary given that the research only PET scanner is already installed in the MRI center which is where the majority of Baptist’s clinical MRI scanners are located.

- (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
Kernersville
Baptist

Kernersville. PET services are not currently available at Kernersville but they are available at Forsyth Medical Center. In Section VI.13, page 89, the applicant

provides the following payer mix for PET procedures provided by Forsyth Medical Center during CY 2012.

**Forsyth Medical Center PET Service Payer Mix
CY 2012**

Payers 1/01/2012 – 12/31/2012	Percent of Total PET procedures
Self Pay/Indigent/Charity	2.99%
Medicare / Medicare Managed Care	59.97%
Medicaid	5.25%
Commercial Insurance	0.58%
Managed Care	29.81%
Other	1.40%
Total	100.00%

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. The following table illustrates those percentages for Forsyth County, the county projected to have the highest patient utilization for PET services at Kernersville, and statewide.

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Forsyth	16%	5.7%	19.5%
Statewide	17%	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 population does not utilize the proposed PET services at the same rate as the older population likely to utilize the proposed PET services.

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 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 applicant's current payer 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 have adequate access to Forsyth Medical Center's existing PET services and the application is conforming to this criterion.

Baptist. In Section VI.15, pages 94-95, the applicant provides the payer mix for PET procedures provided by Baptist in its last full fiscal year, July 1, 2012 to June 30, 2013, and states that *"the payor mix is assumed to remain unchanged following completion of the project..."* Therefore, the following payer mix is representative of the second full fiscal year of the project:

Payers Project Year 2: 7/01/2015 – 6/30/2016	Percent of Total PET Procedures
Self Pay/Indigent/Charity	2.8%
Medicare / Medicare Managed Care	57.9%
Medicaid	12.9%
Commercial Insurance	1.3%
Managed Care	23.3%
Other	1.7%
Total*	100.0%

*Total is rounded to nearest whole number by Project Analyst.

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. The following table illustrates those percentages for Forsyth County, the county projected to have the highest patient utilization for PET services at Baptist, and statewide.

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Forsyth	16%	5.7%	19.5%
Statewide	17%	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 population does not utilize the proposed PET services at the same rate as the older population likely to utilize the proposed PET services.

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 31.6% for those aged 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 applicant's current payer 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 have adequate access to Baptist's existing PET services and 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
Kernersville
Baptist

Kernersville. In Section VI.11, page 87, the applicant states,

“Novant Health’s tertiary hospitals (Novant Health Forsyth Medical Center and Novant Health Presbyterian Medical Center) fulfilled their Hill-Burton obligations long ago. ... NHFMC, NHKMC [sic] all Novant facilities in North Carolina continue to comply with the community service obligation and there is no denial, restriction, or limitation of access to minorities or handicapped persons.”

In Section VI.10, page 87, the applicant states that there have been no civil rights equal access complaints filed against Novant Health, Kernersville, or other Novant Health Acute Care hospitals during the past five years. The application is conforming to this criterion.

Baptist. In Section VI.10 and 11, pages 92-93, the applicant states that it has not had any obligations to provide uncompensated care in the last few years and that it provides considerable bad debt and charity care to residents in the service area needing its services. In addition, the applicant states that it has had no civil rights access complaints filed against it in 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
Kernersville
Baptist

Kernersville. In Section VI.15, page 90, the applicant provides the following payer mix for the proposed PET/CT scanner at Kernersville for the second full fiscal year of operation following completion of the project:

Payers Project Year 2: 1/01/2018 – 12/31/2018	Percent of Total PET Procedures
Self Pay/Indigent/Charity	3.69%
Medicare / Medicare Managed Care	61.41%
Medicaid	4.19%
Commercial Insurance	1.01%
Managed Care	28.86%
Other	0.84%
Total	100%

In Section VI.15, page 91, the applicant states that its projected payer mix for the proposed PET/CT services at Kernersville is based on payer information for Forsyth Medical Center’s PET/CT services for CY 2012 who are residents of the same service area as Kernersville.

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

Baptist. In Section VI.15, pages 94-95, the applicant provides the following payer mix for the proposed PET/CT scanner at Baptist representing the second full fiscal year of operation following completion of the project:

Payers Project Year 2: 7/01/2015 – 6/30/2016	Percent of Total PET Procedures
Self Pay/Indigent/Charity	2.8%
Medicare / Medicare Managed Care	57.9%
Medicaid	12.9%
Commercial Insurance	1.3%
Managed Care	23.3%
Other	1.7%
Total*	100%

*Total is rounded to nearest whole number by Project Analyst.

In Section VI.15, pages 94-95, the applicant indicates that it used its payer mix from its last full fiscal year to represent its projected payer mix for the second year following completion of the project, and assumed it would remain unchanged.

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
Kernersville
Baptist

Kernersville. In Section VI.9, page 85, the applicant states that patients will have access to the proposed PET/CT services through physician referral and written order from staff at either Kernersville or Forsyth Medical Center. A patient’s primary care physician or specialist will refer the patient for PET/CT services in consultation with a member of Forsyth Medical Center or Kernersville’s medical

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

Baptist. In Section VI.9, page 92, the applicant states that it accepts referrals from a wide variety of health care providers and does not expect existing referral patterns to change. In addition, the applicant states that most patients needing treatment are referred by their physicians, either by in-house medical staff or by additional physicians within the service area. The information provided in Section VI.9 is reasonable and credible 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
Kernersville
Baptist

Kernersville. In Section V.1(a-c), pages 60-61, the applicant discusses the health professional training opportunities available at Kernersville. It has clinical education agreements with the following schools, in addition to others: Forsyth Technical Community College, Guilford Technical Community College, UNC-Greensboro, ECPI University, Winston-Salem State University, UNC-Chapel Hill, and Eastern Carolina University. The applicant states, “*The clinical educational agreements that involve NHKMC as a training site for health professions students will include the proposed PET/CT scanner as soon as it becomes operational.*” The information provided is reasonable and credible and supports a finding of conformity with this criterion.

Baptist. In Section V.1(a), page 83, the applicant states that it has many established relationships with many clinical training programs in the Southeast and will continue to provide training for numerous clinical programs. The applicant will continue its relationship with Forsyth Technical Community College to provide clinical experiences for students enrolled in the college’s Nuclear Medicine Technology program. Exhibit 17 contains a list of educational institutions and programs that utilize Baptist’s facilities for clinical training. The information provided is reasonable and credible and supports a finding of conformity with 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.

NC
Kernersville
Baptist

Kernersville. The applicant proposes to acquire a fixed dedicated PET/CT scanner for use at Kernersville. There are six existing and approved PET scanners in HSA II according to the 2013 SMFP. The following table illustrates the number, location, and utilization rate for each of the operational scanners as depicted in Table 9L of the 2013 SMFP:

PET Scanners in HSA II

Center	# of PET scanners	Utilization Rate
		2011 Procedures/ 3000 as Capacity
N.C. Baptist Hospital	1	85.70%
Cone Health	1	60.97%
Forsyth Medical Center	2	47.92%
High Point Regional Health System	1	26.47%
Alamance Regional Medical Center	1	23.37%

In Sections II.5, pages 12-13, V.7, pages 70-72, VI.2, page 75, and X.1, page 114, the applicant discusses how the proposed project will enhance competition in the service area including how it will have a positive impact on the cost-effectiveness, quality and access to the proposed PET services. In response to a report sponsored by the American Hospital Association’s Health Research Education Trust, in which Novant Health received recognition as a top performing hospital, the applicant states in Section III, page 47, “Novant’s goal was and continues to be to develop services that are:

- *Safer and higher quality*
- *More patient-focused*
- *More integrated*
- *More affordable”*

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 applicant adequately demonstrates that its proposal would enhance competition by promoting quality and access to PET

services. However, the applicant does not adequately demonstrate that its proposal would enhance competition by promoting cost effectiveness for the following reason:

The information provided by the applicant, particularly in Section III, is not reasonable and credible and does not adequately demonstrate that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness. This determination is based on the information in the application and the following analysis:

- ◆ Projected utilization of the fixed dedicated PET scanner is not based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein.
- The applicant has been authorized since November 13, 2008 to acquire a second PET scanner. As of the date of this decision, the applicant has not done so. On October 3, 2013, the applicant was notified of an intent to withdraw the certificate of need for the second PET scanner. This application proposes a third PET scanner. The applicant does not adequately demonstrate the need for a third PET scanner given it has not acquired the second PET scanner authorized in 2008 (5 years). Thus, the applicant does not adequately demonstrate that the acquisition of a third unneeded PET scanner would have a positive impact on the cost-effectiveness of PET services provided by Novant Health in Forsyth County.

Therefore, the application is not conforming to this criterion.

Baptist. In Section II.5, pages 19-22, the applicant discusses how the proposed project will enhance competition in the service area, including how it will have a positive impact on the cost-effectiveness, quality and access to the proposed PET services. Baptist discusses how utilizing the proposed PET/CT scanner will benefit patients who may have Alzheimer's Disease or dementia. Baptist plans to expand the use of Amyvid PET imaging to clinically evaluate these diseases. In addition, in Section II.1, page 15, the applicant states that converting the research only PET/CT scanner to clinical use rather than purchasing a new PET/CT scanner, will allow for "*maximum flexibility, economy, and utilization.*" In Section II.7, page 24-25, the applicant describes how it will continue to monitor quality and work to improve patient care and clinical performance, stating that PET services are "*continuously and rigorously monitored for quality, meeting or exceeding standards promulgated by the American College of Radiology accreditation programs.*" Moreover, in Sections V.7, page 87, and VI., pages 88-90, the applicant discusses how medically underserved populations will continue to have access to services.

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 applicant adequately demonstrates that its proposal would enhance competition by promoting quality and access to PET services. However, the applicant does not adequately demonstrate that its proposal would enhance competition by promoting cost effectiveness for the following reason:

The information provided by the applicant, particularly in Section III, is not reasonable and credible and does not adequately demonstrate that the expected effects of the proposal

on competition in the service area include a positive impact on cost-effectiveness. This determination is based on the information in the application and the following analysis:

- ◆ Projected utilization of the fixed dedicated PET scanner does not meet the performance standard of 2,080 scans per PET scanner required by 10A NCAC 14C .3703(a)(1) and is not based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein.

Therefore, the application is not 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
Kernersville
Baptist

Kernersville. Forsyth Medical Center (including the Kernersville campus) is accredited by The Joint Commission and certified for Medicare and Medicaid participation. Forsyth Medical Center's PET/CT Program is accredited by the American College of Radiology in Brain and Oncologic PET imaging. Kernersville will be affiliated with the Forsyth Medical Center PET/CT Program. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

Baptist. Baptist is accredited by The Joint Commission and is certified as a Medicare and Medicaid provider. The facilities, services and programs of its Department of Radiology meet all OSHA, The Joint Commission, and all applicable North Carolina laws and codes. In addition, the applicant states that its radiologic technologists receive their advanced registry from the American Registry of Radiologic Technology within one year of employment. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. 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.

NC
Kernersville
Baptist

Kernersville. Kernersville proposes to acquire a new fixed dedicated PET/CT scanner pursuant to a need determination in the 2013 SMFP for one fixed dedicated PET scanner in HSA II. Therefore, the Criteria and Standards for Positron Emission Tomography Scanner in 10A NCAC 14C .3700 are applicable to this review. The application is not conforming to all applicable Criteria and Standards for Positron Emission Tomography.

Baptist. Baptist proposes to convert one existing research only PET/CT scanner for clinical use pursuant to a need determination in the 2013 SMFP for one fixed dedicated PET scanner in HSA II. Therefore, the Criteria and Standards for Positron Emission Tomography Scanner in 10A NCAC 14C .3700 are applicable to this review. The application is not conforming to all applicable Criteria and Standards for Positron Emission Tomography.

The specific criteria for both applications are discussed below.

**CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY
SCANNER**

.3702 INFORMATION REQUIRED OF APPLICANT

.3702(a) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall use the Acute Care Facility/Medical Equipment application form.”*

-C- **Both applications** were submitted on the Acute Care Facility/Medical Equipment application form.

.3702(b)(1) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: (1) The projected number of procedures to be performed and the projected number of patients to be served for each of the first three years following completion of the proposed project. Projections shall be listed by*

clinical area (e.g., oncology, cardiology), and all methodologies and assumptions used in making the projections shall be provided.”

-NC- **Kernersville.** In Section II, page 19, the applicant provides the projected number of procedures and patients to be served, by clinical area, for each of the first three years following completion of the proposed project for Forsyth Medical Center and Kernersville combined. It does not provide the projected number of procedures and patients by clinical area for Kernersville only. Therefore, the application is nonconforming with this Rule.

-C- **Baptist.** In Section II, page 27, the applicant provides the projected number of PET procedures to be performed and the projected number of patients to be served, by clinical area, for each of the first three years following completion of the proposed project. Assumptions and methodology are provided in Section III.1.

.3702(b)(2) This rule states “*An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: ... (2) Documentation of arrangements made between the applicant and other providers to assure patients of the facility will have access to all of the following services:*

- (A) *nuclear medicine imaging services;*
- (B) *single photon emission computed tomography (including brain, bone, liver, gallium and thallium stress);*
- (C) *magnetic resonance imaging scans;*
- (D) *computerized tomography scans;*
- (E) *cardiac angiography;*
- (F) *cardiac ultrasound;*
- (G) *neuroangiography;*
- (H) *radiation oncology;*
- (I) *medical oncology; and*
- (J) *surgical oncology.*

-C- **Kernersville** provides a letter signed by the Kernersville President in Exhibit 5 that states that all of the above listed services are either provided at Kernersville, Forsyth Medical Center, or both facilities.

-C- **Baptist** provides a letter in Exhibit 8 signed by the Administrative Director of Baptist’s Department of Radiology attesting to the availability of these services for the proposed project.

.3702(b)(3)(A) This rule states “*An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information*

for each facility where the PET scanner will be operated: ... (3) Documentation that the facility will: (A) establish the clinical PET unit, and any accompanying equipment used in the manufacture of positron-emitting radioisotopes, as a regional resource that will have no administrative, clinical or charge requirements that would impede physician referrals of patients for whom PET testing would be appropriate.”

-C- **Kernersville** provides a letter signed by the Kernersville Radiology Manager in Exhibit 5 that states, “...NHKMC will establish the proposed clinical PET/CT unit as a regional resource that will have no administrative, clinical or charge requirements that would impede physician referrals of patients for whom PET testing would be appropriate. Policies and procedures are already in place at the FMC Nuclear Medicine program that addresses this. Please note that NHKMC operates under the existing acute care hospital license of NHFMC...”

-C- **Baptist** states, in Section II, page 28, that the PET service will operate as a regional resource as part of an academic medical center teaching hospital. In addition, it states, “there are no known administrative, clinical or charge requirements planned that would impede physician referrals of patients for whom PET testing would be appropriate.”

.3702(b)(3)(B) This rule states “(a) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, ...(3) Documentation that the facility will: ... (B) provide scheduled hours of operation for the PET scanner of a minimum of 60 hours per week, except for mobile scanners.”

-C- **Kernersville** states, in Section II, on page 20 that the proposed PET/CT scanner will be staffed Monday through Friday from 7:00 a.m. to 7:00 p.m. On-call emergency services are provided for all radiology patients after hours.

-C- **Baptist** states, in Section II, page 28, that it expects the PET/CT scanner to be operating 7:00 a.m. to 7:00 p.m. on weekdays once the “volumes ramp up in FY 14.” In addition, the applicant states that the use of the PET scanner will likely exceed 60 hours per week.

.3702(c) This rule states “An applicant proposing to acquire a mobile PET scanner shall provide copies of letters of intent from and proposed contracts with all of the proposed host facilities at which the mobile PET scanner will be operated.”

-NA- Neither **Kernersville** nor **Baptist** propose to acquire a mobile PET scanner.

.3702(d) This rule states *“An applicant proposing to acquire a mobile PET scanner shall demonstrate that each host facility offers or contracts with a hospital that offers comprehensive cancer services including radiation oncology, medical oncology, and surgical oncology.”*

-NA- Neither **Kernersville** nor **Baptist** propose to acquire a mobile PET scanner.

.3702(e) This rule states *“An applicant shall document that all equipment, supplies and pharmaceuticals proposed for the service have been certified for use by the U.S. Food and Drug Administration or will be used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services’ regulations.”*

-C- **Kernersville** provides a letter in Exhibit 5 from the Radiation Safety Officer at Forsyth Medical Center stating that *“all equipment, supplies, and pharmaceuticals proposed for the service have been certified for use by the U.S. Food and Drug Administration or will be used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services’ regulations.”*

-C- **Baptist** provides documentation in Exhibit 9 verifying that the PET/CT scanner equipment, supplies, and pharmaceuticals proposed to be used for the service have been certified for use by the U.S. Food and Drug Administration.

.3702(f)(1) This rule states *“An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturer’s specifications, and licensing requirements. The following shall be addressed:*

- (1) quality control measures and assurance of radioisotope production of generator or cyclotron-produced agents”*
- (2) quality control measures and assurance of PET tomography and associated instrumentation;*
- (3) radiation protection and shielding;*
- (4) radioactive emission to the environment; and*
- (5) radioactive waste disposal.*

-C- **Kernersville** provides letters in Exhibit 5, from the Novant Health Senior Director, Design and Construction and from the Forsyth Medical Center Radiation Safety Officer, documenting that the proposed PET/CT scanner for Kernersville will be operated in a physical environment that conforms to federal standards, manufacturer’s specifications, and licensing requirements which address all of the components listed under this rule.

-C- **Baptist** provides a letter from its Radiation Safety Officer in Exhibit 10 stating that all of the components listed under this rule are part of its radiation safety program.

.3702(f)(2) This rule states “*An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturer’s specifications, and licensing requirements. The following shall be addressed: ... (2) quality control measures and assurance of PET tomography and associated instrumentation.*”

-C- **Kernersville** provides letters in Exhibit 5, from the Novant Health Senior Director, Design and Construction and from the Forsyth Medical Center Radiation Safety Officer, documenting that the proposed PET/CT scanner for Kernersville will be operated in a physical environment that conforms to federal standards, manufacturer’s specifications, and licensing requirements which address all of the components listed under this rule.

-C- **Baptist** provides a letter from its Radiation Safety Officer in Exhibit 10 stating that all of the components listed under this rule are part of its radiation safety program.

.3702(f)(3) This rule states “*An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (3) radiation protection and shielding.*”

-C- **Kernersville** provides letters in Exhibit 5, from the Novant Health Senior Director, Design and Construction and from the Forsyth Medical Center’s Radiation Safety Officer, documenting that the proposed PET/CT scanner for Kernersville will be operated in a physical environment that conforms to federal standards, manufacturer’s specifications, and licensing requirements which address all of the components listed under this rule.

-C- **Baptist** provides a letter from its Radiation Safety Officer in Exhibit 10 stating that all of the components listed under this rule are part of its radiation safety program.

.3702(f)(4) This rule states “*An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (4) radioactive emission to the environment.*”

-C- **Kernersville** provides letters in Exhibit 5, from the Novant Health Senior Director, Design and Construction and from the Forsyth Medical Center Radiation Safety Officer, documenting that the proposed PET/CT scanner for Kernersville will be operated in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing requirements which address all of the components listed under this rule.

-C- **Baptist** provides a letter from its Radiation Safety Officer in Exhibit 10 stating that all of the components listed under this rule are part of its radiation safety program.

.3702(f)(5) This rule states *"An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (5) radioactive waste disposal."*

-C- **Kernersville** provides letters in Exhibit 5, from the Novant Health Senior Director, Design and Construction and from the Forsyth Medical Center Radiation Safety Officer, documenting that the proposed PET/CT scanner for Kernersville will be operated in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing requirements which address all of the components listed under this rule.

-C- **Baptist** provides a letter from its Radiation Safety Officer, in Exhibit 10, stating that all of the components listed under this rule are part of its radiation safety program.

.3703 PERFORMANCE STANDARDS

.3703(a)(1) This rule states *"An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that: (1) the proposed dedicated PET scanner, including mobile dedicated PET scanners, shall be utilized at an annual rate of at least 2,080 PET procedures by the end of the third year following completion of the project."*

-NC- **Kernersville** did not adequately demonstrate that the proposed PET/CT scanner would be utilized at an annual rate of at least 2,080 procedures by the end of the third year following completion of the project. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. The application is non-conforming with this Rule.

-NC- **Baptist** did not adequately demonstrate that the proposed PET/CT scanner would be utilized at an annual rate of at least 2,080 procedures by

the end of the third year following completion of the project. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. The application is nonconforming with this Rule.

- .3703(a)(2) This rule states *“An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that:...(2) if an applicant operates an existing dedicated PET scanner, its existing dedicated PET scanners, excluding those used exclusively for research, performed an average of 2,080 PET procedures per PET scanner in the last year.”*

-C- **Kernersville** states, in Section II, page 22, that during CY 2012 Forsyth Medical Center’s one existing PET/CT scanner performed 2,573 PET procedures. Therefore, the application is conforming to this Rule.

-C- **Baptist** states, in Section II, page 31, that in fiscal year 2012, July 1, 2011 – June 30, 2012, it provided 2,393 PET procedures on its one existing PET scanner. Therefore, the application is conforming to this Rule.

- .3703(a)(3) This rule states *“An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that: ... (3) its existing and approved dedicated PET scanners shall perform an average of at least 2,080 PET procedures per PET scanner during the third year following completion of the project.”*

-NC- **Kernersville** did not adequately demonstrate that its existing and approved dedicated PET scanners would perform an average of at least 2,080 PET procedures per PET scanner during the third year following completion of the project. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the application is nonconforming with this Rule.

-NC- **Baptist** did not adequately demonstrate that its existing dedicated PET scanner would perform an average of at least 2,080 PET procedures per PET scanner during the third year following completion of the project. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the application is nonconforming with this Rule.

- .3703(b) This rule states *“The applicant shall describe the assumptions and provide data to support and document the assumptions and methodology used for each projection required in this Rule.”*

-NC- **Kernersville** did not provide adequate data to support the assumptions and methodology used for each projection required in this rule. Therefore, the application is not conforming to this Rule.

-NC- **Baptist** did not provide adequate data to support the assumptions and methodology used for each projection required in this Rule. Therefore, the application is not conforming to this Rule.

.3704 SUPPORT SERVICES

.3704(a) This rule states “*An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that radioisotopes shall be acquired from one or more of the following sources and shall identify the sources which will be utilized by the applicant: (1) an off-site medical cyclotron and radioisotope production facility that is located within two hours transport time to each facility where the PET scanner will be operated; (2) an on-site rubidium-82 generator; or (3) an on-site medical cyclotron for radio nuclide production and a chemistry unit for labeling radioisotopes.*”

-C- **Kernersville** provides a letter signed by the Forsyth Medical Center Radiation Safety Officer, in Exhibit 5, stating that the radioisotopes are and will continue to be acquired under contract from a facility located within two hours transport time to both Forsyth Medical Center and Kernersville.

-C- **Baptist** states, in Section II, page 32, that it obtains clinical doses of FDG through a contractual arrangement with a facility located within two hours transport time to Baptist.

.3704(b) This rule states “*An applicant proposing to acquire an on-site cyclotron for radioisotope production shall document that these agents are not available or cannot be obtained in an economically cost effective manner from an off-site cyclotron located within 2 hours total transport time from the applicant's facility.*”

-NA- **Kernersville** does not propose to acquire a cyclotron.

-NA- **Baptist** does not propose to acquire a cyclotron.

.3704(c) This rule states “*An applicant proposing to develop new PET scanner services, including mobile PET scanner services, shall establish a clinical oversight committee at each facility where the PET scanner will be operated before the proposed PET scanner is placed in service that shall: (1) develop screening criteria for appropriate PET scanner utilization; (2) review clinical protocols; (3) review appropriateness and quality of clinical procedures; (4) develop educational programs; and*

(5) oversee the data collection and evaluation activities of the PET scanning service.”

-C- **Kernersville** provides documentation in Exhibit 5 from Forsyth Medical Center’s Radiation Safety Officer that Forsyth Medical Center has in place and will ensure that Kernersville has in place a clinical oversight committee that will address the items listed in the above Rule.

-C- **Baptist** states, in Section II, pages 32-33, that it has a Clinical Oversight Committee which will ensure that each of the provisions of this rule will be addressed for the proposed PET scanner.

.3705 STAFFING AND STAFF TRAINING

.3705(a)(1) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: (1) One or more full-time nuclear medicine imaging physicians who:*

- (A) are licensed by the State to handle medical radioisotopes;*
- (B) have specialized in the acquisition and interpretation of nuclear images, including tomographic studies, for at least one year;*
- (C) have acquired knowledge about PET through experience or postdoctoral education; and*
- (D) have had practical training with an operational PET scanner.”*

-C- **Kernersville** states in Section VII, page 93, that Dr. Listen Orr will be the Medical Director of the PET Imaging program at Kernersville. Exhibit 5 contains Dr. Orr’s resume and a signed letter stating that professional coverage will be provided by trained and certified radiologists from Triad Radiology Associates who meet the requirements of this Rule.

-C- **Baptist** states in Section II, page 33, that Dr. Anita Thomas is the Medical Director for Nuclear Medicine and that she meets all of the qualifications set forth in this rule as indicated in her curriculum vitae provided in Exhibit 2.

.3705(a)(2) This rule states *“An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: ... (2) Engineering and physics personnel with training and experience in the operation and maintenance of PET scanning equipment.”*

-C- **Kernersville** provides letters in Exhibits 5 and 11 signed by the Novant Health Vice President of Corporate Clinical Engineering which state that engineering and physics personnel will be available at all times to provide for the maintenance needs of the proposed PET/CT scanner.

-C- **Baptist** states in Section II, page 33, that it provides internal engineering support with specified training to provide maintenance of the PET/CT equipment. In addition, staff from Radiology Repair, including one on-site engineer and two others with on the job training, provide maintenance and repair of the PET/CT scanners. One physicist is also employed “*who will be available to provide consultations and maintenance as needed for each PET/CT.*”

.3705(a)(3) This rule states “*An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: ... (3) Radiation safety personnel with training and experience in the handling of short-lived positron emitting nuclides.*”

-C- **Kernersville** states in a letter provided in Exhibit 5 that Forsyth Medical Center’s Radiation Safety Officer will expand her duties to cover the proposed PET/CT scanner at Kernersville and that it “*will be staffed with radiation safety personnel with training and experience in the handling of sort-lived [sic] positron emitting nuclides.*” Staff at Forsyth Medical Center who currently support the Forsyth Medical Center PET/CT scanner will also be available to support the proposed PET/CT scanner at Kernersville.

-C- **Baptist** states, in Section II, page 33, that all of the staff will have training that includes “*handling of short-lived positron emitting nuclides*” and that all staff will be required to have continuing education in the safe handling of radioactive materials. In addition, the applicant includes a letter from its Radiation Safety Officer in Exhibit 10 which indicates the applicant has a Radiation Safety Officer on staff.

.3705(a)(4) This rule states “*An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: ... (4) Nuclear medicine technologists certified in this field by the Nuclear Medicine Technology Certification Board or the American Registry of Radiologic Technologists with training and experience in positron emission computed tomographic nuclear medicine imaging procedures.*”

-C- **Kernersville** includes a letter in Exhibit 5 from the Kernersville Radiology Manager confirming that qualified and experienced Nuclear Medicine Technologists who are certified by the Nuclear Medicine

Technology Certification Board or the American Registry of Radiologic Technologists will be available to staff the proposed PET/CT scanner.

-C- **Baptist** states, on page 34, that it's nuclear technicians "*will be certified or registry eligible with the American Registry Radiologic Technology (ARRT) which is the equivalent training of a nuclear medicine technologist.*" In Exhibit 12, the applicant provides a job description for Nuclear Medicine Technologist – PET which indicates that candidates must be certified or certificate eligible with the Nuclear Medicine Technology Certification Board or be registered or registry eligible with the American Registry of Radiologic Technologists.

.3705(b) This rule states "*An applicant proposing to acquire a cyclotron shall document that the cyclotron shall be staffed by radiochemists or radiopharmacists who: (1) have at least one year of training and experience in the synthesis of short-lived positron emitting radioisotopes; and (2) have at least one year of training and experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical synthesis.*"

-NA- **Kernersville** does not propose to acquire a cyclotron.

-NA- **Baptist** does not propose to acquire a cyclotron.

.3705(c) This rule states "*An applicant proposing to acquire a PET scanner, a mobile PET scanner, or a cyclotron, shall document that the personnel described in Paragraphs (a) and (b) of this Rule shall be available at all times that the scanner or cyclotron are operating.*"

-C- **Kernersville** provides letters in Exhibit 5 from the Kernersville Radiology Manager which state that the staff described in Paragraph (a) of this Rule will be "*available at all times that the scanner will be operating.*"

-C- **Baptist** states, on page 34, that all personnel described in paragraph (a) of this rule will be available at all times that the scanner is operating.

.3705(d) This rule states "*An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that a program of continuing staff education will be provided that will insure training of new personnel and the maintenance of staff competence as clinical PET applications, techniques and technology continue to develop and evolve.*"

-C- **Kernersville** provides a letter in Exhibit 5 from the Kernersville Radiology Manager documenting that a program of continuing staff

education is in place at Kernersville to support the PET/CT program and that the program will continue to be provided to maintain staff competence in clinical PET applications as they evolve. Copies of Forsyth Medical Center's Nuclear Medicine Department Training and Competency policies are included in Exhibit 5.

-C- **Baptist** states, on page 34, that "*all staff are subject to continuing staff education requirements.*" In addition, the applicant states that the PET department has established competencies pursuant to The Joint Commission's requirements that are reviewed within 30 days of employment, at 90 days, and then annually.

COMPARATIVE ANALYSIS

Pursuant to N.C. G. S. 131E-183(a)(1) no more than one new fixed dedicated PET scanner may be approved in this review for HSA II. Because the two applications collectively propose two new fixed dedicated PET scanners, both applications cannot be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the analyst also conducted a comparative analysis of the proposals to decide which proposal should be approved. However, for the reasons set forth below and in the rest of the findings, the application submitted by Kernersville and the application submitted by Baptist are denied.

Geographic Distribution

The following table shows the locations of the existing fixed PET scanners in HSA II, which includes Alamance, Caswell, Davidson, Davie, Forsyth, Guilford, Randolph, Rockingham, Stokes, Surry, and Yadkin counties.

COUNTY	FACILITIES	EXISTING PET SCANNERS	APPROVED PET SCANNERS	TOTAL # OF PET SCANNERS
Alamance	Alamance Regional Medical	1	0	1
Forsyth	Forsyth Memorial Hospital	1	1	2
	North Carolina Baptist	<u>1</u>	<u>0</u>	<u>1</u>
	Subtotal	2	1	3
Guilford	Cone Health	1	0	1
	High Point Regional Health	<u>1</u>	<u>0</u>	<u>1</u>
	Subtotal	2	0	2
TOTAL		5	1	6

As shown in the above table, there are six existing or approved fixed PET scanners in HSA II, including one fixed PET scanner in Alamance County, two fixed PET scanners and one approved PET scanner in Forsyth County, and two existing PET scanners in Guilford County. There are no existing or approved fixed PET scanners in any of the other eight counties in HSA II.⁴ Both Kernersville and Baptist propose to locate the PET/CT scanner in Forsyth County, approximately 11.5 miles from each other's site.⁵ The Kernersville site is in the central eastern border of Forsyth County, just west of Guilford County, and is approximately 12 miles from High Point Regional Health System and 21.5 miles from Cone Health. Given the proximity of the two sites to each other and the proximity of High Point Regional Health System to Kernersville, the proposed locations are comparable with regard to geographic distribution of PET scanners within HSA II. However, neither Kernersville nor Baptist's applications are approvable standing alone.

⁴ Mobile PET services are available at Randolph Hospital, Thomasville Medical Center, and Northern Hospital of Surry County.

⁵ Source: MapQuest.

Populations to be Served

Kernersville and Baptist propose to locate the PET/CT scanner at the hospital: Kernersville's on a mobile pad proximate and adjacent to the hospital, connected via a covered walkway, and Baptist's located inside the hospital in the MRI building. The majority of both Kernersville and Baptist's PET patients are proposed to come from Forsyth County, representing 80% and 22.4%, respectively, in the first two years following project completion. Kernersville proposes to serve PET patients residing primarily in Forsyth, Davidson, and Stokes counties which it deems to be in the eastern portion of its service area based on its eastern location in Forsyth County. Baptist proposes to serve PET patients from a 21-county service area with most patients coming from Forsyth, Davidson, Guilford and Surry counties, and the state of Virginia. Given the proximity of the two sites to each other, with each being in Forsyth County, and the overlap in the populations they propose to serve, the analyst concludes that both are effective alternatives for the proposed PET scanner. However, neither application is approvable standing alone.

Demonstration of Need

Neither **Kernersville** nor **Baptist** adequately demonstrated that the number of PET scans they projected to perform was based on reasonable, credible or supported assumptions. See Criterion (3) for discussion. In addition, Kernersville did not adequately demonstrate a need for a third fixed PET scanner when taking into account the considerable delays in developing Novant's second and approved fixed PET scanner at Forsyth Medical Center. Therefore, neither Kernersville nor Baptist's proposal is the more effective alternative with regard to demonstration of need and neither application is approvable standing alone.

Access by Underserved Groups

Kernersville and Baptist provided the following information regarding the percentage of PET procedures projected to be reimbursed by Medicare or Medicaid:

Projected Percentage of Total Procedures in Year Two		
Application	Medicaid	Medicare
Kernersville	4.2%	61.4%
Baptist	12.9%	57.9%

As shown in the above table, Baptist proposes to provide the highest percentage of total PET procedures to Medicaid recipients, whereas Kernersville proposes to provide the highest percentage of total PET procedures to Medicare recipients. However, neither application is approvable standing alone.

Revenues

Kernersville's proposed fixed PET scanner is projected to begin operating 1/01/2017. **Baptist's** proposed fixed PET scanner is projected to begin operating 7/01/2015.

Average Net Revenue Per Procedure

Application	# of PET Procedures	Net Revenue	Average Net Revenue Per Procedure
Kernersville (Year One – 1/01/2017 – 12/31/2017)	1,468	\$3,536,589	\$2,409
Baptist (Year Three – 7/01/2017 – 6/30/2018)	4,182	\$8,525,213	\$2,039

As shown in the above table, Kernersville projects the highest average net revenue per procedure. Baptist projects the lowest average net revenue per procedure. However, neither Kernersville nor Baptist demonstrated that the number of projected PET scans was based on reasonable, credible and supported assumptions. See Criterion (3) for discussion. Therefore for this reason, the projections of revenues provided by both applicants that are based on the number of procedures to be performed during the first three years after completion of the project, are not reliable and are unsupported. Therefore, neither Kernersville nor Baptist's applications are effective alternatives with regard to this comparative factor.

Operating Expenses

As shown in the table below, Kernersville projects the lowest average operating expense per procedure. Baptist projects the highest average operating expense per procedure. However, neither applicant adequately demonstrated that the number of PET scans they projected to perform was based on reasonable, credible and supported assumptions. Therefore, both applicants' projections of operating expenses that are based on the number of procedures to be performed, are not reliable and are unsupported. Therefore, neither applicant is an effective alternative with regard to this comparative factor.

Average Operating Expense Per Procedure

Application	# of PET Procedures	Total Operating Expenses	Average Operating Expense Per Procedure
Kernersville (Year One - 1/01/2017 – 12/31/2017)	1,468	\$1,339,326	\$912
Baptist (Year Three – 7/01/2017 – 6/30/2018)	4,182	\$5,987,778	\$1,432

CONCLUSION

Each application is individually conforming to the need determination in the 2013 SMFP for one fixed dedicated PET scanner in HSA II. However, N.C.G.S. 131E-183(a)(1) that states the need determination in the SMFP is the determinative limit on the number of fixed dedicated PET scanners that can be approved the Certificate of Need Section. The Certificate of Need Section determined that neither the application submitted by Kernersville, nor the application submitted by Baptist, is approvable standing alone. Therefore, both applications are denied.