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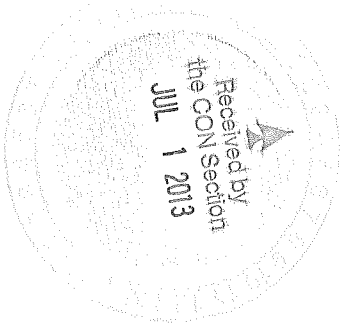

July 1, 2013

RE: Written Comments regarding Novant Health Kernersville Medical Center, PET/CT CON Application, HSA II, Project I.D. #G-10127-13

Dear Mr. Smith, Ms. Frisone and Ms. Hale:

I am writing to provide comments from North Carolina Baptist Hospital (NCBH) in response to the competing CON application filed by Novant Health Kernersville Medical Center (NKFMC) in Health Service Area II (HSA II). These comments are filed in accordance with NCGS 131E-185(a1)(1). After a review of the NHKMC application, NCBH is concerned that NHKMC does not reflect the most reasonable alternative to improve the access, cost-efficiency and quality of care for residents in HSA II.

Introduction

There are several significant issues that should be reviewed in order to select the best applicant for the proposed project. There are several specific issues that follow the CON review criteria in §131E-185 where the NHKMC project is not compliant or the NCBH project is superior. Each of the following will be discussed in turn:

I. Reasonableness of Identified Population and Projected Utilization (Criterion 3)
   a. Projected Service Area
   b. Projected Volumes

II. Least Costly, Most Effective Alternative (Criterion 4)

III. Availability of Funds and Financial Feasibility (Criterion 5)

IV. Unnecessary Duplication of Existing and Approved Services (Criterion 6)

V. Comparative Factors

I. REASONABLENESS OF IDENTIFIED POPULATION

A. Projected Service Area

The NHKMC service area intentionally excludes Guilford County.

The original Forsyth Medical Center - Kernersville application to locate a new hospital in Kernersville (Project I.D. No. G-7604-06) identified Guilford County as a significant portion of its service area, comprising 10.7% of the total market. The table below is taken from page 7 of the CON Section's Required State Agency Findings in that review:

ZIP CODE	COUNTY	CITY	PROJECTED NUMBER OF DISCHARGES YEAR THREE (7/1/11 – 6/30/12)	PERCENTAGE OF TOTAL DISCHARGES
27284 / 27285 (1)	Forsyth	Kernersville	2,011	59.8%
27051	Forsyth	Walkertown	255	7.6%
27009	Forsyth	Belews Creek	65	1.9%
27265	**Guilford**	**High Point**	**280**	**8.3%**
27235	**Guilford**	**Colfax**	**46**	**1.4%**
27310	**Guilford**	**Oak Ridge**	**35**	**1.0%**
Other			673	20.0%
Total			3365	100.0%

However, in the NHKMC PET/CT application, Guilford is lumped into "All other" on page 56 of the application which accounts for 15% of the total patient origin and is inclusive of eight counties and other states. This suggests that NHKMC expects to serve few PET patients from Guilford County despite the fact that Guilford county patients comprise a significant portion of the hospital's acute care patients. It is also important to note that on page 55 of the NHKMC application, Novant states the following:

> This PET Service area is consistent with its historical operating experience and will be the proposed service area for the FMC PET/CT scanners and the proposed NHKMC PET/CT scanner. It is expected that NHKMC will serve more patients in the eastern portion of the service area, Forsyth, Stokes, and Davidson Counties due to its location.

NHKMC intends to serve more patients in the eastern portion of its service area, yet excludes Guilford despite the fact that NHKMD is located less than one mile from Guilford County (on the Guilford/Forsyth county line) and is already serving that population in its hospital. In fact, a review of the Novant Health Website- http://www.novanthealth.org/giveback/foundations.aspx demonstrates that western Guilford County is clearly a significant part of the NHKMC service area while counties such as Stokes and Davidson are not mentioned.

Kernersville Medical Center Foundation
Serving the residents in eastern Forsyth and western Guilford counties, gifts to the Foundation help us meet the medical needs of people in our communities, regardless of their ability to pay. Gifts to the foundation allow donors to express their appreciation for excellent and compassionate patient care. Donors can also invest in specific areas of the medical center. By investing in Kernersville Medical Center, you are investing in your community.

B. Projected Volumes

NHFMC and NHKMC projected PET volumes relied upon unrealistic, unsubstantiated assumptions of PET scans per patient

The growth methodologies used in each respective applicant's CON applications are virtually identical with two key differences. The first is that NCBH uses a patient to scan ratio of 1.2793 versus 2.0 used by NHKMC. The second is that NCBH is also bringing a new type of PET scan- Amyvid for Alzheimer's patients.

the NHKMC application projects that by 2019, NHFMC's existing and approved PETs will be performing 2,170 procedures each, and the NHKMC scanner will perform 2,138 procedures, for a total increase from 2,573 in 2012 to 6,478 in 2019 (a very large 152% volume increase or a 22% average annual increase volume per year). In order to meet these targets, NHKMC states on page 42 of its application that each cancer patient will require two scans. The only support provided for this critical assumption is a PET/NET article that is relevant to cancer patients only and states on page 1002 of the application "After completing the treatment regimen 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." There is no indication in the article that two scans per patient is the norm, and nothing in the FMC application which would indicate that this is consistent with FMC's experience.

NHKMC makes the same assumption regarding cardiac and neurological scans per procedure, citing other PET/Net Solutions articles in Exhibit 18 of the application to support the use of PET for cardiac and neurological patients. However, those articles contain no discussion of multiple scans per patient, and NHKMC offers no other basis for assuming each of those patients will need two scans per patient.

NHKMC also offers no historical experience to support this assumption and two scans per patient is not consistent with FMC's history. In its 2008 CON application for its second PET scanner (Project I.D. No. G-8129-08), NHFMC stated that in 2007, only 40% of its patients received more than one scan. NHFMC's 2008 application based future scan projections on that historical experience. See Required State Agency Findings, attached hereto as *Exhibit 1*, pp. 37-38.

Two scans per patient is highly overstated and is not consistent with NCBH's experience. On page 60 of its PET/CT application, NCBH projected 1.2793 scans per patient for most

patients, based on its historical 3-year fiscal year average. For Alzheimer's/Dementia patients, the projected ratio was one scan per patient (see pp. 62-63).

If the number of scans per patient in NHKMC's application is reduced from 2 to 1.4, that drops total scans in 2017-2019 to 4,111, 4,322 and 4,535. Based on the requirement in 10A NCAC 14C.3703(3) to demonstrate 2,080 procedures per scanner, Novant would barely show a need for its one existing and one approved PET scanner and would not be able to demonstrate that there is no need for a third PET scanner as shown in the table below.

	CY 2017	FY 2018	CY 2019
Cancer Cases	2,669	2,684	2,699
Neuro and Cardiac Cases	267	403	540
TOTAL	2,936	3,087	3,239
X 2 scans per patient from G -10127-13	5,872	6,174	6,478
X 1.4 scans per patient from G-8129-08	4,110	4,322	4,535
Difference	(1,762)	(1,852)	(1,943)

NHFMC and NHKMC projected PET volumes relied upon unrealistic, unsubstantiated assumptions

NHKMC does not provide any support in its application for what growth factors will occur in the interim years to substantiate the 152% volume increase from CY 12 – CY 2019. The only support provided in its application is that Novant has built a new medical office building and relocated a linear accelerator. There is no discussion of new physician recruitment, and it appears that Novant is simply relocating a portion its cancer treatment program rather than growing its cancer program. Physician letters of support in Exhibit 4 to the NHKMC application do not describe a need for Novant to acquire a third PET/CT scanner, only that they support locating a PET/CT scanner in Kernersville, in order to provide a continuum of care to their existing patients.

NHKMC also states on page 28 of its application that researchers and physicians continue to educate Medicare and commercial payers regarding the effectiveness and value of PET/CT imaging and that this will eventually broaden the modality's acceptance and lead to payers' openness to approving more procedures. There is no literature to support this assumption in Novant's application.

Novant is unable to demonstrate success in meeting previous PET/CT volume targets

Novant currently has one operational PET/CT scanner located in NHFMC. The one existing PET/CT performed 2,573 PET procedures in CY 2012 and 2,615 in FFY 12, barely exceeding the 2,080 requirement. In addition, when you compare actual reported PET scans for 2011 and 2012 to what was projected in Novant's 2008 application – G-8129-08, Novant did not meet its volume targets and is unable to meet the performance requirements for the two PET/CT scanners it currently has approval for.

Comparison of G-8129-08 projections to actuals (3 month time differential due to CY-FFY reporting)

From NC License Renewal Applications	FFY 2010	FFY 2011	FFY 2012-ending Sept. 20 2012
ACTUAL REPORTED NOVANT PET SCANS	3,346	2,875	2,615
From G-8129-08 application	CY 2010	CY 2011	CY 2012-ending Dec. 2012
NHFMC Total Projected PET SCANS	3,708	4,057	4,250
Difference	(362)	(1,182)	(1,635)

For these reasons, NHKMC appears to be non-conforming to Criterion 3.

II. LEAST COSTLY, MOST EFFECTIVE ALTERNATIVE (CRITERION 4)

NHKMC has proposed a mobile site.

NHKMC has proposed to locate the PET/CT scanner in trailer on a mobile pad in the parking lot of the hospital. The application never explains why this is an effective alternative. The vast majority of patients receiving PET scans are cancer patients, who can be very ill. Going outside of a building to a trailer for a PET scan is not as convenient as locating the PET scanner in the building. Further, there is no discussion on how this is a benefit to patients. Most of Novant's current PET/CT patients come from the counties west of NHFMC, not east and there was not discussion of how the residents in the eastern portion of the NHFMC's service area are disadvantaged or have trouble accessing PET/CT services due to their eastern location.

Novant has failed to develop its approved PET/CT scanner.

Novant and NHFMC's failure to timely develop its second fixed PET/CT scanner approved in 2008 and its efforts to convert that fixed scanner into a mobile PET/CT scanner clearly demonstrate that a third fixed PET/CT scanner owned and operated by Novant in Forsyth County clearly is not an effective alternative to fill the SMFP's identified need determination for one new fixed PET/CT scanner for HSA II. Indeed, one must question whether Novant really wants a third fixed PET/CT, or simply wants to "leave its options open" (as stated in its CON application), in order to achieve some other end.

In order to understand what "options" Novant seeks, a brief review of Novant's efforts (and lack thereof) to develop its second approved fixed PET/CT scanner is necessary. In 2008, NHFMC filed a CON application to acquire a second fixed PET/CT scanner to be located at NHFMC, pursuant to a need determination in the 2008 SMFP, Project I.D. No. G-8120-08. By decision issued October 10, 2008, the CON Section conditionally approved NHFMC's application and disapproved a competing application filed by Triad PET Scanner Alliance LLC and Diagnostic Radiology & Imaging, LLC ("Triad") to acquire a PET/CT scanner and locate it in an existing diagnostic center in Kernersville.[1]

[1] In its Findings, p. 72, the Agency found that given the size of HSA II and the relatively close distance between the two facilities, NHFMC's proposed site in Winston-Salem and Triad's proposed site in Kernersville were comparable with regard to geographic distribution.

Triad did not appeal that decision, and NHFMC's CON for Project I.D. No. G-8120-08 was issued effective November 13, 2008. The approved capital expenditure for the project was $4,527,228.

NHFMC's initial Progress Report, submitted June 30, 2009, indicated intent to complete the project by October 30, 2010, approximately 11 months after the initial approved completion date in the CON. Subsequent Progress Reports filed in through March 2011 sought and obtained CON Section approval for further delays in the development of the project, claiming that funding for the project had not yet been approved.

Novant and NHFMC filed a Declaratory Ruling Request with NCDHSR on August 12, 2011 seeking to convert the approved second fixed PET/CT scanner to a mobile PET/CT scanner, to serve Novant's facilities in Winston-Salem, Kernersville, Thomasville, and Salisbury. That request was denied by the Director by Declaratory Ruling issued October 29, 2011. In response to the denial, Novant filed a Petition for Judicial Review with the Wake County Superior Court on November 23, 2011. A copy of Novant's and NHFMC's Petition for Judicial Review, which contains the Request for Declaratory Ruling and the Director's Declaratory Ruling, is attached as *Exhibit 2.* Novant and NHFMC did nothing to proceed on their Petition for approximately seven months before filing a Notice of Voluntary Dismissal with Prejudice in that case on June 1, 2012. A copy of that Notice is attached hereto as *Exhibit 3.*

Thereafter, NHFMC submitted Progress Reports on July 31, 2012 and November 30, 2012, indicating intent to develop the project as soon as funding was approved. In the November 30, 2012 Progress Report, NHFMC raised the possibility of seeking permission to relocate the fixed PET/CT scanner to NHKMC or Novant Health Clemmons Medical Center ("NHCMC"), "to ensure that the greatest segment of the patient population can be served by the project." NHFMC reported that it should have the results of its inquiry within 90 days. Copies of the Progress Reports for Project I.D. No. G-8120-08 are attached as *Exhibit 4.* NHFMC's most recent Progress Report filed April 30, 2013 (included in NHKMC's application at p. 254), two weeks before its CON application in this review, repeats this representation verbatim. Once again, NHFMC reports that the results of its inquiry should be complete within 90 days.

The application's only explanation as to why relocating the development of its second fixed PET/CT is not an effective alternative is as follows:

> [G]iven the state-specified May 15, 2013 CON Application deadline, Novant Health determined that it should file an application for a new PET/CT scanner to keep open as many options as possible to get a PET/CT scanner on the NHICMC campus within a reasonable timeframe.

NHKMC Application, p. 53.

One wonders why Novant believes that filing a CON application to acquire a third PET/CT scanner is the most effective alternative to get a fixed PET/CT scanner on the

NHKMC campus within a reasonable time frame. Novant has had the opportunity to develop its approved fixed PET/CT scanner for almost five years. Novant could have sought a Declaratory Ruling at any time to relocate that PET/CT scanner. Novant's delay in developing its second fixed PET/CT scanner leaves little to no room for justifying an application for an additional scanner to maintain a reasonable timeframe. The clear purpose of reviewing alternatives is to provide the state with the ability to choose the applicant that reasonably establishes that its project is the least costly and most effective of any every option that the applicant has. NHKMC's application does not reasonably meet this burden.

The above factors and explanation must cause one to question Novant's real intent. The combination of Novant's inaction on development of its second fixed PET/CT, its attempts to convert its approved fixed PET/CT scanner to a mobile PET/CT, and its proposal in this application to acquire a mobile PET/CT scanner and put it in a trailer, leads to the inevitable conclusion that a mobile PET/CT scanner is what Novant consider as its most effective alternative.[2] Novant appears to hope to accomplish this goal by obtaining approval to develop a third fixed PET/CT scanner, putting it into service as a fixed scanner as described in its application, and subsequently obtaining a change in the PET/CT status from fixed to mobile.

However, the Director's Declaratory Ruling clearly eliminates that option. The Declaratory Ruling found that because the SMFP has identified no need for a mobile MRI scanner in the State, and because converting the approved fixed PET/CT scanner to a mobile CT scanner would constitute a material change in the project, Novant's request must be denied. Pursuant to G.S. 150B-4, a Declaratory Ruling is binding on the Department and the person requesting it. In addition, based upon the Court of Appeals decision in the case of Catawba Memorial Hospital v. North Carolina Department of Human Resources, a copy of which is attached as *Exhibit 5,* any future attempt by Novant, NHFMC or NHKMC to convert a fixed PET/CT scanner to a mobile PET/CT scanner would be barred.

As discussed under Criterion 3 above, NHKMC has demonstrated a need for, at most, two fixed PET/CT scanners. Since Novant already has one existing and one approved fixed PET/CT scanner, the acquisition of a third PET/CT scanner in Kernersville is not an effective alternative. If Novant believes that its approved PET/CT scanner can more effectively serve its patient population at NHKMC, then it should seek a Declaratory Ruling to relocate that PET/CT scanner, rather than seek a third PET/CT scanner which it clearly does not need.

For these reasons, NHKMC appears to be non-conforming to Criterion 4.

[2] This intent is further evidenced by Novant's petition to the State Health Coordinating Council to create a need determination for a mobile PET/CT scanner in the 2014 SMFP. That petition is pending before the SHCC.

III. AVAILABILITY OF FUNDS AND FINANCIAL FEASIBILITY (CRITERION 5)

Criterion 5 requires the applicant to demonstrate the availability of funds to finance the capital and operating needs of the project, and to demonstrate the financial feasibility of the project, based upon reasonable projections of costs and charges.

For the reasons discussed under Criterion 3 above, NHKMC's application clearly does not demonstrate financial feasibility. Quite simply, a realistic analysis of NHKMC's utilization projections demonstrates, at best, the need for two, not three PET/CT scanners. Because Novant's costs and charges are based, in part, on its utilization projections, the application fails to demonstrate financial feasibility.

In addition, NHKMC fails to demonstrate the availability of funds to finance the capital needs of the project. The Progress Reports related to NHFMC's approved PET/CT scanner show a history of inconsistent statements about the funding of its approved, undeveloped, second fixed PET/CT scanner. NHFMC's explanations in its CON Progress Reports for that PET/CT scanner are inconsistent and should raise serious concerns about the reasonableness of the financing of a third scanner. Below are a few statements from NHFMC's CON Progress Reports for its second fixed PET/CT scanner.

- In its July 31, 2012 CON Progress Report, NHFMC states that, "we are currently in the process of seeking internal Novant funding to support the commencement of design and construction for this second PET/CT scanner..."
- In its next CON Progress Report, dated November 30, 2012, NHFMC states that, "this project is part of the 2013 Capital Budget, with funding pending approval in January 2013 *to support the beginning of design and then construction.*" (emphasis added).
- In its CON Progress Report from April 1, 2010, NHFMC states that "design completed January 19, 2010. We expect to receive construction funding in third quarter 2010."
- Even its most recent Progress Report, contained on page 254 of the NHKMC application, does not demonstrate that funds have been or will be approved for the project.

See *Exhibit 4*.

These contradictory statements about the funding and progress of NHFMC's second scanner should raise concern about the reasonableness of any projection in NHKMC's application related to guaranteed funding for a third PET/CT scanner. The commitment to funding for NHFMC's second scanner remains unclear during the six year period between NHFMC's application and its April 30, 2013 CON Progress Report. As a result, the lack of clarity and consistency in the historical evidence should lead to a finding of non-conformity because future projections are unlikely to be reasonable.

For these reasons, NHKMC appears to be non-conforming to Criterion 5.

IV. UNNECESSARY DUPLICATION OF EXISTING AND APPROVED SERVICES (CRITERION 6)

As discussed above Novant already has an approved PET/CT scanner which it has not developed almost five years after approval. Its utilization projections are overstated, and in reality, Novant only has need of, at most, the two PET/CT scanners it already is authorized to operate. A third PET/CT scanner definitely would be an unnecessary duplication of its existing and approved services.

For these reasons, NHKMC appears to be non-conforming to Criterion 6.

V. COMPARATIVE ANALYSIS

Below are factors that the Agency has found to be relevant in past PET/CT reviews when conducting a comparative analysis of competing proposals such as those considered here. Further, the specific factors below were used in the 2008 HSA II PET/CT review, where Novant/NHFMC was awarded its second fixed scanner.

1. Geographic Distribution

In the 2008 review, the Agency found that given the total square miles included within HSA II and the proximity of the two sites in Winston-Salem and Kernersville to each other, the proposed locations were comparable with regard to geographic distribution of PET scanners within HSA II. The same is essentially true in this instance. However, as noted above, most of Novant's current PET/CT patients come from the counties west of NHFMC, not east and there was no discussion of how the residents in the eastern portion of the NHFMC's service area are disadvantaged or have trouble accessing PET/CT services due to their eastern location. In addition, NHKMC's proposed location is significantly closer than NCBH's to two existing PET/CT scanners operating with excess capacity. High Point Regional Health System and Moses Cone Health System each currently operate underutilized PET/CT scanners. A PET/CT scanner at NHKMC would place an additional scanner only twelve miles from High Point Regional and only 20 miles from Moses Cone.

2. Populations to be Served

Both NCBH and NHKMC propose to locate their PET/CT scanner at a hospital. However, NCBH's proposal will place the scanner inside the hospital, where there is an established, comprehensive cancer center, as well as a comprehensive program to serve the growing demand for services by patients with Alzheimer's disease in HSA II and statewide. NHKMC's proposal adds a scanner at a location that it identifies as a satellite cancer center. The explanation of service found in response to Question II.5 at pages 12-13 of the NHKMC application shows how more steps in construction and integration of services are yet to be completed to be operational and serve the patient population. In addition, NHKMC's proposal to place its scanner outside the hospital is less effective because of the potential negative impact of added logistics on the patient population served. As a result, NCBH's proposal is clearly the most effective alternative to bring the

highest quality of this needed service to the largest scope of patients in HSA II, and be operational much quicker.

3. **Demonstration of Need**

NCBH adequately demonstrates that its projected utilization is reasonable and NCBH adequately documents in its projections the methodology on which its assumptions are based. NHKMC did not meet this burden. NHKMC's projections are not reasonable and supported, and its assumptions regarding projected utilization were not adequately documented. As a result of NHKMC not adequately demonstrating need in its proposal, NCBH's proposal is the only effectively alternative in this review.

4. **Access by Underserved Groups**

NHKMC provides lower charity care and bad debt to its patients when compared to NCBH.

The proposed Charity Care and Bad Debt in Year 2 of the Project is provided in Charity Care and Bad Debt Comparison in Year 2 of the Project below. The comparison demonstrates that NBCH will provide a higher percentage of charity care and bad debt than NHKMC.

Charity Care and Bad Debt Comparison in Year 2 of the Project

Applicant	Charity Care	%	Bad Debt	%
NHKMC	$494,498	10.76%	$231,600	4.4%
NCBH	$945,555	11.4%	$425,475	5.2%

Source:
NHKMC Application: Page 85
NCBH Application: Proforma - Form C

NHKMC has projected less access to Medicare and Medicaid patients than NCBH.

As shown in the table below, NCBH proposes to serve the highest percentage and number of Medicare and Medicaid recipients of the two applicants.

Access by the Underserved – Medicaid and Medicare Patients

Applicant	**Medicaid %**	**Medicaid # Procedures**	**Medicare %**	**Medicare # Procedures**	**Total %**
NHKMC	4.19%	78	61.41%	1,137	65.6%
NCBH	12.9%	527	57.9%	2,365	70.8%

Source:
NHKMC Application: Page 90
NCBH Application: Page 95

As a result of the above, combined with NHKMC's overestimated utilization projections, NCBH's proposal is the more effective alternative to provide access to underserved groups.

5. **Revenues**

Due to the fact that NHKMC's utilization projections are overstated, a comparison of the proposed gross and net revenues in each application is not possible.

6. **Operating Expenses**

Due to the fact that NHKMC's utilization projections are overstated, a comparison of the proposed operating in each application is not possible.

For these reasons, NCBH's proposal should be found comparatively superior to that of NHKMC, and thus, overall, the most effective alternative.

CONCLUDING SUMMARY

In conclusion, the NHKMC application contains a number of crucial errors, which include:

1. Failure to adequately identify its proposed population, or to demonstrate the need that population has for the services proposed.
2. Failure to demonstrate that it has proposed the least costly and most effective alternative
3. Failure to demonstrate the availability of funds for the project or the financial feasibility of the proposal.
4. Unnecessary duplication of Novant exists and approved PET/CT scanners.
5. Overall, a less effective alternative than NCBH's proposal to convert an existing research PET/CT scanner to clinical use.

In contrast, NCBH has provided reliable data in its application that is based on sound and substantiated assumptions.

For these reasons, NCBH recommends approval of its project and disapproval of NHKMC's project.

Thank you for the opportunity to provide these comments and your careful consideration of these important issues. Please do not hesitate to contact me at (336) 716-1025.

Respectfully Submitted,

JA Hoekstra for Lynn Pitman

Lynn S. Pitman
Associate VP of Strategic and Business Planning

EXHIBIT LIST

1. Required State Agency Findings, 2008 PET/CT review
2. Novant Petition for Judicial Review filed with the Wake County Superior Court on November 23, 2011
3. Novant Notice of Voluntary Dismissal with Prejudice filed June 1, 2012
4. Novant and NHFMC Progress Reports for Project I.D. No. G-8129-08
5. Catawba Memorial Hospital v. North Carolina Department of Human Resources, 112 N.C.App. 557, 436 S.E.2d 390 (1993)

EXHIBIT 1

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: October 10, 2008
TEAM LEADER: Martha J. Frisone
ASSISTANT CHIEF: Craig R. Smith

PROJECT I.D. NUMBERS: **G-8120-08/** Triad PET Scanner Alliance, LLC (lessor) and Diagnostic Radiology & Imaging, LLC (lessee)/ Acquire a PET/CT scanner, which will be located at Greensboro Imaging – Kernersville, an existing diagnostic center in Kernersville/ Forsyth County

G-8129-08/ Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center/ Acquire a second PET/CT scanner/ 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 – TPSA & DRI
C – Novant & FMC

The 2008 State Medical Facilities Plan (2008 SMFP) identifies a need for one additional fixed dedicated positron emission tomography (PET) scanner in HSA II. Thus, the 2008 SMFP establishes a limit of one fixed dedicated PET scanner that may be approved in HSA II, which includes Alamance, Caswell, Davidson, Davie, Forsyth, Guilford, Randolph, Rockingham, Stokes, Surry and Yadkin counties. Two applications were submitted to the Certificate of Need Section, each proposing to acquire a fixed

dedicated PET scanner 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.

Triad PET Scanner Alliance, LLC (**TPSA**) (lessor) proposes to acquire a PET/CT scanner and lease it to Diagnostic Radiology & Imaging, LLC (**DRI**) (lessee). The proposed PET/CT scanner would be located in Kernersville at Greensboro Imaging – Kernersville (GIK), an existing diagnostic center owned and operated by DRI. The applicants propose to develop no more than one additional dedicated fixed PET scanner in HSA II, which is conforming to the applicable need determination in the 2008 SMFP.

Novant Health, Inc. (**Novant**) and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center (**FMC**) propose to acquire a second PET/CT scanner, which will be located in the Radiology Department at FMC. The applicants propose to develop no more than one additional dedicated fixed PET scanner in HSA II, which is conforming to the applicable need determination in the 2008 SMFP.

In addition, Policy GEN-3 in the 2008 SMFP is applicable to the review of these proposals. Policy GEN-3 states:

> *"A CON application to meet the need for new healthcare facilities, services or equipment shall be consistent with the three Basic Principles governing the State Medical Facilities Plan (SMFP); promote cost-effective approaches, expand health care services to the medically underserved, and encourage quality health care services. The Applicant shall document plans for providing access to services for patients with limited financial resources, commensurate with community standards, as well as the availability of capacity to provide those services. The Applicant shall also document how its projected volumes incorporate the three Basic Principles in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area."*

TPSA & DRI. In Section V.7, page 64, the applicants state *"Cost effectiveness will be realized by providing diagnostic services in a dedicated outpatient, lower cost setting. The proposed global fee*

allows for cost transparency to the consumer." Further, in Section II.1, page 19, the applicants state

> *"the proposed project is expected to reduce health care costs by providing PET services in a lower cost setting. Increased transparency of the total cost of PET services will be introduced with the use of a global rate. Cost savings will be passed on to patients, payors, and the government agencies that finance health care. Further, the proposed PET scanner will be added to an existing diagnostic center, which will allow further efficiency of existing resources and obviate the need for additional administrative staff."*

In Section VI.2, page 66, the applicants state *"The services of TPSA/DRI will be available to any clinically appropriate patient in need without restriction of any kind. The proposed project will enhance the current level of accessibility of patients to PET services in their own community."* Further, in Section VI.3, page 66, the applicants state *"All clinically appropriate referrals are accepted, regardless of their financial circumstances. ... Financial assistance and counseling is provided to patients who will suffer extreme hardship in paying their bill."* In Section II.6, page 22, the applicants state

> *"The proposed project will be located within a freestanding CON approved diagnostic center and will meet all applicable federal, state, and county laws and regulations, including building codes and safety requirements. TPSA and GIK will adhere to Food and Drug Administration, Occupational Safety and Health Administration, and Americans with Disabilities Act requirements. Further, the radiology staff associated with the proposed project will follow the American College of Radiology guidelines and all clinical staff will be certified in CPR and Basic Cardiac Life Support. As DRI, LLC proposed in its CON application for GIK, DRI, LLC will pursue accreditation from the American College of Radiology."*

The applicants adequately demonstrate that medically underserved groups would have access to the proposed services. The applicants also adequately demonstrate their ability to encourage quality health care services. Additionally, the applicants demonstrate projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See

Criteria (3) and (13) for additional discussion. However, the applicants failed to adequately demonstrate the need for the project, and therefore, failed to demonstrate the proposed project is a cost-effective approach. Consequently, the application is not conforming to Policy Gen-3 and is not conforming to this criterion.

Novant & FMC. In Section III.2, pages 59-62, the applicants state

> *"The proposed project to expand PET/CT diagnostic capacity at FMC will promote cost-effective approaches, expand health care services to the medically underserved, and encourage quality health care services by providing more efficient health care services to the patient population served by FMC. In Section VI of this Application, FMC provides documentation regarding the projected level of care provided to residents of the service area as a function of payor category, including Medicare, Medicaid, and Charity, which the CON statutory review criteria identify as the 'medically underserved.' A large majority of residents from Forsyth County and the surrounding service area, as documented in the patient origin information in CON Application Section III and Exhibit 3, receive PET/CT services at FMC. The proposed project will result in improved access to all residents of the service area since FMC's future PET/CT scan volumes are projected to be larger than they are currently. FMC has the availability of capacity to provide those services now and in the future.*
>
> *Please see FMC's responses to Section VI, Questions 2 through 6 and Exhibit 8 for a copy* [sic] *Novant's policies on Charity Care, Uninsured Discount, Catastrophic Discount & Payment Plan, for documentation of MIC's* [sic] *plans for providing services for patients with limited financial resources, commensurate with community standards, as well as the availability of capacity to provide those services. These four Charity Care policies apply today to the PET/CT diagnostic services provided at FMC and will continue to apply to the provision of those services when a second PET/CT scanner is added. For example, based on the government's 2008 Federal Poverty Level (FPL) definitions a family of four with annual income of 563,600 is eligible for a full Charity Care write-off of all charges with the completion of a simple one-page form that is attached to the Novant Charity Care policy. This means*

these patients will get no bill from Novant for services rendered. It is the applicant's belief that Novant's Charity Care policy set at 300% of FPL is one of the most generous in North Carolina and today it applies at 12 North Carolina Hospitals, as well as 130 outpatient facilities that provide imaging, surgery, rehabilitation, etc. Furthermore, Novant's 'Uninsured Discount' policy ensures that those patients who do not qualify for the above Charity Care Write-Off, but remain unable to pay the full cost of their care have access to discount off Novant's charges that is based on the average regional discount given by Novant to managed care payors. Then, if the patient's remaining balance after the application of the uninsured discount is more than $5,000, the patient may be eligible for Novant's 'Catastrophic Discount.' All these policies and processes are fully described in Novant Health's Charity Care policies included in CON application Exhibit 6.

In addition, 'community benefit' information for all Novant health's providers in North Carolina (hospitals, physician practices, and outpatient services) shows the following. During CY 2007 (January 1 - December 31, 2007), Novant Health provided $300 Million in Total Community Benefit, which includes the costs of treating charity care patients, unreimbursed costs of treating patients with Medicare, Medicaid, and other government health coverage, and estimated costs of treating Bad Debt patients. Bad Debt is inherent in providing health services to all individuals without regard for their willingness or ability to pay. The $300 Million in Novant's Total Community Benefit dollars is an increase of about 50% when compared to Novant Health's CY 2006 Total Community Benefit dollars, driven in part by Novant Health's Charity Care policies described below. During CY 2007 Novant Health's Charity Care portion of Direct Community Benefit was ~$68 Million and Novant Health's Bad Debt portion of Direct Community Benefit was ~$33 Million. This is further evidence of Novant Health's overall commitment to accessible health services for medically underserved populations, including those patients served by FMC's PET/CT imaging program. FMC has the availability of capacity to provide those services as 'community benefit' when necessary, including PET/CT diagnostic imaging services, now and in the future.

...

Please see FMC's responses to Section II Questions 6 and 7 and Exhibit 7 for a copy Novant's policies and procedures related to quality care. As discussed in Section II of this application, FMC's Radiology Department has established a focused quality management program dedicated to ongoing quality assessment and improvement to provide high quality, cost-effective health care that meets the needs of cancer patients and enhances clinical effectiveness and health outcomes for that population. These quality processes, tools, and activities are in place today at FMC's PET/CT imaging program and will continue to apply in the future to FMC's expanded PET/CT imaging program. In addition, outside third parties have quantified and recognized FMC's overall clinical excellence in patient care. First based on the NC Center for Hospital Quality and Patient Safety, Forsyth Medical Center ranks in the 'top 10% or 90th percentile for all North Carolina hospitals' on the following measured identified by the Center: Heart Attack Treatment, Heart Failure Treatment, Surgical Care, Pneumonia Treatment. See the NC Hospital Association's 'NC Center for Hospital Quality and Patient Safety' reports in Exhibit 15 and also www.nchospitalquality.org. These excellent quantified quality scores reflect an overall attention to quality processes of patient care and outcomes that include diagnostic services, such as imaging. Second, in 2008 VHA (Voluntary Hospitals of America) 'Clinical Excellence Awards' VHA has recognized Forsyth Medical Center with the highest quality award of 'Superior System Performance/Clinical Excellence' for metrics related to patient care for Acute Myocardial Infarction (AMI), Surgical Complications & Infection Prevention (SCIP), Heart Failure(HF), and Pneumonia (PN). Again, these excellent quantified quality scores reflect an overall attention to quality processes of patient care and outcomes that include diagnostic services, such as imaging. Third, in 2007 Novant Health, Inc. and its providers and facilities are participating in the 'National ePrescribing Patient Safety Initiative,' designed to address preventable medication errors. This effort includes a coalition of the nation's most prominent technology companies and leading

healthcare organizations, such as Aetna, Allscripts, Cisco, Dell, Fujitsu, Google, Intel, Microsoft, Sprint, Nextel, SureScripts, WellPoint, Wolters Kluwer Health, Novant Health, University of South Florida Physicians Group (Tampa), LSU Health Network (New Orleans), George Washington University Medical Faculty Associates (Washington D.C), Maine General Health (Augusta, ME), Advocate Health Partners (Mt Prospect, IL), University of Mississippi Medical Center, Holston Medical Group (Kingsport,TN), Healthcare Partners Medical Group (Torrence, CA), Sierra Health Services & Southwest Medical Associates (Las Vegas), [sic] *UMass Memorial Healthcare (Worcester, MA). See the article in Exhibit 15. This reflects Novant's focus on continuing to improve key processes of patient care delivery in the future. Fourth, Novant Health continues to invest major capital in the installation of an electronic medical record (EMR) at six locations within the next two years and eventually with the remaining 256 Novant Health locations. Novant's commitment to the EMR conversion represents a mindset for capturing essential medical and patients information to allow providers speedier access to patient information and to give nurses and physicians more decision making tools. The EMR will also serve to decrease harmful errors caused by handwritten notes and will significantly improve access to medical information from almost any location. See the article in Exhibit 15. Fifth, Novant Health is one of the first health systems in the nation to invest in the Microsoft Amalga system, which pulls together patient medical information from multiple sources, such as imaging, lab, pharmacy and surgery and presents it all in one single view for physicians. Novant believes this system will reduce the administrative burden (of gathering this information from disparate sources) on physicians, so that they can better spend their time and expertise on patient care management and decision making. See the article in Exhibit 15. The EMR, Amalga, and ePrescribing initiative illustrate Novant and FMC's commitment to the improvement of patient care, including clinical ancillary services such as lab, imaging, and pharmacy, through the simplification and error-proofing of key processes of care.*

Furthermore, in May 2007 Novant Health, Inc. announced its participation with a group of the nation's leading

hospitals to address medical errors by developing a comprehensive approach to patient safety. Other participants in the 'Safest Hospital Alliance' include Wellmont Health System and Adventist Health System. The Alliance's Safest Hospital initiative improves safety by creating metrics and identifying best practices. Please see the recent article on this issue included in Exhibit 15. It is Novant and FMC's position that patient safety is intimately intertwined with quality of care. So patient safety initiatives are part of the quality of care initiatives at FMC, including at the PET/CT imaging program.

...

Novant Health, Inc. is a national leader in cost-effective approaches for health care services. In 2008 Novant is ranked 4th nationally among the 'Top 100 Integrated Healthcare Networks based on an analysis conducted by Verispan, a health informatics company. Please see the recent article on this issue included in Exhibit 15. According to 'Modern Healthcare' 'the best performing integrated healthcare systems continue to improve efficiency and have bottom lines to show it including improved occupancy, well-integrated information systems, and strong margins.'

...

Novant Health is committed to providing care at the community level, where possible, and when needed, state-of-the-art specialty care at Forsyth Medical Center. The service area was identified by reviewing the population currently utilizing PET services at FMC. As a result, FMC's projected utilization is based upon the population of the proposed service area and incorporates the three Basic Principles governing the State Medical Facilities Plan (SMFP)."

Further, in Section V.7, pages 81-83, the applicants state

"FMC proposes to finance the second PET/CT scanner from Novant Health's Accumulated Reserves, so that interest expense related to tax-exempt bonds is avoided. Also, the addition of a second PET/CT scanner will allow the PET/CT imaging program at FMC to provide patients and their

physicians with more timely access to a preferred slot for the patient's PET scan. In addition, FMC will continue to cross-train certain nuclear medicine staff for PET/CT scanner operation, to further enhance the cost-effectiveness of the project. The existing PET/CT scanner and the proposed PET/CT scanner are/will be located in combined and contiguous space to promote both patient privacy and efficiency of operation. The proposed PET/CT scanner will also provide back-up capacity for the other PET/CT scanner at FMC, in the event that one of the scanners is unexpectedly out of service.

...

The proposed additional PET/CT scanner includes state-of-the-art capabilities such as a 64-slice CT scanner component, to compliment [sic] *and enhance the PET's metabolic diagnostic studies. In addition, the FRA radiologists who interpret the PET studies are all board-certified and the FMC PET Technologists are specialty trained and are required to maintain both current AART registration and ACLS certification. The proposed PET/CT scanner will be part of a tertiary health system with a regionally recognized and accredited Cancer Center, with sub-specialized cancer treatment and support programs, and a busy, well-established PET/CT imaging program section, supported and lead by well-qualified radiologists and staff. The radiologists and referring physicians also have well-established channels of communication regarding the findings in the PET/CT studies, which enhance the treatment planning and delivery of care for these patients. FMC, including the radiology department and its PET Imaging program are JCAHO-accredited. FMC's Cancer Program is accredited by the American College of Surgeons Commission on Cancer and is a member of the Southeast Cancer Control Consortium within the Clinical Community Oncology Program/CCOP which allows FRCC cancer patients access to Clinical Trials. The FMC PET/CT program also is a participating site in the National Oncologic PET Registry.*

...

The standard of care at large and sophisticated cancer centers, like the Derrick L. Davis Forsyth Regional Cancer Center at FMC, is for ready access to diagnostic PET imaging studies. FMC's current PET/CT scanner operates 16 hours per day, Monday – Friday, from 7 a.m. to 11 p.m. to accommodate the current demand. Cancer patients, due to the nature of their disease, are often debilitated and fragile and tend to prefer to avoid the evening PET scanner slots, if possible. When a second PET/CT scanner is added at FMC, it will permit FMC to offer PET imaging slots for two scanners five days per week, 12 hours per day, from 7 a.m. to 7 p.m. This approach increases the access to PET diagnostics from 80 hours per week (1 scanner X 16 hours/day X 5 days/week) to 120 hours per week (2 scanners X 12 hours/day X 5 days/week). This will also allow the FMC PET imaging staff and the FRA radiologists to maintain and promote a high level of patient and referring physician satisfaction with local access to a sophisticated and well-established PET imaging program affiliated with a tertiary health system that is home to a recognized and accredited Cancer Center. The addition of a second PET scanner will also allow FMC the flexibility to expand the type of diagnostic PET studies it can offer, to include cardiac and breast imaging."

Novant and FMC adequately demonstrate the project is a cost effective approach and that medically underserved groups would have access to the proposed services. The applicants also adequately demonstrate their ability to encourage quality health care services. Further, the applicants adequately demonstrated that their projected volumes for the proposed PET scanner incorporate the basic principles in meeting the needs of the patients to be served. See Criteria (3) and (13c) for additional discussion. Therefore, the application is consistent with Policy GEN-3 and conforming to this criterion.

Although the two applications in this review are each conforming to the need determination in the 2008 SMFP, one dedicated fixed PET scanner is the limit on the number of PET scanners that may be approved in this review. Therefore, both applications cannot be approved. See the Comparative Analysis section 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 – TPSA & DRI
C – Novant & FMC

TPSA & DRI. Triad PET Scanner Alliance, LLC (**TPSA**) is a newly created limited liability company (LLC) with the following two members:

- North Carolina Baptist Hospital (Baptist); and
- Diagnostic Radiology & Imaging, LLC.

Diagnostic Radiology & Imaging, LLC (**DRI**) is also an LLC with the following two members:

- The Moses H. Cone Memorial Hospital d/b/a Moses Cone Health System (Cone); and
- Radiology Imaging Partners, LLC.[1]

TPSA proposes to acquire a PET/CT scanner and lease it to DRI. DRI would locate the PET/CT scanner in Kernersville at Greensboro Imaging – Kernersville (GIK), an existing diagnostic center owned and operated by DRI, which currently offers the following imaging services:

- one CT scanner;
- one X-ray unit;
- one mammography unit;
- one ultrasound unit; and
- one bone density unit.

DRI proposes to renovate existing space for the proposed PET/CT scanner. The applicants do not propose to acquire a cyclotron; rather, they will obtain their radioisotopes from an off-site medical cyclotron and radioisotope production facility.

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[1] Radiology Imaging Partners, LLC is owned by the partners of Greensboro Radiology, PA, which provides professional interpretation services to DRI.

Population to be Served

In Section III.5(a), page 53, the applicants state the proposed primary and secondary service area consists of Forsyth, Guilford, Rockingham, Stokes, Randolph and Davidson counties. In Section III.5(d), page 54, the applicants state

> *"The patient origin was calculated by collecting the actual PET scans in each county in Federal Fiscal Year 2007 ... from the 2008 State Licensure Renewal Application* [sic] *and calculating the patient origin distribution for the proposed service area. These percentages were then applied to the projected volumes for TPSA for the proposed service area. ... Finally, the volumes from the inmigration counties were added as projected in Step 7 ... of the projection methodology."*

The following table illustrates projected patient origin for PET services, as reported by the applicants in Section III.5(c), page 54.

COUNTY	YEAR TWO (4/1/2010 – 3/31/2011)	
	# OF PATIENTS	% OF TOTAL
Primary and Secondary Service Area		
Forsyth	576	32.6%
Guilford	629	35.7%
Stokes	69	3.9%
Rockingham	41	2.3%
Randolph	90	5.1%
Davidson	208	11.8%
Subtotal	1,612	91.4%
Inmigration		
Advance [1]	30	1.7%
Davie	30	1.7%
Caswell	30	1.7%
Surry	30	1.7%
Yadkin	30	1.7%
Subtotal	151	8.6%
Total [2]	1,763	100.0%

(1) Advance is not a county. Rather, it is an unincorporated area within Davie County.
(2) Totals do not add due to rounding.

As shown in the above table, the applicants project 30 PET patients from Advance plus 30 PET patients from Davie County. However, Advance is an unincorporated area located within Davie County. The applicants do not state in the application that the 30 residents of Davie County expected to utilize the proposed PET/CT scanner is in addition to the 30 residents of Advance expected to utilize the proposed PET/CT scanner. Thus, it is not clear whether the

applicants project to serve only 30 residents of Davie County, including residents of Advance, or 60 residents of Davie County.

Need Analysis

In Section III.1(a), pages 34-45, the applicants state

> *"The unmet need for PET services that necessitated this project includes several factors, namely, the need determination in the 2008 State Medical Facilities Plan for a new PET scanner in HSA II, the needs of the population of HSA II arising from the growing population, the incidence of cancer, expanding clinical applications for PET, the increase in the types of PET scans approved for reimbursement, and the rise in physician awareness and consequent increase in referrals of patients for PET scans. All of these factors have resulted in an exponential growth in the demand for PET procedures.*
>
> ...
>
> *As the population of HSA II grows, the need for PET services will also increase. ... HSA II is projected to grow at a consistent rate of 1.1% from 2000 to 2010, and ... this trend is expected to continue on an annual basis at a rate of 1.1% through 2012, the third project year.*
>
> ...
>
> *The population of HSA II and the proposed six-county service area is also growing older ..., a trend which is expected to accelerate as the baby boom generation ages. Nationally, the cancer incidence rate increases dramatically with age, according to Surveillance. Epidemiology, and End Results (SEER) incidence data. Therefore, as the HSA II population ages, the need for PET, ad* [sic] *diagnostic tool primarily serving caner patients, will continue to increase.*
>
> ...
>
> *Nearly 80% of the PET Scans* [sic] *in the proposed service area were for cancer detection, diagnosis, and treatment planning, and that number is likely to be understated as it does not include some codes that are used to diagnose and*

rule out cancer. As discussed in detail below under the heading Clinical Acceptance and Reimbursement for PET, the majority of clinical indications and reimbursement have been in the oncology area to date. ... According to the North Carolina Central Cancer Registry, in 2005, HSA II had an average cancer incidence rate of 482.0 (per 100,000 population) mirroring North Carolina's cancer incidence rate of 482.9.

...

... [S]*everal counties in the proposed service area have cancer incidence rates well in excess of the HSA II and state average. As more emphasis is placed on early detection, the value of PET services is even more pronounced and it is even likely that we may see the rate of cancer incidence increase while the rate of cancer deaths decrease if more cancer can be identified early through the use of PET as a diagnostic tool.*

...

The reimbursement of FDC PET has evolved considerably over the past 10 years. CMS has gradually expanded the coverage of PET imaging, starting in 1998 with changes through 2008.

...

In 2005, the National Oncologic PET Registry (NOPR) was developed in response to the Centers for Medicare and Medicaid Services proposal to expand coverage for positron emission tomography (PET) with F-18 fluorodeoxyglucose (FDG) to include cancers and indications not presently eligible for Medicare reimbursement. The NOPR began accepting facility registrations in late November 2005 and patient registration began on May 8, 2006. Medicare reimbursement for these cancers can now be obtained if the patient's referring physician and the provider submit data to a clinical registry to assess the impact of PET on cancer patient management. The NOPR implemented the registry for CMS. The NOPR is sponsored by the Academy of Molecular Imaging and managed by the American College of Radiology through the American College of Radiology Imaging Network. The NOPR received input from, and is

endorsed by the ACR, the American Society for Clinical Oncology, and the Society for Nuclear Medicine.

The cancers that were not previously eligible for Medicare reimbursement covered under the register are the following:

- *Brain*
- *Cervical - Other staging applications, diagnosis, restaging, and monitoring response to treatment*
- *Colorectal - Monitoring response to treatment*
- *Esophagus - Monitoring response to treatment*
- *Head and Neck (non-CNS/thyroid) - Monitoring response to treatment*
- *Lymphoma - Monitoring response to treatment*
- *Melanoma - Monitoring response to treatment*
- *Non-Small Cell Lung — Monitoring response to treatment*
- *Ovarian*
- *Pancreatic*
- *Small Cell Lung*
- *Soft Tissue Sarcoma*
- *Thyroid — Diagnosis, other staging and restaging (e.g., of medullary cell tumors), and monitoring response to treatment*
- *Testicular*
- *All other cancers not listed herein (all indications)*

On March 25, 2008 the NOPR Working Group submitted a request to the CMS requesting that it reconsider the current National Coverage Determinations (NCD). The pending NOPR request is to remove the current prospective data collection requirements as required for FDG PET used in diagnosis, staging, restaging and monitoring response to treatment for brain, cervical, ovarian. pancreatic, small cell lung and testicular cancers, as well as for cancer indications not previously specified in Section 220.6 of the NCD manual. The request was founded on the empirical evidence from registry data collected over the previous 18 months. A study resulting from the data collected through the registry has been published in the Journal of Clinical Oncology, revealing that 'PET is associated with a 36.5% change in physicians' pre-PET treatment or no-treatment decision, and these changed [sic] *spanned the full spectrum of potential oncologic uses of PET (diagnosis, initial staging, restaging, and detection of suspected recurrence.)'*

'In addition, the 36.5% figure only considers full changes between non-treatment and treatment, which underestimates the clinical impact of PET imaging. PET was actually associated with a management change in almost three-quarters of patients when the addition or deletion to specific modes of therapy are included, and as well as alterations in the type of non-treatment care recommended.'

The CMS has an open public comment period that ended May 10. A final decision is pending as of the submission of this application.

...

As PET technology becomes more available and its clinical applications expand, it becomes more practical for physicians to refer patients for PET scans. Also, as CMS reimbursement for the procedure expands, more facilities, physicians, and patients are willing to use PET technology. Within North Carolina, HSA II and the proposed service area, the existing PET providers have experienced a dramatic increase in physician referrals for PET scans within the first few years of operation. As PET technology spreads, this trend is expected to continue. As the number of PET scanners available throughout the state increases, the number of physicians and patients who are aware of this technology and utilize it will also increase.

...

All of the aforementioned factors ... have led to an exponential growth in the demand for PET procedures. This is evident in the growth of PET procedures, as PET has emerged as a standard of care for a growing number of conditions. In 2004 there were 284,645 PET procedures in the United States (reference Table 9). By 2014, Sg2, a national healthcare technology consulting firm, projects that the national PET volume will be 688,538 representing an annual increase of 9.2[%] and substantially above the projected service area population growth.

...

In Federal Fiscal Year 1994, there were 699 PET procedures completed in the entire state of North Carolina

as reported in the SMFP. By FFY 2006, there were 31,643.

...

... [T]*his growth in PET procedures reflects the increased availability of PET scanners in North Carolina, a trend consistent with national statistics.*

...

... [T]*here are currently five established fixed PET providers within HSA II. Each established provider experienced an annual growth rate over the past three years of at least 20%.*

Fixed & Mobile PET providers in HSA II				
HSA II Growth	***2004-2005***	***2005-2006***	***2006-2007***	***Compound Annual Growth Rate***
NCBH (Fixed)[2]	*1266*	*1477*	*2017*	*26.2%*
MCHS (Fixed)	*1352*	*1760*	*1955*	*20.2%*
FMC (Fixed)	*1579*	*2417*	*2983*	*37.4%*
HPRH (Fixed)	*356*	*574*	*785*	*48.5%*
Alamance (Fixed)[3]	*288*	*374*	*480*	*28.3%*
Hugh Chatham (Mobile)		*50*	*84*	*68.0%*
Northern [Hosp. of Surry] *(Mobile)*			*90*	*N/A*
Total HSA II	*4841*	*6652*	*8394*	*31.7%*

Thus as indicated in the 2008 SMFP, and as confirmed by the expansion in reimbursement and physician referrals for PET, there is a need for an additional PET scanner in HSA II. As demonstrated by population statistics, the incidence of cancer patients in the proposed service area, [sic] *the growing number of applications for PET* [sic] *there is continuing sustained demand for PET procedures in the proposed service area. This demand coupled with the support of local physicians and the detailed demand provided in response to III.1.b. below results in the need for the proposed project."*

The following table illustrates projected utilization of PET services at GIK, as reported by the applicants in Section III.1(b), page 51.

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2 According to its 2008 Hospital License Renewal Application, Baptist performed only 1,919 PET procedures during FFY 2007.

3 Alamance Regional Medical Center was approved to acquire a fixed PET/CT scanner on April 14, 2007. The PET scans reported in the table above were performed on a mobile PET scanner.

The proposed PET/CT scanner is projected to begin operating on April 1, 2009.

	# OF PET PROCEDURES		
	YEAR ONE 4/1/09 – 3/31/10	YEAR TWO 4/1/10 – 3/31/11	YEAR THREE 4/1/11 – 3/31/12
Primary and Secondary Service Area	1,094	1,612	2,186
Inmigration	151	151	151
Total	1,245	1,763	2,336

As shown in the above table, the applicants project that the proposed PET/CT scanner will perform a total of 2,336 PET procedures during Year Three. The applicants provide the assumptions and methodology used to project utilization of the proposed PET/CT scanner in Section III.1(b), pages 45-50. The applicants' methodology is summarized and discussed below.

Step One – On page 45, the applicants state *"TPSA calculated the total number of PET patients from each county in the proposed service area by referencing the patient origin tables from each provider from page 28 in the 2008 Annual Hospital License Renewal Application."* The following table illustrates the total number of PET patients from each county in the proposed primary and secondary service area during FFY 2007, as reported by the applicants on page 45.

COUNTY	NUMBER OF PET PATIENTS
Forsyth	1,994
Guilford	2,178
Stokes	239
Rockingham	142
Davidson	721
Randolph	311
Total	5,585

As shown in the above table, the applicants state that, during FFY 2007, 5,585 residents of the proposed primary and secondary service area had one or more PET procedures. This number includes inpatients and outpatients. However, the applicants do not propose to serve inpatients.

Step Two – On page 46, the applicants state

> *"A review of the difference in procedures reported and patients reported in the Annual Hospital License Renewal*

Application reveals that there remain differences in practice patterns or confusion in reporting in the marketplace among existing PET providers as to whether each patient has one procedure or whether the patient has multiple procedures. This occurs despite the recent addition of the following statement on the License renewal application: 'PET procedure is defined as a single discrete PET scan of a patient (single CPT coded procedure), not counting other radiopharmaceutical or supply charge codes.' TPSA/DRI has consulted with its clinical advisors and believes that it is more likely that a significant proportion of patients have more than one PET procedure during a 12-month period due to the need for second imaging for comparison, over reads, second opinions and progression of disease. In Step 2, TPSA/DRI pulled the number of patients and procedures and determined the statewide rate of PET scans per patient is 1.14."

The applicants provide the following table in Section III.1(b), pages 46-47.

"Table 14
Number of PET Procedures per Patient reported in North Carolina
Federal Fiscal Year Ending in 2007

Totals	*Patients*	*Scans*	*Scans per Pt*
Alamance Regional	*480*	*480*	*1.00*
Albemarle	*265*	*265*	*1.00*
Cape Fear Valley	*1,450*	*2,268*	*1.56*
CMC-Union	*308*	*312*	*1.01*
CMC	*1,931*	*3,654*	*1.89*
Catawba Valley Med Ctr	*1,574*	*1,574*	*1.00*
Mission	*1,619*	*1,607*	*0.99*
NC Baptist	*1,676*	*2,017*	*1.20*
MCHS	*1,781*	*1,955*	*1.10*
Forsyth Med Ctr	*2,986*	*2,983*	*1.00*
HPRH	*787*	*785*	*1.00*
Gaston Memorial	*983*	*984*	*1.00*
Presbyterian	*1,941*	*2,173*	*1.12*
Duke	*3,856*	*3,858*	*1.00*
UNC	*1,279*	*1,878*	*1.47*
Rex	*2,131*	*2,139*	*1.00*
New Hanover	*895*	*895*	*1.00*
Pitt County	*964*	*981*	*1.02*
Craven Regional	*850*	*852*	*1.00*
Nash General	*421*	*421*	*1.00*
Grace Hospital	*74*	*74*	*1.00*
	28,251	*32,155*	*1.14*

UNC and NCBH include AC-3 volumes of 89 & 377 respectively as these patients are unlikely to be excluded from pt origin data due to administrative data systems.
Source: Page 28 of the 2008 Annual Hospital License Renewal Application"

In Section III.1, page 46, the applicants state the data in Table 14 *"depicts the data for all of the PET providers in the State."* (Emphasis added.) However, the applicants did not include all existing fixed PET scanners and mobile PET host sites in their analysis of the statewide ratio of PET procedures to PET patients. Specifically, they did not include the existing fixed PET scanner located at Carolinas Medical Center –NorthEast and they included only 2 of the 23 mobile host sites[4] in their analysis. The applicants do not explain in the application their rationale for the fixed PET scanners and mobile host sites they chose to include in their analysis. Moreover, the applicants admit that the data in the 2008 hospital license renewal applications is potentially problematic. Indeed, of the 21 providers listed in Table 14, 13 or 62% [13 / 21 = 0.619] report a ratio of only one PET procedure per patient. For all these reasons, the applicants do not adequately demonstrate that it is reasonable to assume 1.14 PET procedures per patient based on the data in the 2008 hospital license renewal applications.

Step Three – On page 47, the applicants state *"In Step 3, the total number of PET patients was multiplied by the statewide average procedures per patient to determine the PET procedures per county."* The following table illustrates the number of PET patients and the number of PET procedures, as calculated by the applicants on page 47.

PRIMARY AND SECONDARY SERVICE AREA COUNTIES	NUMBER OF PET PATIENTS	NUMBER OF PET PROCEDURES (1.14 PER PATIENT)
Forsyth	1,994	2,270
Guilford	2,178	2,479
Stokes	239	272
Rockingham	142	162
Davidson	721	821
Randolph	311	354
Total	5,585	6,357

As shown in the above table, based on their assumption of 1.14 PET procedures per patient, the applicants estimate that 6,357 PET procedures were performed during FFY 2007 on the 5,585 residents of the primary and secondary service area they identified in Step One of their methodology. However, as discussed above,

[4] The 23 mobile host sites do not include the two mobile host sites that have been approved for a fixed PET scanner (Alamance Regional Medical Center and Nash General Hospital). Those sites are included with the existing and approved fixed PET scanners.

the applicants did not adequately demonstrate that their assumption of 1.14 PET procedures per patient is reasonable and supported. Consequently, the applicants did not adequately demonstrate that their estimate of the number of PET procedures performed during FFY 2007 is reasonable and supported.

Step Four – On page 48, the applicants state

> *"In Step 4, TPSA/DRI projects the service area county demand for PET through the Federal Fiscal Year 2012 which encompasses proposed project year three. TPSA considered a number of variables in determining the most appropriate growth rate statistic to employ, as this rate is central to the projection methodology. As previously noted, the HSA II average annual growth rate for established PET providers totals 31.7%. The applicants conclude that demand for PET services will continue to grow at a robust rate. However, historical increases have been influenced by the rapid proliferation of PET technology. Hence, the applicants determined that applying one third of this historical rate or an annual growth factor of 10.6%, represents an accurate, yet conservative, forecast of future PET demand within the proposed service area. Moreover, this annual growth rate projection is consistent with the previously referenced Sg2 statistic of 9.2% annual growth."*

The following table illustrates the results of Step 4, as reported by the applicants on page 48.

	ACTUAL	PROJECTED				
	FFY 2007	FFY 2008	FFY 2009	FFY 2010	FFY 2011	FFY 2012
Total # of PET procedures performed or to be performed on residents of the primary and secondary service area counties	6,357	7,028	7,770	8,591	9,498	10,501
Projected incremental increase in the # of PET procedures to be performed on residents of the primary and secondary service area over the # actually performed during FFY 2007 (i.e., projected market growth)		671	1,413	2,234	3,141	4,144

As shown in the above table, the applicants assume that the estimated number of PET procedures performed during FFY 2007 (6,357) would increase 10.6% annually through FFY 2012.

However, as discussed above, the applicants did not adequately demonstrate that their estimate of the number of PET procedures performed during FFY 2007 is reasonable and supported. Therefore, they did not adequately demonstrate that the number of PET procedures projected to be performed through FFY 2012 is reasonable and supported. Consequently, the applicants did not adequately demonstrate that the projected market growth shown in the above table is reasonable and supported.

Step Five – On pages 48-49, the applicants state

> *"The projections were based on Federal Fiscal Year data as that is the time period of data that is publicly available in licensure renewal application* [sic]. *The Federal Fiscal Year is October 1 through September 30. However, the proposed equipment is scheduled to be in operation on April 1, 2009. Therefore, in Step 5 TPSA/DRI adjusted the FFY data to the Project Years by allocating half of FFY 2009 and half of FFY 2010 to Project Year 1, allocating half of FFY 2010 and half of FFY 2011 to Project Year 2, allocating half of FFY 2011 and half of FFY 2012 to Project Year 3."*

The following table illustrates the results of Step Five, as reported by the applicants on page 49.

	PROJECT YEAR 1	PROJECT YEAR 2	PROJECT YEAR 3
Projected Market Growth Adjusted to Project Years	1,824	2,687	3,643

See discussion above regarding the reasonableness of the federal fiscal year estimates and projections.

Step Six – On page 49, the applicants state

> *"In Step 6, TPSA/DRI applied assumed market shares to the incremental increase in volume to TPSA/DRI and other existing PET providers. TPSA/DRI assumed a 60% share of this incremental increase, leaving the remaining 40% to be served by the existing providers. It is important to note that TPSA/DRI is bringing an innovative, cost-effective, highly accessible alternative to the exiting* [sic] *fixed providers most of which are approaching capacity. Physician letters of support contained in Exhibit 13 clearly*

document a strong level of referral volumes for the proposed project."

The following table illustrates the results of Step Six, as reported by the applicants on page 50.

	PY 1	PY 2	PY 3
Projected Market Growth	1,824	2,687	3,643
% of Market Growth Projected to Utilize the Proposed PET/CT scanner at GIK	60%	60%	60%
Projected # of PET procedures to be performed on the proposed PET/CT scanner at GIK	1,094	1,612	2,186

As shown in the above table, the applicants project that the proposed PET/CT scanner would perform 1,094 PET procedures in Year One on residents of the primary and secondary service area. Exhibit 13 contains six letters from physicians in which they provide an estimate of the number of patients to be referred to the proposed PET/CT scanner. Collectively they estimate they will refer 960 patients to the proposed PET scanner, which would be 1,094 PET procedures based on the applicants' assumption of 1.14 PET procedures per patient [962 x 1.14 = 1,094.4]. This is the projected number of PET procedures in Year One. It is also 60% of the projected market growth in Year One [1,094 / 1,824 = 0.599]. However, as discussed above, the applicants did not adequately demonstrate that their assumption of 1.14 PET procedures per patient is reasonable and supported. Therefore, they did not adequately demonstrate that the proposed PET/CT scanner would perform 1,094 PET procedures during Year One.

As shown in the table above, in Years Two and Three, the applicants assume GIK would continue to capture 60% of the projected market growth. However, the applicants also project that the number of PET procedures to be performed at GIK would increase 47% [1,612 / 1,094 = 1.47] between Year One and Year Two. Further, the applicants project that the number of PET procedures to be performed at GIK would increase 35.6% [2,186 / 1,612 = 1.356] between Year Two and Year Three. However, the applicants do not provide documentation to support the projected growth in referrals. The physician letters do not state that referrals are expected to increase in Years Two and Three. Further, the physician letters make no reference to planned physician recruitment which might be expected to increase referrals. Therefore, the applicants did not adequately demonstrate that the proposed PET/CT scanner would perform 1,612 procedures in

Year Two or 2,186 procedures in Year Three on residents of the primary and secondary service area.

Step Seven – On page 50, the applicants state

> *"In Step 7, TPSA, LLC added the inmigration from out of the area. The 7.25% inmigration rate was added to reflect the amount of patients that will seek the services of TPSA/DRI from outside the six counties in the proposed service area. Inmigration rates were calculated by taking the average of inmigration of HSA II Fixed Scanners with >1,000 patients and more than 3 years of experience: MCHS 4.5% and FMC 10%. Inmigration was defined as the percentage of patients from outside the top 6 counties for each respective provider. The inmigration rate was multiplied by 2,080 for all three project years to introduce further conservatism by indexing the inmigration limit to capacity. NCBH was excluded due to its tertiary patient origin as the top six counties for NCBH reflect only 46% of its patient origin. Thus, NCBH inmigration outside of top 6 counties is 54%. High Point was excluded due to its lower volume and smaller service area."*

However, the applicants do not explain how the experience at Cone and FMC is similar to the expected experience at GIK. The applicants state they included only facilities that have provided PET services for three or more years. However, GIK does not currently provide PET services. Thus, the experience at GIK would be more like that of a facility that has just started providing PET services rather than the experience of facilities that have provided PET services for three or more years.

Further, the applicants do not adequately demonstrate that GIK is sufficiently similar to either Cone or FMC such that it is reasonable to assume that the experience at GIK would be similar to the experience at either hospital. The PET/CT scanners at Cone and FMC are located in and operated by tertiary hospitals as part of a comprehensive cancer center. In contrast, the proposed PET/CT scanner at GIK would be located in and operated by a diagnostic center offering only imaging services which is not located on or even near a hospital campus. Moreover, the applicants' data shows that the inmigration percentage varies significantly. The applicants do not adequately explain why it is more reasonable to use the average inmigration percentage for Cone and FMC combined than

to use the lower inmigration percentage at Cone. Thus, the applicants do not adequately demonstrate that inmigration would be 7.25% at GIK for PET services.

In addition, the applicants appear to have overstated the number of PET patients from Davie County as shown in the following table, which illustrates the projected number of PET patients attributed to "inmigration," as reported by the applicants in Section III.1(b), page 51.

COUNTY	# OF PATIENTS		
	YEAR ONE	YEAR TWO	YEAR THREE
Advance [1]	30	30	30
Davie	30	30	30
Caswell	30	30	30
Surry	30	30	30
Yadkin	30	30	30
Total	151	151	151

[1] Advance is not a county. Rather, it is an unincorporated area located within Davie County.

As shown in the above table, the applicants project 30 PET patients from "Advance" plus 30 PET patients from Davie County. However, Advance is an unincorporated area located within Davie County. The applicants do not state in the application that the 30 residents of Davie County expected to utilize the proposed PET/CT scanner is in addition to the 30 residents of Advance expected to utilize the proposed PET/CT scanner. Thus, it is not clear whether the applicants project to serve only 30 residents of Davie County, including residents of Advance, or 60 residents of Davie County.

In summary, projected utilization of the proposed PET/CT scanner is overstated in each of the first three operating years.

In addition, pursuant to 10A NCAC 14C .3703(a)(2), the applicants are required to demonstrate that the existing PET/CT scanners at Baptist and Cone performed at least 2,080 PET procedures in the last year. TPSA and DRI are both limited liability companies (LLCs), each with two members. The members of TPSA are:

- Baptist; and
- DRI.

The members of DRI are:

- Cone; and
- Radiology Imaging Partners, LLC.

In Section I.13(c), pages 12-13, the applicants state *"The joint venture members of TPSA and DRI have extensive experience and knowledge in providing cancer services .... MCHS* [Cone] *has extensive experience providing comprehensive cancer services to its patients. ... The Cancer Center at North Carolina Baptist Hospital is a national leader in cancer care and research."* In addition, in Section II.1, pages 16-18, the applicants state

> *"The physicians who have expressed support for the proposed project are affiliated with MCHS* [Cone] *and NCBH* [Baptist] *and the proposed service area was chosen to match areas where both providers have established cancer programs and referral relationships. ... The proposed ownership model, a joint venture affiliated with two of the leading major medical centers and their related health systems and affiliate networks and a major provider of imaging services in the Piedmont Triad, is an innovative alternative that no single provider could offer on its own. The participants in the joint venture and its owners recognize the collaborative value of the combined effort and have carefully designed the proposed project to emphasize the competitive competencies and experience that each brings to the project."*

Baptist and Cone each operates one fixed PET/CT scanner in HSA II. The following table illustrates the number of PET procedures performed at Baptist and Cone during FFY 2007, as reported by the hospitals in their 2008 hospital license renewal applications.

HOSPITAL	# OF PET PROCEDURES REPORTED ON THE 2008 HOSPITAL LICENSE RENEWAL APPLICATION
Baptist	1,919
Cone	1,955

As shown in the above table, during FFY 2007, only 1,919 PET procedures were performed on the one existing PET/CT scanner at Baptist. Further, only 1,955 PET procedures were performed on the one existing PET/CT scanner at Cone. Thus, the existing

PET/CT scanners at Baptist and Cone did not perform at least 2,080 PET procedures in the last year as required by 10A NCAC 14C .3703(a)(2).

Moreover, pursuant to 10A NCAC 14C .3703(a)(3), the applicants are required to demonstrate the existing PET/CT scanners at Baptist and Cone are each projected to perform at least 2,080 PET procedures during the third operating year of the project. However, the applicants failed to provide projected utilization for the existing PET/CT scanners at Baptist and Cone. Thus, they failed to demonstrate that the existing PET/CT scanners at Baptist and Cone would each perform at least 2,080 PET procedures during Year Three as required by 10A NCAC 14C .3703(a)(3).

In summary, the applicants did not adequately demonstrate the need the population to be served has for the proposed fixed PET/CT scanner. Therefore, the application is nonconforming with this criterion.

Novant & FMC. Novant Health, Inc. (**Novant**) and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center (**FMC**) propose to acquire a second PET/CT scanner and install it in renovated space in the Radiology Department of the hospital with the existing PET/CT scanner. The applicants do not propose to acquire a cyclotron; rather, they will continue to obtain radioisotopes from an off-site medical cyclotron and radioisotope production facility.

Population to be Served

The following table illustrates current and projected patient origin for PET services, as reported by the applicants in Section III.4(b), pages 83-84, and Section III.5(c), page 86.

COUNTY	% OF TOTAL	
	CURRENT PATIENT ORIGIN	PROPOSED PATIENT ORIGIN
Primary Service Area		
Forsyth	52.8%	53.2%
Davidson	12.9%	13.0%
Stokes	6.9%	6.9%
Surry	6.0%	6.1%
Yadkin	5.6%	5.7%
Davie	4.8%	4.8%
Wilkes	4.2%	4.3%
Subtotal	93.1%	94.0%
All Other HSA II Counties	2.4%	2.4%
Other Inmigration	4.5%	3.7%
Total [1]	100.0%	100.1%

[1] Totals do not add due to rounding.

In Section III.5(d), page 66, the applicants state *"The only change in patient origin is the decrease in Other Inmigration as a result of the newly approved PET scanner at Iredell Memorial Hospital."* The applicants adequately identified the population to be served.

Need Analysis

In Section III.1(a), pages 35-51, the applicants state

> *"FMC is proposing to add a second fixed PET/CT scanner in response to the increased demand for PET/CT services at FMC; the increasing use of PET for non-cancer applications and the need determination for one dedicated fixed PET scanner in HSA II. The existing PET/CT Scanner at FMC is located in the Department of Radiology and has been operational since January 2005 .... The proposed second PET scanner will be installed in the FMC Department of Radiology, adjacent to the current PET scanner.*
>
> ...
>
> *Although the 2008 SMFP indicates that one additional fixed PET scanner is needed in the HSA II Planning Region, it does not identity where, within the service area, that scanner should be located; thus, the analysis supporting the SMFP need determination must be extended to determine where an additional scanner should be*

located. In order to determine where the additional scanner should be located in the service area, FMC examined several elements that contribute to the need for and utilization of PET scanners. Those factors include:

- *Expanding PET Scanning Capabilities;*
- *Historical utilization of the Existing PET Scanners in HSA II and North Carolina;*
- *Historical Utilization of the Existing PET Scanner at FMC;*
- *Historical Cancer Incidence Rates in the FMC PET Service Area;* [sic] *and Counties*
- *Increasing 55+ Population in FMC PET Service Area.*

...

The Centers for Medicare and Medicaid Services (CMS) currently provides reimbursement for positron emission tomography with FDG-18 fluorodeoxyglucose (FDG-PET) and non-FDG-PET scans for the following clinical conditions:

Clinical Condition FDG-PET	*PET Coverage – is subject to additional guidelines set forth below and in the conditions and requirements of the CMS National Coverage Determinations*
Breast Cancer	*Staging, restaging, and monitoring response to therapy*
Colorectal Cancer	*Diagnosis, staging and restaging*
Esophageal Cancer	*Diagnosis, staging and restaging*
Head & Neck Cancers (excluding CNS and thyroid)	*Diagnosis, staging and restaging*
Lung Cancer (Non-Small Cell)	*Diagnosis, staging and restaging*
Lymphoma	*Diagnosis, staging and restaging*
Melanoma (Excludes evaluation of regional nodes)	*Diagnosis, staging and restaging*
Myocardial Viability	*Primary or initial diagnosis, or following an inconclusive SPECT prior to revascularization*
Refractory Seizures	*Covered for pre-surgical evaluation to determine localization of a focus of refractory seizure activity*
Solitary Pulmonary Nodule	*Characterization of indeterminate single pulmonary nodule*
Thyroid Cancer	*Restaging*
Cervical Cancer	*Staging as an adjunct to conventional imaging*
Dementia	*Differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's Disease (AD) – or – CMS approved practical clinical trial*
Clinical Condition NON FDG-PET	*PET Coverage – is subject to additional guidelines set forth below and in the conditions and requirements of the CMS National Coverage Determinations described below*
Perfusion of the heart using Rubidium 82 tracer	*Covered for noninvasive imaging of the perfusion of the heart*
Perfusion of the heart using ammonia N-13 tracer	*Covered for noninvasive imaging of the perfusion of the heart*

...

Private insurance coverage generally follows Medicare rulings and coverage decisions.

...

The National Oncologic PET Registry (NOPR) was developed in response to the CMS proposal to expand coverage for positron emission tomography with FDC-18 fluorodeoxyglucose (FDG-PET) to include cancers and indications not presently eligible for reimbursement by CMS. Reimbursement for those cancers can now be obtained if the patient's referring physician and the provider submit data to a clinical registry to assess the impact of FDC-PET on cancer patient management. The NOPR is implementing that registry for CMS. The FMC PET/CT Imaging program participates in the NOPR Registry.

...

Clinicians changed the intended [plan of] *care of more than one in three cancer patients as the result of FDG-PET scan findings, according to a study of data from the National Oncologic PET Registry, published online March 24, 2008 in the Journal of Clinical Oncology.*

...

On April 10, 2008, NOPR recommended that CMS provide coverage of FDC-PET scans for diagnosis, staging, and re-staging for all cancers. NOPR's recommendation is excellent news from a patient care perspective as well as for PET providers throughout the country. NOPR's recommendation is quite likely to result in an increased access to the technology and utilization, in clinically appropriate ways, of FDG-PET scans. ...

...

The use of PET for cardiac imaging is an evolving application for the technology. With the increasing support and recommendations the modality is receiving it will be

used more often as an initial test to diagnose coronary artery disease. Articles supporting the expanding use of PET cardiac imaging and other non-cancer applications are included in Exhibit 4.

...

... [A]*nnual PET procedure growth in North Carolina has been extremely rapid. Total PET utilization increased by double digits annually since inception in North Carolina in 2004. Growth in FFY 2007 is no longer at a double digit level but remains quite robust at 9.3%.*

...

... [A]*nnual PET growth in HSA II has been extremely rapid. ... Growth in FFY 2007 continues to exceed 20%.*

...

... [T]*here are three fixed PET scanners located in the eastern counties of HSA II. ...*

...

Very few patients from the five eastern counties seek PET services at FMC or NCBH, and with the exception of Davidson County the same is true for the western six counties. Few patients leave the six county region, and they seek care at FMC or NCBH. This is documented in the county PET market share analysis included in Exhibit 3, Table 7.

Use rates for PET services are higher in the western six counties and utilization of the two PET scanners is greater.

...

...

... [T]*here are more fixed PET scanners per population in the five eastern Counties* [sic] *of HSA II. However, use of PET is greater per population in the western counties of the HSA. Therefore, the need for an additional PET scanner is greater in the six western counties of the HSA, where FMC*

is located.

...

The existing PET scanner at FMC is the most highly utilized single PET scanner in the State. ... [I]n FFY 2006, the FMC PET scanner had highest volume of all twenty-five operational or approved fixed PET scanners in the State.

...

The existing PET scanner at FMC also had the highest volume of all five operational or approved fixed PET scanners in the HSA II Planning Region ....

...

Currently, FMC is running its one PET for two full shifts, 7:00 AM to 11:00 PM, Monday through Friday. Cancer patients, which make up the large majority of PET patients at this time, are fragile and often very ill. Having to schedule these patients late in the day and in the evening, has resulted in a hardship on the patient. The second PET scanner is needed to meet both the increased demand for PET at FMC as well as to provide better scheduling options for patients at a critical time in their diagnosis, staging and treatment of their disease.

Growth at FMC is expected to continue as FMC operationalizes the proposed second fixed PET scanner. Rapid improvements in the technology and the steady growth in the number and type of clinical studies for which CMS authorizes reimbursement will contribute to increased utilization of PET scans at FMC.

...

It is reasonable to expect that the number of scans per patient will continue to increase if/when reimbursement for FDG-PET scans for diagnosis, staging, and re-staging for all cancers is implemented by CMS consistent with the recommendation of the NOPR on April 10, 2008.

...

... [P]*rojected cancer incidence in Forsyth and the other FMC PET Service Area counties has remained relatively stable over the seven year period. That trend is expected to continue through the end of the third project year.*

...

... [T]*he FMC PET Service Area is projected to grow a total of 7.6% during the years 2007 through 2014, with a CAGR of 1.05% annually. In each of the Service Area counties, the largest growth is projected for the 55+ age group, with a CAGR of 2.36%. The National Cancer Institute / American Cancer Society (NCI/ACS) predicts that 77% of all new cancer cases will be diagnosed in persons 55 and over."*

The following table illustrates current and projected utilization of PET services at FMC, as reported by the applicants in Section IV.2, pages 68-69, and Section III.1(b), page 58. The existing PET/CT scanner began operating during Federal Fiscal Year (FFY) 2004. The proposed fixed PET scanner is projected to begin operating on January 1, 2010.

CALENDAR YEAR (CY)	# OF PET PROCEDURES				% INCREASE (DECREASE)
	PRIMARY SERVICE AREA	OTHER HSA II COUNTIES	OTHER INMIGRATION	TOTAL	
2005 (actual)				1,794	NA
2006 (actual)				2,588	44.3%
2007 (actual)				3,026	16.9%
2008 (projected)				3,466	14.5%
2009 (projected)				3,492	0.8%
2010 (projected) (Year 1)	3,460	113	136	3,708	6.2%
2011 (projected) (Year 2)	3,785	124	148	4,057	9.4%
2012 (projected) (Year 3)	3,965	130	155	4,250	4.8%

As shown in the above table, the existing PET/CT scanner at FMC performed 3,026 PET procedures during CY 2007, which is more than the 2,080 required by 10A NCAC 14C .3703(a)(2). Further, the applicants project that the existing and proposed PET/CT scanners will perform a total of 4,250 PET procedures during Year Three, which is an average of 2,125 procedures per scanner [4,250 / 2 = 2,125]. The applicants provide the assumptions and methodology used to project utilization of the existing and

proposed PET/CT scanners in Section III.1(b), pages 51-58. The applicants' methodology is summarized and discussed below.

Step One – In Step One, the applicants obtained the estimated number of new cancer cases in 2007 for each county in the primary service area and the other HSA II counties from the North Carolina Cancer Registry. See Exhibit 4 of the application.

Step Two – In Step Two, the applicants calculated age specific cancer incidence rates for each county in the primary service area and the other HSA II counties. In Section III.1(b), page 52, the applicants state *"FMC divided projected 2007 new cancer cases for each of the FMC/FRCC PET Service Area counties into two age groups: persons under 55 and person 55 and over based upon the* [National Cancer Institute/American Cancer Society] *assumption that the over 55 population will represent 77% of new cancer cases."* The following table illustrates the age specific cancer incidence rates and the projected number of new cancer cases in 2007, as calculated by the applicants. See page 52 and Exhibit 3, Tables 1 and 2.

COUNTY	CANCER INCIDENCE RATE PER 100,000	PROJECTED NEW CANCER CASES IN 2007
Forsyth		
< 55	140.2	362
55 and older	1,527.4	1,213
Total	466.4	1,575
Davidson		
< 55	154.9	182
55 and older	1,545.5	608
Total	504.5	790
Davie		
< 55	161.3	48
55 and older	1,484.9	162
Total	514.3	210
Stokes		
< 55	151.5	53
55 and older	1,522.3	177
Total	493.9	230
Surry		
< 55	177.8	94
55 and older	1,567.2	316
Total	560.1	410
Wilkes		
< 55	178.7	86
55 and older	1,524.9	289
Total	558.0	375
Yadkin		
< 55	162.7	46
55 and older	1,548.0	154
Total	523.2	200
All Other HSA II Counties		
< 55	140.8	922
55 and older	1,553.3	3,088
Total	469.7	4,010

Step Three – In Step Three, the applicants used the age specific cancer incidence rates from Step Two and projected population by age cohort obtained from the N.C. Office of State Demographics to estimate the number of new cancer cases in each county in the primary service area and the other HSA II counties through CY 2014. The following table illustrates the projected number of new cancer cases for each county in the service area through the third operating year (CY 2012), as calculated by the applicants. See page 53 and Exhibit 3, Tables 1-4.

PROJECTED NUMBER OF NEW CANCER CASES THROUGH YEAR THREE

COUNTY	CY 2007	CY 2008	CY 2009	CY 2010 YEAR ONE	CY 2011 YEAR TWO	CY 2012 YEAR THREE
Forsyth	1,575	1,610	1,646	1,682	1,720	1,759
Davidson	790	805	820	835	850	866
Davie	210	216	221	227	233	240
Stokes	230	235	240	245	250	255
Surry	410	415	420	426	431	437
Wilkes	375	380	386	391	396	402
Yadkin	200	204	208	212	216	221
All Other HSA II Counties	4,010	4,088	4,168	4,250	4,334	4,419
TOTAL	**7,800**	**7,953**	**8,109**	**8,268**	**8,430**	**8,599**

Step Four – On pages 53-54, the applicants state

"The number of projected PET scans for cancer cases in the FMC PET Service Area during the period 2008 through 2012 was estimated using the following two assumptions:

1. *At the present time, 90% of the cancer cases are appropriate for PET scan. This percentage is expected to increase to 100% in the near future. It is reasonable to expect that the percentage of cancer eases appropriate for PET to increase to 100% when reimbursement for FDG-PET scans for diagnosis, staging, and re-staging for all cancers is implemented by CMS consistent with the recommendation of the NOPR on April 10, 2008. However, to be conservative, FMC phased-in an increase of only 5% during the first three project years (CYs 2010- 2012), to achieve a total of 95% by the end of project year 3.*

2. *In CY 2007, approximately 40% of the cancer cases which are appropriate for PET scan at FMC received more than one PET scan. For purposes of these projections, this percentage remains constant through the third year of operation of the project. ... [T]he percent of patients scanned more than once at FMC was over 39% in calendar year 2007, and the overall trend is increasing as reflected in Exhibit 3, Table 9 ....*

Based upon discussions with the physicians and staff of the FMC Department of Radiology, PET/CT imaging program,

those assumptions are consistent with their participation in NOPR, as well as the experience of patients at FMC.

The following table illustrates the projected number of PET procedures for each county in the primary service area and other HSA II counties through the third operating year, as calculated by the applicants. See page 54 and Exhibit 3, Tables 1 and 2.

PROJECTED NUMBER OF PET PROCEDURES FOR CANCER CASES

COUNTY	CY 2008	CY 2009	CY 2010 YEAR ONE	CY 2011 YEAR TWO	CY 2012 YEAR THREE
Forsyth	2,029	2,074	2,120	2,288	2,339
Davidson	1,014	1,033	1,052	1,131	1,152
Davie	272	279	286	310	319
Stokes	296	302	308	332	339
Surry	523	530	536	573	581
Wilkes	479	486	493	527	535
Yadkin	257	262	267	288	293
All Other HSA II Counties	5,151	5,252	5,355	5,764	5,877
TOTAL	**10,021**	**10,218**	**10,417**	**11,213**	**11,435**

Step Five – On page 55, the applicants state

"The number of projected PET scans for non-cancer cases in the FMC PET Service Area during the period 2008 through 2012 was estimated using the following two assumptions:

1. *In CY 2007, approximately 1.5% of PET scans at FMC were performed on patients who did not have cancer. Those PET scans were performed for cardiology and neurology cases.*

2. *The percentage of non-cancer cases appropriate for PET at FMC is expected to increase to 5% in CY 2010, 7% in CY 2011, and 10% in CY 2012. Those PET scans are anticipated to be performed for cardiology and neurology cases.*

Those assumptions are consistent with the expectations of physicians utilizing PET at FMC and staff of the Department of Radiology, Nuclear Medicine Section. In addition, literature included in Exhibit 4 discusses the future use of PET for cardiac procedures and neurological procedures."

The following table illustrates the projected number of cardiac and neurological PET procedures to be performed in each county in the service area through the third operating year, as calculated by the applicants. See page 55 and Exhibit 3, Tables 1 and 2.

PROJECTED NUMBER OF PET PROCEDURES FOR CARDIAC AND NEUROLOGICAL CASES

COUNTY	CY 2008	CY 2009	CY 2010 YEAR ONE	CY 2011 YEAR TWO	CY 2012 YEAR THREE
Forsyth	41	41	106	160	234
Davidson	20	21	53	79	115
Davie	5	6	14	22	32
Stokes	6	6	15	23	34
Surry	10	11	27	40	58
Wilkes	10	10	25	37	53
Yadkin	5	5	13	20	29
All Other HSA II Counties	103	105	268	403	588
TOTAL	**200**	**205**	**521**	**784**	**1,143**

Step Six – In Step Six, the applicants combined the results of Steps Four and Five. The following table illustrates the total number of PET procedures projected to be performed for each county in the primary service area and other HSA II counties through the third operating year, as calculated by the applicants. See page 56 and Exhibit 3, Tables 1 and 2.

PROJECTED NUMBER OF PET PROCEDURES FOR CANCER, CARDIAC AND NEUROLOGICAL CASES

COUNTY	CY 2008	CY 2009	CY 2010 YEAR ONE	CY 2011 YEAR TWO	CY 2012 YEAR THREE
Forsyth	2,069	2,074	2,226	2,448	2,573
Davidson [1]	1,034	1,033	1,105	1,210	1,268
Davie	277	284	301	332	350
Stokes	302	308	324	355	373
Surry	534	540	563	613	639
Wilkes	489	495	517	564	588
Yadkin	262	267	281	308	323
All Other HSA II Counties	5,254	5,357	5,623	6,167	6,465
TOTAL	**10,221**	**10,358**	**10,940**	**11,997**	**12,579**

[1] In CY 2009, for Davidson County, the applicants did not add the 41 non-cancer PET procedures to the 1,033 cancer PET procedures.

Step Seven – On pages 56-57, the applicants state

"FMC calculated its annual and three-year average market share of the FMC PET Service Area based upon data from the 2006, 2007, and 2008 Annual Hospital Licensure Renewal Applications ....

...

FMC's market share of PET volume has increased and

decreased across the years and counties .... Because of the fluctuation in annual market share, FMC utilized the three-year average market share to project its future PET volume in calendar years 2008 through 2012. Additionally, FMC used the aggregate three-year average market share for the Other HSA II Counties of 2.0% because its market share of those counties is small in comparison to its market share from the western HSA II counties.

FMC multiplied the projected number of PET scans for cancer and non-cancer cases in the FMC PET Service Area, determined in Step 6, by the County three-year average market share to project the PET scans that FMC will perform in calendar years 2008 through 2012."

The following table illustrates the three year average market share for FMC and the projected number of PET procedures to be performed at FMC on residents of the primary service area and the other HSA II counties through the third operating year, as calculated by the applicants. See page 57 and Exhibit 3, Tables 1 and 2.

PROJECTED NUMBER OF PET PROCEDURES TO BE PERFORMED AT FMC ON RESIDENTS OF THE PRIMARY SERVICE AREA AND OTHER COUNTIES IN HSA II

COUNTY	FMC'S AVERAGE MARKET SHARE (FFY 2005 – FFY 2007)	CY 2010 YEAR ONE	CY 2011 YEAR TWO	CY 2012 YEAR THREE
Forsyth	76.6%	1,706	1,876	1,971
Davidson	53.4%	589	646	676
Davie	71.0%	161	166	170
Stokes	76.8%	248	273	286
Surry	51.3%	289	315	328
Wilkes	52.6%	272	297	309
Yadkin	69.3%	195	213	224
Subtotal		3,460	3,786	3,964
All Other HSA II Counties	2.0%	113	124	130

Step Eight – On page 58, the applicants state

"FMC projects immigration of 3.7% from counties and states other than the twelve Service Area [sic] *counties. FMC's historical patient origin for PET services is 4.5%. However, a new fixed PET scanner was recently approved in Iredell County, which was 1.1% of FMC patient origin in FFY 2007. Therefore, FMC decreased In-migration*

[sic] *to reflect the impact of the new scanner in Iredell County as reflected in Exhibit 3, Table 15. In-migration from other North Carolina counties and other states is expected to remain constant based upon FMC's experience as* [sic] *tertiary medical center with a regional cancer center."*

The following table illustrates total projected utilization of both PET/CT scanners at FMC through the third operating year, as calculated by the applicants. See page 58 of the application.

	Projected # of PET Procedures		
	CY 2010 Year One	CY 2011 Year Two	CY 2012 Year Three
Primary Service Area	3,460	3,785	3,965
Other HSA II Counties	113	124	130
Inmigration (3.7%)	136	148	155
Total	3,708	4,057	4,250

The applicants adequately demonstrate that projected utilization is reasonably based on historical utilization of the existing PET/CT scanner at FMC and increased utilization based on expanded coverage by Medicare and third party payors and expanded uses for the technology.

In summary, the applicants adequately identified the population to be served and adequately demonstrated the need that population has for the proposed PET/CT scanner. Therefore, the application is conforming to this criterion.

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

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 – TPSA & DRI

C – Novant & FMC

TPSA & DRI. In Section II.5, pages 20-22, the applicants discussed several alternatives they considered prior to submission of this application. However, the application is not conforming to all applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (13a), (13b), (18a) and the Criteria and Standards for Positron Emission Tomography Scanner promulgated in 10A NCAC 14C .3700. Therefore, the applicants did not adequately demonstrate that the proposal is their most effective alternative and the application is nonconforming to this criterion.

Novant & FMC. In Section II.5, pages 21-23, the applicants discussed several alternatives they considered prior to submission of this application. Further, the application is conforming to all applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20) and the Criteria and Standards for Positron Emission Tomography Scanner promulgated in 10A NCAC 14C .3700. Therefore, the applicants adequately demonstrated that the proposal is their most effective alternative and the application is 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 – TPSA & DRI
C – Novant & FMC

TPSA & DRI. In Section VIII.1, page 78, the applicants project the total capital cost for the project will be as follows:

	TPSA	DRI	TOTAL
Renovation Costs		$320,893	$320,893
Fixed Equipment	$1,940,875		$1,940,875
Movable Equipment		$47,000	$47,000
Furniture		$17,000	$17,000
Consultant Fees	$20,000	$50,000	$70,000
Information Technology		$50,000	$50,000
Jurisdictional Fees		$9,034	$9,034
Contingency	$200,288	$107,671	$307,959
Total	$2,161,163	$601,598	$2,762,761

In Section IX.1, page 82, the applicants state there will be no start-up or initial operating expenses. In Section VIII.3, page 87, the applicants state that the capital costs of the project will be financed with two conventional loans. Exhibit 21 contains a May 12, 2008 letter signed by a Senior Vice President of First Citizens Bank addressed to TPSA, which states *"Please be advised that First Citizens Bank & Trust Co, Inc. would be pleased to provide financing in the amount of $2,161,163.00 for a PET-CT scanner for Triad PET Scanner Alliance, LLC."* Exhibit 21 also contains a May 14, 2008 letter signed by a Credit Underwriter with Wachovia Bank, N.A. addressed to DRI, which states *"Please be advised that Wachovia Bank, NA would be pleased to provide equipment financing in the form of a conventional loan to our client, Diagnostic Radiology and Imaging, LLC in the amount of $601,598."* The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project.

In the projected revenue and expense statement, the applicants project that revenues for the PET/CT scanner will exceed operating expenses in the third operating year. The assumptions used by the applicants in preparation of the pro formas are in Tab 13 of the application. However, the applicants' utilization projections are unsupported and unreliable. Consequently, operating expenses and revenues that are based on the applicants' projected utilization are also not reliable. See Criterion (3) for discussion of projected utilization. Therefore, the applicants did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, the application is nonconforming with this criterion.

Novant & FMC. In Section VIII.1, page 120, the applicants project the total capital cost for the project will be $4,527,228, including $1,277,870 for renovation costs, $2,935,708 for fixed equipment, $37,000 for information technology, $121,919 for consultant fees and $154,731 for contingencies. In Section IX.1, page 110, the applicants project there will be no start-up or initial operating expenses. In Section VIII.3, page 101, the applicants state that the capital cost of the project will be financed with the accumulated reserves of Novant. Exhibit 8 contains audited financial statements for Novant. As of December 31, 2007, Novant had $321,913,000 in cash and cash equivalents, $279,169,000 in short-term investments, $835,829,000 in long-term investments, $3,448,599,000 in total assets and $1,655,127,000 in net assets (total assets less total liabilities).

Exhibit 8 also contains a May 7, 2007 letter signed by the Chief Financial Officer for Novant, which states

> *"As the Chief Financial Officer for Novant Health, Inc., I have authority to obligate funds from accumulated reserves of Novant Health for projects undertaken by Forsyth Medical Center. ... I can and will commit Novant's reserves to cover all of the capital costs associated with this project, including the project capital cost of $4,527,228. ... In addition, Novant and FMC reserve the right to consider in the future funding of all or a portion of this project using bond proceeds."*

The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the proposed project.

In the projected revenue and expense statement, the applicants project that revenues will exceed operating expenses in each of the first three years of operation. The assumptions used by the applicants in preparation of the pro formas are reasonable, including projected utilization, operating expenses and charges. See the Financials Tab of the application for the pro formas and assumptions. See Criterion (3) for discussion of utilization projections. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is conforming to this criterion.

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

NC – TPSA & DRI
C – Novant & FMC

TPSA & DRI. The 2008 SMFP establishes a need for one additional fixed dedicated PET scanner in HSA II, which includes Alamance, Caswell, Davidson, Davie, Forsyth, Guilford, Randolph, Rockingham, Stokes, Surry and Yadkin counties. See Criterion (1) for discussion. TPSA and DRI do not propose to acquire more than one fixed dedicated PET scanner to be installed and operated in HSA II. However, the applicants failed to adequately demonstrate the need for the level of services proposed to be provided. See Criterion (3) for discussion. Consequently, TPSA

and DRI did not adequately demonstrate that the proposed project would not result in unnecessary duplication of existing or approved PET services in HSA II. Therefore, the application is nonconforming to this criterion.

Novant & FMC. The 2008 SMFP establishes a need for one additional fixed dedicated PET scanner in HSA II, which includes Alamance, Caswell, Davidson, Davie, Forsyth, Guilford, Randolph, Rockingham, Stokes, Surry and Yadkin counties. See Criterion (1) for discussion. Novant and FMC do not propose to acquire more than one fixed dedicated PET scanner to be installed and operated in HSA II and adequately demonstrates the need for the level of services proposed to be provided. See Criterion (3) for discussion. Novant and FMC adequately demonstrate that the proposed project would not result in unnecessary duplication of existing or approved PET services in HSA II. Therefore, the application is conforming to this criterion.

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

C – Both Applications

TPSA & DRI. The following table illustrates the applicants' projected staffing for GIK, as reported in Section VII.2, page 76.

POSITION	PROJECTED FULL-TIME EQUIVALENT (FTE) STAFF POSITIONS		
	YEAR ONE	YEAR TWO	YEAR THREE
X-ray Technicians	1.688	1.688	1.688
Ultrasound Technicians	1.125	1.125	1.125
Mammography/Bone Density Technicians	1.125	1.125	1.125
CT scanner Technicians	2.250	2.250	2.250
PET/CT scanner Technicians	3.000	3.000	3.000
Physicists	0.500	0.500	0.500
Reception and *"Pre Cert"*	2.250	2.250	2.250
Transcriptionists	1.125	1.125	1.125
Total	**13.063**	**13.063**	**13.063**

As shown in the above table, DRI proposes to employ 3.0 FTE Nuclear Medicine Technologist staff positions for the proposed PET/CT scanner. In Section VII.3(a), page 73, the applicants state *"Existing DRI staff will be used for administrative functions."* In

Section VII.3(c), page 73, the applicants state *"Reference letters in Exhibit 12 ... from NCBH and MCHS indicating a willingness to assist in the process of obtaining clinical staff for DRI employment or contracting."* Further, in Section V.3(c), page 63, the applicants state that Taylor H. Stroud, M.D. has agreed to serve as the medical director for the proposed PET/CT scanner. Exhibit 17 contains a letter signed by Dr. Stroud, which states that he has agreed to serve as medical director. Exhibit 16 contains a copy of his curriculum vitae, which documents his education and training as a board-certified radiologist and nuclear medicine physician. In Section VII.6, page 74, the applicants state the existing administrative and support personnel at GIK are adequate to support the proposed PET/CT scanner. Also, in Section II.8, page 32, and Exhibit 5, the applicants identify the providers of physics and engineering services. The applicants demonstrated the availability of adequate health manpower and administrative personnel for the provision of dedicated PET services, and therefore, the application is conforming to this criterion.

Novant & FMC. The following table illustrates the applicants' current and projected staffing for PET services, as reported in Section VII.2, page 93.

POSITION	CURRENT FTE STAFF POSITIONS CY 2008	PROJECTED FTE STAFF POSITIONS		
		YEAR ONE CY 2010	YEAR TWO CY 2011	YEAR THREE CY 2012
Nuclear Medicine / PET Technologist	5.6	8.6	8.6	8.6
Diagnostic Operations Assistants	0.0	1.5	1.5	1.5
Radiation Safety Officer	0.2	0.2	0.2	0.2
Director, FMC Radiology	0.1	0.1	0.1	0.1
Clinical Manager, FMC Radiology	0.3	0.3	0.3	0.3
Supervisor, Nuclear Medicine	1.0	1.0	1.0	1.0
Total	**7.2**	**11.7**	**11.7**	**11.7**

As shown in the above table, FMC proposes to employ 3.0 additional FTE PET Technologist staff positions and 1.5 administrative operations assistant staff positions for the existing and proposed PET/CT scanners. In Section VII.6, page 96, the applicants state *"The project will be staffed using existing administrative, support, and physician personnel."* In Section VII.3(c), page 94, the applicants state *"No difficulties are anticipated in filling the positions to support the additional ... volumes at FMC."* Further, in Section V.3(c), page 78, the applicants state that the current medical director for PET services, Liston Orr, MD, will continue to serve as medical director. Exhibit 5 contains a letter

signed by Dr. Orr, which states that he is the medical director for PET services at FMC. Exhibit 5 also contains a copy of his curriculum vitae, which documents his education and training as a board-certified radiologist and nuclear medicine physician. In Section VII.6, pages 96, the applicants state FMC's existing administrative and support personnel are adequate to support the proposed PET/CT scanner. Also, in Section II.8, page 33, and Exhibit 5, the applicants identify FMC's providers of physics and engineering services. The applicants demonstrated the availability of adequate health manpower and administrative personnel for the provision of dedicated PET services, and 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 – Both Applications

TPSA & DRI. In Section IV.5, page 60, the applicants demonstrate that all of the necessary ancillary and support services will be available. In Section II.8, pages 30-31, the applicants identify DRI's source for radioisotopes and state that they will form a clinical oversight committee for the proposed PET services. In Section V.2, page 62, DRI states *"Formal transfer agreements are not required for the provision of outpatient diagnostic imaging services."* DRI lists the existing health care facilities with which it has informal arrangements, including Cone and Baptist. Exhibit 13 contains letters signed by area physicians supporting the applicant's proposal to acquire a PET scanner. Exhibit 18 contains letters of support for the proposal from the following: 1) Cone; 2) Hoots Memorial Hospital; and 3) Stokes Reynolds Memorial Hospital. The applicants adequately demonstrated that the proposed project would be coordinated with the existing health care system and that the necessary ancillary and support services will be available. Therefore, the application is conforming to this criterion.

Novant & FMC. In Section IV.5, page 71, the applicants demonstrate that all of the necessary ancillary and support services will be provided. In Section II.8, pages 32, and Exhibit 5, the applicants identify FMC's source for radioisotopes and state that FMC has an existing clinical oversight committee for PET

services. In Exhibit 12, the applicants list the existing health care facilities with which FMC has transfer agreements. Exhibit 13 contains letters signed by area physicians supporting the applicants' proposal to acquire a second PET/CT scanner. The applicants adequately demonstrated that the proposed project would be coordinated with the existing health care system and that the necessary ancillary and support services will be available. 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 Applications

(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 Applications

(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 Applications

(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 Applications

(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;

NC – TPSA & DRI
C – Novant & FMC.

TPSA & DRI are both limited liability companies (LLCs), each with two members. The members of TPSA are:

- Baptist; and
- DRI.

The members of DRI are:

- Cone; and
- Radiology Imaging Partners, LLC.

In Section I.13(c), pages 12-13, the applicants state *"The joint venture members of TPSA and DRI have extensive experience and knowledge in providing cancer services .... MCHS* [Cone] *has extensive experience providing comprehensive cancer services to its patients. ... The Cancer Center at North Carolina Baptist Hospital is a national leader in cancer care and research."* In addition, in Section II.1, pages 16-18, the applicants state

"The physicians who have expressed support for the proposed project are affiliated with MCHS [Cone] *and NCBH* [Baptist] *and the proposed service area was chosen to match areas where both providers have established cancer programs and referral relationships. ... The proposed ownership model, a joint venture affiliated with two of the leading major medical centers and their related health systems and affiliate networks and a major provider of imaging services in the Piedmont Triad, is an innovative alternative that no single provider could offer on its own. The participants in the joint venture and its owners recognize the collaborative value of the combined effort and have carefully designed the proposed project to emphasize the competitive competencies and experience that each brings to the project."*

Baptist and Cone each operate one fixed PET/CT scanner in HSA II. However, the applicants did not provide the current payor mix for the existing PET/CT scanners at Baptist or Cone. Therefore, they did not demonstrate that medically underserved populations currently have adequate access to the existing PET services at Baptist and Cone. Consequently, the application is nonconforming with this criterion.

Novant & FMC. In Section VI.11, page 91, the applicants report the following payor mix for the existing PET scanner at FMC.

CY 2007 PAYOR MIX FOR PET SERVICES AT FMC

PAYOR CATEGORY	% OF TOTAL PET PROCEDURES
Self pay / Indigent	2.49%
Medicare	52.06%
Medicaid	4.87%
Commercial Insurance & Managed Care	17.61%
BCBS of NC	19.73%
State Employees Health Plan	1.82%
Other Government	1.42%
TOTAL	**100.00%**

The applicants demonstrated that medically underserved populations currently have adequate access to FMC's existing PET services.

(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;

NC – TPSA & DRI
C – Novant & FMC

TPSA & DRI. In Section VI.8, page 68, the applicants state *"TPSA is a newly created entity. Neither TPSA nor DRI have experienced any civil rights equal access complaints in the last five years."* TPSA and DRI are both LLCs, each with two members. The members of TPSA are:

- Baptist; and
- DRI.

The members of DRI are:

- Cone; and
- Radiology Imaging Partners, LLC.

In Section I.13(c), pages 12-13, the applicants state *"The joint venture members of TPSA and DRI have extensive experience and knowledge in providing cancer services .... MCHS* [Cone] *has extensive experience providing comprehensive cancer services to its patients. ... The Cancer Center at North Carolina Baptist Hospital is a national leader in cancer care and research."* In addition, in Section II.1, pages 16-18, the applicants state

"The physicians who have expressed support for the proposed project are affiliated with MCHS [Cone] *and NCBH* [Baptist] *and the proposed service area was chosen to match areas where both providers have established cancer programs and referral relationships. ... The proposed ownership model, a joint venture affiliated with two of the leading major medical centers and their related health systems and*

affiliate networks and a major provider of imaging services in the Piedmont Triad, is an innovative alternative that no single provider could offer on its own. The participants in the joint venture and its owners recognize the collaborative value of the combined effort and have carefully designed the proposed project to emphasize the competitive competencies and experience that each brings to the project."

Baptist and Cone each operate one fixed PET/CT scanner in HSA II. However, the applicants do not state whether Baptist or Cone have had any civil rights equal access complaints in the last five years. Therefore, the application is nonconforming with this criterion.

Novant & FMC. In Section VI.8, page 90, the applicants state *"There have been no such complaints filed against Novant Health, Inc., Novant Health Triad Region (NHTR), and FMC during the past five years."*

(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 – Both Applications

TPSA & DRI. In Section VI.12, page 77, the applicants project the payor mix for PET services during the second operating year, as illustrated in the table below.

4/1/2010 – 3/31/2011
PET/CT SCANNER
PROJECTED PAYOR MIX

PAYOR CATEGORY	% OF TOTAL PET PROCEDURES
Self Pay / Indigent / Charity	4%
Medicare	60%
Medicaid	6%
Commercial Insurance, Managed Care & Workers Compensation	30%
TOTAL	**100%**

In Section V.12, pages 70-71, the applicants state

"To develop the proposed payer mix, TPSA/DRI analyzed the payer mix reported by Solucient for PET procedures for the counties in HSA II. The following Table 25 displays the Solucient payer mix:

Table 25
Existing and Projected Payer Mix in Proposed Service Area
From Solucient Market Planner Plus

	2007	2012
Medicaid Nonrisk	3.5%	3.3%
Medicare Nonrisk	52.9%	53.8%
Medicare Risk	7.1%	7.4%
Private Nonrisk	26.0%	25.2%
Private Risk	8.9%	8.8%
Uninsured	1.6%	1.5%
Total:	100.0%	100%

Source: Solucient Market Planner Plus. Accessed March 11 and April 2, 2008.

TPSA/DRI then adapted the Solucient payer mix to adjust it for its own admission policies. Specifically, TPSA/DRI did not believe the low Medicaid percentage represented the experience of its Members [sic] *or the patients DRI would accept per its admission policy. Thus, TPSA/DRI increased the Medicaid percentage significantly, increased the self-pay, and reduced the commercial payer mix expectations."*

The applicants demonstrated that medically underserved populations would have adequate access to the proposed PET services. Therefore, the application is conforming to this criterion.

Novant & FMC. In Section VI.12, page 92, the applicants project the payor mix for PET services during the second operating year, as illustrated in the table below.

CY 2011
PET/CT SCANNER
PROJECTED PAYOR MIX

PAYOR CATEGORY	% OF TOTAL PROCEDURES
Self pay / Indigent	2.48%
Medicare	54.69%
Medicaid	5.06%
Commercial Insurance & Managed Care	15.44%
BCBS of NC	19.74%
State Employees Health Plan	0.86%
Other Government	1.73%
TOTAL	**100.00%**

Novant and FMC demonstrated that medically underserved populations would 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 – Both Applications

TPSA & DRI. See Section VI.7 of the application. The information provided by the applicants is reasonable and credible and supports a finding of conformity with this criterion.

Novant & FMC. See Section VI.7 of the application. The information provided by the applicants 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 – Both Applications

TPSA & DRI. See Section V.1 and referenced exhibits for documentation that GIK will accommodate the clinical needs of health professional training programs in the area *"via training agreements in place with MCHS* [Cone] *and NCBH."* The

information provided is reasonable and credible and supports a finding of conformity with this criterion.

Novant & FMC. See Section V.1 and referenced exhibits for documentation that FMC currently accommodates the clinical needs of health professional training programs in the area and that it will continue to do so. 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 – TPSA & DRI
C – Novant & FMC

TPSA & DRI did not adequately demonstrate that their proposal to acquire a fixed dedicated PET scanner would have a positive impact upon the cost effectiveness of the proposed services. Therefore, the application is nonconforming to this criterion. See Criteria (1), (3) and (5) for discussion.

Novant & FMC adequately demonstrate that their proposal to acquire a fixed dedicated PET scanner would have a positive impact upon the cost effectiveness, quality and access to the proposed services. Therefore, the application is conforming to this criterion. See Criteria (1), (3), (5), (7), (8), (13) and (20) for discussion.

(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 – Both Applications

TPSA & DRI are both limited liability companies (LLCs), each with two members. The members of TPSA are:

- Baptist; and
- DRI.

The members of DRI are:

- Cone; and
- Radiology Imaging Partners, LLC.

In Section I.13(c), pages 12-13, the applicants state *"The joint venture members of TPSA and DRI have extensive experience and knowledge in providing cancer services .... MCHS* [Cone] *has extensive experience providing comprehensive cancer services to its patients. ... The Cancer Center at North Carolina Baptist Hospital is a national leader in cancer care and research."* In addition, in Section II.1, pages 16-18, the applicants state

> *"The physicians who have expressed support for the proposed project are affiliated with MCHS* [Cone] *and NCBH* [Baptist] *and the proposed service area was chosen to match areas where both providers have established cancer programs and referral relationships. ... The proposed ownership model, a joint venture affiliated with two of the leading major medical centers and their related health systems and affiliate networks and a major provider of imaging services in the Piedmont Triad, is an innovative alternative that no single provider could offer on its own. The participants in the joint venture and its owners recognize the collaborative value of the combined effort and have carefully designed the proposed project to emphasize the competitive competencies and experience that each brings to the project."*

Cone and Baptist are accredited by the Joint Commission of Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, DFS, no incidents occurred at either hospital, within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

Novant & FMC. FMC is accredited by the Joint Commission of Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, DFS, no incidents occurred at the hospital, within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. 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 – TPSA & DRI
C – Novant & FMC

TPSA & DRI. The proposal is not conforming to all applicable Criteria and Standards for Positron Emission Tomography Scanner, promulgated in 10A NCAC 14C .3700, as discussed below.

Novant & FMC. The proposal is conforming to all applicable Criteria and Standards for Positron Emission Tomography Scanner, promulgated in 10A NCAC 14C .3700, as 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."*

-C- **TPSA & DRI** provided 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, by clinical area, in Section II.8, page 25, Section III.1, page 51, and Exhibit 4. The assumptions and methodologies used are provided in Section III.1, page 34-51. See Criterion (3) for discussion regarding the reasonableness of the projections.

-C- **Novant & FMC** provided 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, by clinical area, in Section II.8, page 27, Section IV.2, page 69, and Exhibit 3. The assumptions and methodologies used are provided in Section III.1, pages 35-58. See Criterion (3) for discussion regarding the reasonableness of the projections.

.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; and [sic]
(G) neuroangiography;
(H) radiation oncology;
(I) medical oncology; and
(J) surgical oncology.

-C- **TPSA & DRI.** In Section II.8, page 25, the applicants state *"Mobile MRI, CT, and ultrasound services will be available onsite at GIK. If any of the other aforementioned services are required, GIK will refer the patient to MCHS* [Cone], *NCBH* [Baptist] *or the provider of the patient's choosing."* Exhibit 5 contains letters from Cone and Baptist, each stating that all of the services listed in this rule are provided at the hospital and will be available for GIK's PET patients.

-C- **Novant & FMC.** Exhibit 5 contains a letter signed by the Chief Operating Officer of FMC that all of the services listed above are and will continue to be available at FMC.

.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- **TPSA & DRI** state in Section II.8, page 26, that they will establish the proposed fixed PET/CT scanner as a regional resource and that they will not have any administrative, clinical or charge requirements that would impede physician referrals of patients for whom PET testing would be appropriate. See also the letter in Exhibit 8.

-C- **Novant & FMC** state in Section II.8, pages 28-29, that the proposed and existing fixed PET/CT scanners will continue to operate as a regional resource and that they do not and will not have any administrative, clinical or charge requirements that would impede physician referrals of patients for whom PET testing would be appropriate.

.3702(b)(3)(B) 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: ... (B) provide scheduled hours of operation for the PET scanner of a minimum of 12 hours per day, six days a week, except for mobile scanners."*

-C- **TPSA & DRI** state in Section II.8, page 26, that the scheduled hours of operation for the proposed PET/CT scanner will be 7 am to 7 pm Monday through Friday. Thus, the proposed PET/CT scanner will be staffed and operational 12 hours per day five days per week.

-C- **Novant & FMC** state in Section II.8, page 29, that the scheduled hours of operation for the existing and proposed PET/CT scanners will be 7 am to 7 pm Monday through Friday. Thus, the existing and proposed PET/CT scanners will be staffed and operational 12 hours per day, five days 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 application** proposes the acquisition of 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 application** proposes the acquisition of 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- **TPSA & DRI.** Exhibit 7 contains a letter from the U.S. Food and Drug Administration notifying the vendor that the proposed PET/CT scanner has been certified for clinical use. Exhibit 9 also contains a letter from PETNET Solutions, the pharmaceutical vendor, which states that the pharmaceuticals comply with the requirements of the U.S. Food and Drug Administration.

-C- **Novant & FMC.** Exhibit 5 contains a letter from the U.S. Food and Drug Administration notifying the vendor that the proposed PET/CT scanner has been certified for clinical use. Exhibit 5 also contains a letter signed by FMC's Radiation Safety Officer, which states that the pharmaceuticals obtained from PETNET Solutions comply with the requirements of 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."*

-NA- **Both applications.** Neither proposal includes the production of radioisotopes on site. See 10A NCAC 14C .3704(b), below.

.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, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (2) quality control measures and assurance of PET tomography and associated instrumentation.*

-C- **TPSA & DRI.** In Section II.8, page 27, the applicants describe their quality control measures for the proposed PET services. Exhibit 10 contains a copy of GIK's proposed PET Quality Management Program.

-C- **Novant & FMC.** Exhibit 5 contains a letter signed by FMC's Radiation Safety Officer which states FMC will continue to have quality control measures for PET services.

.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, manufacturer's specifications, and licensing requirements. The following shall be addressed: ... (3) radiation protection and shielding.*

-C- **TPSA & DRI.** In Section II.8, pages 28, the applicants describe their radiation protection and shielding policies and procedures.

-C- **Novant & FMC.** Exhibit 5 contains a letter signed by FMC's Radiation Safety Officer which states FMC will continue to have radiation protection and shielding policies and procedures.

.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, manufacturer's specifications, and licensing requirements. The following shall be addressed: ... (4) radioactive emission to the environment.*

-C- **TPSA & DRI.** In Section II.8, pages 28, the applicants describe their policies and procedures regarding radioactive emissions to the environment.

-C- **Novant & FMC.** Exhibit 5 contains a letter signed by FMC's Radiation Safety Officer which states FMC will continue to have policies and procedures regarding radioactive emissions to the environment.

.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, manufacturer's specifications, and licensing requirements. The following shall be addressed: ... (5) radioactive waste disposal.*

-C- **TPSA & DRI.** In Section II.8, pages 28, the applicants describe their policies and procedures regarding radioactive waste disposal.

-C- **Novant & FMC.** Exhibit 5 contains a letter signed by FMC's Radiation Safety Officer which states FMC will continue to have policies and procedures regarding radioactive waste disposal.

.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 a proposed mobile dedicated PET scanner, 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- **TPSA & DRI** 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.

-C- **Novant & FMC** 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.

.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 at least 2,080 PET procedures per PET scanner in the last year."*

-NC- **TPSA & DRI.** In Section II.8, page 29, the applicants state that this rule is *"Not applicable. Neither TPSA nor DRI operate an existing dedicated PET scanner."* However, the rule is applicable. TPSA and DRI are both limited liability companies (LLCs), each with two members. The members of TPSA are:

- Baptist; and
- DRI.

The members of DRI are:

- Cone; and
- Radiology Imaging Partners, LLC.

In Section I.13(c), pages 12-13, the applicants state *"The joint venture members of TPSA and DRI have extensive experience and knowledge in providing cancer services .... MCHS* [Cone] *has extensive experience providing comprehensive cancer services to its patients. ... The Cancer Center at North Carolina Baptist Hospital is a national leader in cancer care and research."* In addition, in Section II.1, pages 16-18, the applicants state

> *"The physicians who have expressed support for the proposed project are affiliated with MCHS* [Cone] *and NCBH* [Baptist] *and the proposed service area was chosen to match areas where both providers have established cancer programs and referral relationships. ... The proposed ownership model, a joint venture affiliated with two of the leading major medical centers and their related health systems and affiliate networks and a major provider of imaging services in the Piedmont Triad, is an innovative alternative that no single provider could offer on its own. The participants in the joint venture and its owners recognize the collaborative value of the combined effort and have carefully designed the proposed project to emphasize the competitive competencies and experience that each brings to the project."*

Baptist and Cone each operate one fixed PET/CT scanner in HSA II. The following table illustrates the number of PET procedures performed at Baptist and Cone during FFY 2007, as reported by the hospitals in their 2008 hospital license renewal applications.

HOSPITAL	# OF PET SCANNERS	# OF PET PROCEDURES REPORTED ON THE 2008 HOSPITAL LICENSE RENEWAL APPLICATION
Baptist	1	1,919
Cone	1	1,955

As shown in the above table, during FFY 2007, only 1,919 PET procedures were performed on the one existing PET/CT scanner at Baptist. Further, only 1,955 PET procedures were performed on the one existing PET/CT scanner at Cone. Thus, the existing PET/CT scanners at Baptist and Cone did not perform at least 2,080 PET procedures in the last year as required by this rule. Consequently, the application is nonconforming with this rule.

-C- **Novant & FMC.** In Section II.8, page 31, the applicants state that the one existing PET/CT scanner at FMC performed 3,026 PET procedures during CY 2007. According to its 2008 Hospital License Renewal Application, 2,983 PET procedures were performed at FMC during FFY 2007 (10/1/06 – 9/30/07). Novant and FMC do not operate any other existing PET scanners in HSA II.

.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- **TPSA & DRI.** In Section II.8, page 29, the applicants state that this rule is *"Not applicable. Neither TPSA nor DRI operate an existing dedicated PET scanner."* However, the rule is applicable. TPSA and DRI are both LLCs, each with two members. The members of TPSA are:

- Baptist; and
- DRI.

The members of DRI are:

- Cone; and
- Radiology Imaging Partners, LLC.

In Section I.13(c), pages 12-13, the applicants state *"The joint venture members of TPSA and DRI have extensive experience and knowledge in providing cancer services .... MCHS* [Cone] *has extensive experience providing comprehensive cancer services to its patients. ... The Cancer Center at North Carolina Baptist Hospital is a national leader in cancer care and research."* In addition, in Section II.1, pages 16-18, the applicants state

> *"The physicians who have expressed support for the proposed project are affiliated with MCHS* [Cone] *and NCBH* [Baptist] *and the proposed service area was chosen to match areas where both providers have established cancer programs and referral relationships. ... The proposed ownership model, a joint venture affiliated with two of the leading major medical centers and their related health systems and affiliate networks and a major provider of imaging services in the Piedmont Triad, is an innovative alternative that no single provider could offer on its own. The participants in the joint venture and its owners recognize the collaborative value of the combined effort and have carefully designed the proposed project to emphasize the competitive competencies and experience that each brings to the project."*

Baptist and Cone each operate one fixed PET/CT scanner in HSA II. However, the applicants did not provide projected utilization for the existing PET/CT scanners at Baptist and Cone. Therefore, they did not demonstrate that each would perform at lease 2,080 PET procedures during the third operating year of the project as required by this rule. Consequently, the application is nonconforming with this rule.

-C- **Novant & FMC.** In Section II.8, page 31, the applicants project that the existing and proposed PET/CT scanners would perform 4,250 PET procedures during the third

operating year, which is an average of 2,125 PET procedures per scanner. The applicants adequately demonstrate that the existing PET/CT scanner at FMC would perform an average of at least 2,080 PET procedures during Year Three. See Criterion (3) for discussion of projected utilization.

.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- **TPSA & DRI** describe their assumptions and methodology used to project utilization for the proposed PET/CT scanner in Section III.1, pages 34-51. However, the applicants did not provide adequate data to support and document their assumptions. See Criterion (3) for discussion.

-C- **Novant & FMC** describe their assumptions and methodology used to project utilization for the existing and proposed PET/CT scanners in Section III.1, pages 35-58, and provide adequate data to support and document their assumptions. See Criterion (3) for discussion.

.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- **TPSA & DRI** state in Section II.8, page 30, that radiopharmaceuticals will be obtained from PETNET Solutions and PETNET Solution's production facility in Winston-Salem is located within 11 miles or 20 minutes transport time. Exhibit 9 contains a letter from PETNET Solutions, which states that it is *"excited to work closely with the Triad PET Scanner Alliance."*

-C- **Novant & FMC** states in Section II.8, page 32, that FMC will continue to obtain its radiopharmaceuticals from PETNET Solutions and PETNET Solution's production facility in Winston-Salem is located within 8 miles or 10 minutes transport time. Exhibit 5 contains a copy of the existing contract between Novant (for FMC) and PETNET Solutions.

.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- **Neither application** proposes to acquire an on-site 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- **TPSA & DRI** propose to develop a new PET service. In Section II.8, page 31, TPSA and DRI state that they will form a PET Review Committee, which will be responsible for each item listed above.

-NA- **Novant & FMC** do not propose to develop a new PET service. FMC has provided fixed PET services since 2005. Nevertheless, in Exhibit 5, the applicants provide a letter signed by FMC's Radiation Safety Officer, which states that FMC has an existing clinical oversight committee responsible for each item listed above.

.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- **TPSA & DRI.** In Section V.3(c), page 63, the applicants state that Taylor H. Stroud, M.D., a member of Greensboro Radiology, P.A., has agreed to serve as the medical director for PET services. Greensboro Radiology, P.A. provides all professional interpretation services for Cone and DRI. Exhibit 17 contains a letter signed by Dr. Stroud, which states he has agreed to serve as medical director. Exhibit 16 contains a copy of his curriculum vitae, which documents he is board-certified in nuclear medicine and radiology.

-C- **Novant & FMC.** In Section V3(c), page 78, the applicants state that Liston Orr, M.D. is the current and proposed medical director for PET services. Exhibit 5 contains a letter from Dr. Orr, which states that he is the medical director for PET services at FMC. Exhibit 5 also contains a copy of his curriculum vitae, which documents he is board-certified in nuclear medicine and radiology.

.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- **TPSA & DRI** state in Section II.8, page 32, that DRI will contract with Cone for engineering and physics personnel with training and experience in the operation and maintenance of PET scanning equipment. Exhibit 5 contains letters from Cone and Baptist, each expressing an interest in providing engineering and physics personnel for the proposed PET/CT scanner at GIK.

-C- **Novant & FMC**. Exhibit 5 contains a letter signed by the Corporate Director Clinical Equipment Management Program for Novant, which states that engineering and physics personnel with training and experience in the operation and maintenance of PET scanning equipment will be available at all times the equipment is operating.

.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- **TPSA & DRI** state in Section II.8, page 32, that DRI will contract with Cone for radiation safety personnel with training and experience in the handling of short-live positron emitting nuclides. Exhibit 5 contains letters from Cone and Baptist, each expressing an interest in providing radiation and safety personnel for the proposed PET/CT scanner at GIK.

-C- **Novant & FMC**. Exhibit 5 contains a letter signed by FMC's Supervisor for Nuclear Medicine/PET, which states that FMC will employ radiation safety personnel with training and experience in the handling of short-live positron emitting nuclides for the proposed PET/CT scanner.

.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- **TPSA & DRI** state in Section II.8, page 32, that they will employ three FTE nuclear medicine technologist staff positions. The job description provided in Exhibit 20 states that certification by the Nuclear Medicine Technology Certification Board or the American Registry of Radiologic Technologists will be required as well as one year of nuclear medicine experience.

-C- **Novant & FMC** state in Section VII.2, page 93, that they will employ 8.6 FTE nuclear medicine technologist staff positions. Exhibit 5 contains a letter signed by FMC's Supervisor for Nuclear Medicine/PET, which states that the nuclear medicine technologists will be certified by the Nuclear Medicine Technology Certification Board or the American Registry of Radiologic Technologists and will have training and experience in the handling of short-live positron emitting nuclides for the proposed PET/CT scanner. The job description provided in Exhibit 16 states that one year of experience is preferred.

.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- **Neither application** proposes 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- **TPSA & DRI** state in Section II.8, page 33, that *"The appropriate personnel will be available during all scheduled hours of operation."*

-C- **Novant & FMC.** Exhibit 5 contains letters signed by FMC's medical director for PET services, Novant's

Corporate Director Clinical Equipment Management Program and FMC's Supervisor for Nuclear Medicine/PET, which state that the nuclear medicine imaging physician, engineering and physics personnel, radiation safety personnel and nuclear medicine technologists will be available at all times that the PET/CT 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- **TPSA & DRI** state in Section II.8, page 33, that *"DRI will provide continuing education for the proposed PET staff. ... DRI staff will have access to the continuing education provided by MCHS* [Cone] *and NCBH* [Baptist] *as well as training from either the Winston-Salem or Greensboro AHEC. DRI will continue to support attendance at professional continuing education programs to ensure that all staff remain current with the training, certifications, and re-certifications requirements of their respective specialty area."*

-C- **Novant & FMC**. Exhibit 5 contains a letter signed by FMC's Supervisor for Nuclear Medicine/PET, which states that *"a program of continuing staff education will continue to be provided to insure training of new personnel and the maintenance of staff competence."*

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. For the reasons set forth below and in the rest of the findings, the application submitted by **Novant & FMC** is approved and the application submitted by **TPSA & DRI** is denied.

Geographic Distribution

The following table shows the location of the existing and approved fixed PET scanners in HSA II, which includes Alamance, Caswell, Davidson, Davie, Forsyth, Guilford, Randolph, Rockingham, Stokes, Surry and Yadkin counties. Collectively, the 11 counties encompass a total of 5,400 square miles.

COUNTY	FACILITIES	EXISTING PET SCANNERS	APPROVED PET SCANNERS	TOTAL # OF PET SCANNERS
Alamance	Alamance Regional Medical Center	0	1	1
Guilford	Moses Cone Health System	1	0	1
	High Point Regional Health System	1	0	1
	Subtotal	2	0	2
Forsyth	North Carolina Baptist Hospital	1	0	1
	Forsyth Medical Center	1	0	1
	Subtotal	2	0	2
TOTAL		4	1	5

As shown in the above table, there are five existing or approved fixed PET scanners in HSA II, including one approved PET scanner in Alamance County, two existing PET scanners in Guilford County and two existing PET scanners in Forsyth County. There are no existing or approved fixed PET scanners in any of the other eight counties in HSA II.[5] Both TPSA & DRI and Novant & FMC propose to locate the PET/CT scanner in Forsyth County, approximately 15.5 miles from each other's site.[6] Given the total square miles included within HSA II and the proximity of the two sites to each other, the analyst concludes that the proposed locations are comparable with regard to geographic distribution of PET scanners within HSA II.

Populations to be Served

Novant & FMC propose to locate the PET/CT scanner in the hospital, which has a comprehensive cancer center, and will serve inpatients and outpatients. In Section IV.2, page 68, Novant & FMC state that, during CY 2005, CY 2006 and CY 2007, 13.8% of all PET procedures were performed on inpatients. Further, 6% of all PET procedures performed by the existing fixed PET scanners[7] in North Carolina were performed on inpatients. In contrast, **TPSA & DRI** propose to locate the PET/CT scanner in a freestanding diagnostic center and will serve only outpatients. Novant & FMC is the only application that

5 Mobile PET services are available at two host sites in Surry County.
6 Source: MapQuest.
7 Including the two mobile sites that have been approved to acquire a fixed PET scanner.

proposes to serve inpatients and as well as outpatients. Therefore, the proposal submitted by Novant & FMC is the more effective alternative with regard to serving inpatients.

Demonstration of Need

Novant & FMC adequately demonstrated that the number of PET scans they project to perform is reasonable, adequately documented their assumptions regarding projected utilization and provided data supporting their methodology. On the other hand, **TPSA & DRI** overestimated the number of PET scans to be performed, did not adequately document their assumptions regarding projected utilization and did not provide sufficient data to support their methodology. See Criterion (3) for discussion. Therefore, the proposal submitted by Novant & FMC is the more effective alternative with regard to demonstration of need.

Access by Underserved Groups

TPSA & DRI and Novant & FMC provided the following information regarding the percentage of patients having a PET procedure projected to be Medicare or Medicaid beneficiaries.

PROJECTED PERCENTAGE OF TOTAL PROCEDURES IN YEAR TWO

APPLICATION	MEDICAID RECIPIENTS	MEDICARE RECIPIENTS
TPSA & DRI	6.00%	60.00%
Novant & FMC	5.06%	54.69%

As shown in the above table, TPSA & DRI proposes to provide the highest percentage of total procedures to both Medicare and Medicaid recipients. Therefore, the proposal submitted by TPSA & DRI is the more effective alternative with regard to access by underserved groups.

Revenues

TPSA & DRI's proposed fixed PET scanner is projected to begin operating on April 1, 2009 while **Novant & FMC's** proposed fixed PET scanner is not projected to begin operating until January 1, 2010, nine months later. Therefore, the analyst compared projected revenues in Novant & FMC's second operating year (CY 2011) to projected revenues in TPSA & DRI's third operating year (4/1/11 – 3/31/12). TPSA & DRI and Novant & FMC both deduct bad debt and charity care from revenue. Novant & FMC states that FMC's charge includes only the technical component. TPSA & DRI states that DRI's total or "global" charge includes a technical and a professional component. This means that the patient or third party payor receives one bill, which includes the charge for use of the facility and the charge for the physician's interpretation. However, TPSA & DRI did not provide sufficient information to enable the analyst to subtract the professional component from total net revenues. Specifically, they combined the professional fees with billing services and did not identify the per procedure professional charge (fee) which would have allowed the analyst to calculate total professional fees without billing services.

AVERAGE NET REVENUE PER PROCEDURE

APPLICATION	# OF PET PROCEDURES	NET REVENUE	AVERAGE NET REVENUE PER PROCEDURE
TPSA & DRI (Year Three - 4/1/11 – 3/31/12)	2,336	$3,319,034	$1,420.82
Novant & FMC (Year Two – CY 2011)	4,057	$10,357,095	$2,552.89

As shown in the above table, Novant & FMC project the highest average net revenue per procedure. TPSA & DRI project the lowest average net revenue per procedure. However, TPSA & DRI overestimated the number of PET procedure to be performed. See Criterion (3) for discussion. Therefore, TPSA & DRI's projections of revenues that are based on the number of procedures to be performed are not reliable and are unsupported. Therefore, the application submitted by **Novant & FMC** is the most effective alternative with regard to projected net revenue per procedure which is based on reasonable assumptions.

Operating Expenses

TPSA & DRI's proposed fixed PET scanner is projected to begin operating on April 1, 2009 while **Novant & FMC's** proposed fixed PET scanner is not projected to begin operating until January 1, 2010, nine months later. Therefore, the analyst compared projected operating expenses in Novant & FMC's second operating year (CY 2011) to projected operating expenses in TPSA & DRI's third operating year (4/1/11 – 3/31/12). TPSA & DRI states that DRI's total or "global" charge includes a technical and a professional component. This means that DRI would incur an operating expense for physician interpretation of the PET scans. However, TPSA & DRI did not provide sufficient information to enable the analyst to subtract the operating expense for physician interpretation from total operating expenses. Specifically, they combined the professional fees with billing services and did not identify the per procedure professional charge (fee) which would have allowed the analyst to calculate total professional fees without billing services.

AVERAGE OPERATING EXPENSE PER PROCEDURE

APPLICATION	# OF PET PROCEDURES	TOTAL OPERATING EXPENSES	AVERAGE OPERATING EXPENSE PER PROCEDURE
TPSA & DRI (Year Three – 4/1/11 – 3/31/12)	2,336	$2,933,990	$1,255.99
Novant & FMC (Year Two – CY 2011)	4,057	$3,182,921	$784.55

As shown in the above table, Novant & FMC projects the lowest average operating expense per procedure. TPSA & DRI projects the highest average operating expense per procedure. Moreover, TPSA & DRI overestimated the number of PET procedures to be performed. See Criterion (3) for discussion. Therefore, TPSA & DRI's projections of operating expenses that are based on the number of procedures to be performed are not reliable and unsupported. Consequently, TPSA & DRI's average operating expense per procedure would be higher because fixed costs would be spread out over fewer procedures. Therefore, the application submitted by **Novant & FMC** is the most effective alternative with regard to projected average operating expense per procedure which is based on reasonable assumptions.

SUMMARY

The following is a summary of the reasons the proposal submitted by **Novant & FMC** is determined to be the most effective alternative in this review.

- Novant & FMC demonstrated that the number of PET procedures projected to be performed is reasonable, adequately documented their assumptions regarding projected utilization and provided data supporting their methodology. See Criterion (3) for discussion.
- Novant & FMC propose to serve inpatients as well as outpatients. See Comparative Analysis for discussion.
- Novant & FMC project the lowest average operating expense per procedure. See Comparative Analysis for discussion.

The following is a summary of the reasons the proposal submitted by **TPSA & DRI** is determined to be a less effective alternative than the proposal submitted by Novant & FMC.

- TPSA & DRI overestimated the number of PET scans that would be performed, did not adequately document their assumptions regarding projected utilization and did not provide sufficient data to support their methodology. See Criterion (3) for discussion.
- TPSA & DRI propose to serve only outpatients. See Comparative Analysis for discussion.
- TPSA & DRI project the highest average operating expense per procedure. Further, because TPSA & DRI overestimated the number of PET procedures to be performed, operating expenses that are based on the number of procedures to be performed are not reliable and are unsupported. See Criterion (5) for discussion. Consequently, TPSA & DRI's average operating expense per procedure would be higher because fixed costs would be spread out over fewer procedures.

CONCLUSION

Each application is individually conforming to the need determination in the 2008 SMFP for one fixed dedicated PET scanner in HSA II. However, N.C.G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed dedicated PET scanners that can be approved by the Certificate of Need Section. The Certificate of Need Section determined that the application submitted by **Novant & FMC** is the most effective alternative proposed in this review for the development of one additional fixed dedicated PET scanner in HSA II and is approved. Therefore, the proposal submitted by **TPSA & DRI** is denied.

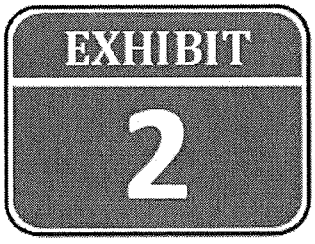
1. **Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall materially comply with all representations made in the certificate of need application.**

2. **Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**

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

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY RULING BY NOVANT HEALTH, INC. AND FORSYTH MEMORIAL HOSPITAL, INC. D/B/A FORSYTH MEDICAL CENTER



REQUEST FOR DECLARATORY RULING

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY RULING BY NOVANT HEALTH, INC. AND FORSYTH MEMORIAL HOSPITAL, INC. d/b/a FORSYTH MEDICAL CENTER

Address: 3333 Silas Creek Parkway
Winston-Salem, North Carolina 27103

Pursuant to N.C. Gen. Stat. § 150B-4 and 10A N.C.A.C. 14A.0103, Novant Health, Inc. ("Novant") and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center ("Forsyth") request that the North Carolina Department of Health and Human Services, Division of Health Service Regulation (the "Department") issue a declaratory ruling as to the applicability of Chapter 131E, Article 9 of the North Carolina General Statutes and of the Department's rules to the facts described below. Specifically, N.C. Gen. Stat. § 131E-181(a) provides that a certificate of need ("CON") is "valid only for the defined scope, physical location, and person named in the application." N.C. Gen. Stat. §§ 131E-181(b) and 131E-189(b) require the recipient of a CON to materially comply with the representations made in its application.

Novant and Forsyth request a declaration that a conversion of a PET/CT scanner from fixed status to mobile status would not constitute a change in scope for purposes of N.C. Gen. Stat. § 131E-181 of the CON Law and that this location change would not affect Forsyth's material compliance with representations made in the CON application or the conditions imposed upon the CON.

STATEMENT OF FACTS

On November 13, 2008, the CON Section issued a CON to Novant and Forsyth to acquire a second fixed PET/CT scanner to be installed at Forsyth, 3333 Silas Creek Parkway, Winston-Salem, NC 27103. *See* Exhibit A (CON issued for Project I.D. No. G-8129-08). This project has not yet been implemented.

Over the past few years, Novant Health, Inc., the ultimate parent entity of Forsyth, has expanded its hospital network and acquired MedQuest, a provider of diagnostic imaging services. In light of Novant's expansion, Novant has been seeking to assure that its imaging assets are utilized most effectively within its evolving comprehensive network. As part of this initiative, Novant has relocated various imaging assets, including MRI scanners, within Forsyth County to locations where they can be used most effectively. Novant has further concluded that Forsyth's second fixed PET/CT scanner could be more effectively utilized as a mobile PET/CT scanner in order to serve Forsyth and certain additional Novant-owned hospital sites that are located within a reasonable proximity to Forsyth.

Specifically, Novant submits that an efficiently scheduled mobile PET/CT could provide effective PET/CT service at Forsyth during the majority of the week and then provide daily coverage as needed to Thomasville Medical Center ("Thomasville"), Rowan Regional Medical Center ("Rowan") and Kernersville Medical Center ("Kernersville"). Each of these hospitals is owned by Novant. At these locations, a Novant-owned mobile PET/CT scanner would be able to provide PET scans to both inpatients and outpatients, as contemplated in its PET/CT scanner CON Application for Project I.D. No. G-8129-08. *See* CON Application, pages 68-69. Novant and Forsyth would enter into a services agreement with Forsyth,

Thomasville, Rowan and Kernersville. Thomasville, Rowan and Kernersville would not be acquiring the proposed mobile PET/CT scanner.[1]

Thomasville and Rowan have demonstrated the need for PET/CT since Novant implemented mobile PET/CT services at those hospitals to enhance patient access to PET/CT services and relieve some of the burden on Forsyth. Thomasville and Rowan each receive one day of mobile PET/CT services per week from a third party vendor, but this service is extremely expensive, and the third party vendor, which is the only provider of mobile PET/CT in North Carolina, has very limited capacity to add days or even hours at any host site should they need it.

Kernersville opened on March 16, 2011. Although Kernersville does not currently have PET technology, the CON Section approved Kernersville for linear accelerator services beginning in March 2012. *See* Exhibit B. It is anticipated that with the addition of linear accelerator services, Kernersville's cancer program will grow, and with that growth will come a need for PET scanner technology to aid in the detection and treatment of cancer.

PET volume at Forsyth remains strong, although volume trending indicates that patients will at times seek services closer to home when it is available. As noted above, efficient scheduling of a mobile PET/CT scanner will address Forsyth's need for additional PET/CT services while at the same time providing a cost-effective mobile PET/CT option for Thomasville, Rowan and Kernersville. At the present time, it is anticipated that Forsyth would receive four (4) days of mobile PET/CT service each week and Thomasville, Rowan and Kernersville would each receive one (1) day a mobile PET/CT service each week. However, as the owner of the mobile PET/CT scanner, Novant and Forsyth would be able to

[1] Forsyth, as a co-applicant on the CON for Project I.D. No. G-8129-08, would be acquiring a mobile PET/CT scanner.

adjust the schedule among these four hospitals as needed. For example, if Thomasville did not need a day of service during a particular week, but Forsyth did, Thomasville could give that day of service to Forsyth. This type of flexibility does not exist with a third party vendor which contracts with multiple host sites owned by different entities.

Converting the fixed PET/CT to a mobile PET/CT will also decrease health care costs substantially. The capital cost to acquire and implement this mobile PET/CT scanner is $1,909,020, which includes both the PET/CT scanner and the coach. *See* Exhibit C (equipment and coach quotes) and Exhibit D (certified cost estimate). This is *$2,618,208* below the originally approved capital costs of $4,527,228 for Project I.D. No. G-8129-08. *Compare* Exhibit A (CON) with Exhibit D. Each of the proposed sites has an existing mobile pad that will accommodate the mobile PET/CT scanner. The capital costs in Exhibit D include all costs needed to acquire and operationalize the PET/CT scanner, including the PET/CT scanner, the coach, the cost to transport the coach from Oneonta, New York to North Carolina (estimated to be $2,500), the radiation physicist's time to calibrate the unit, and a $50,000 contingency.

Further, Novant is paying a significant amount for current mobile PET/CT services. Novant estimates that it will save between $750,000 and $1,000,000 annually if Novant used its own resources to provide mobile PET/CT services. There will therefore be no increase in costs or charges to the public for PET/CT services as a result of this proposal. Novant will also comply with all conditions placed upon the CON for Project I.D. No. G-8129-08. Rowan, Thomasville and Kernersville will not be acquiring a PET scanner; rather, they will enter into a service agreement with Novant and Forsyth, the entities to whom the CON was issued. *See* Exhibit A.

If this request is approved, PET service at Kernersville would only be offered after March 16, 2012, the one year anniversary of Kernersville Medical Center. *See* N.C. Gen. Stat. § 131E-183(16)e. This declaratory ruling request is for these Novant-owned hospitals only; Novant would seek further regulatory approval to service any other locations. The scope of services would not change from what was originally proposed in Project I.D. No. G-8129-08. The only service that will be offered is PET/CT scans.

ANALYSIS

The CON law would require a full review of Forsyth's proposal if it represented a material change in the physical location or scope of the project. N.C. Gen. Stat. § 131E-181(a). A fixed PET scanner's service area is the Health Service Area (HSA) in which the scanner is located. *See* page 142 of the 2011 SMFP. Forsyth, Kernersville and Thomasville are all located within HSA II. Although Rowan is located in HSA III, it is in a county adjacent to HSA II. *See* page 396 of the 2011 SMFP. Moreover, Forsyth's existing PET scanner serves patients from Rowan County at the present time, as well as patients from Forsyth and Davidson Counties. *See* Exhibit E. In its CON application for Project I.D. No. G-8129-08, Forsyth defined its proposed PET/CT scanner service area to include all of HSA II (*see* application pages 56-57). Forsyth's CON application also anticipated 3.7% inmigration for its PET/CT scanner services, with that inmigration coming from outside HSA II (*see* application page 66). It is reasonable to expect that some of this inmigration would come from Rowan County, given its proximity to HSA II and the fact that Forsyth's existing PET scanner serves some Rowan residents. A mobile PET scanner's service area is the planning region in which the scanner is located. HSAs I, II and III are all located in the western region, and Rowan County is located in this region. *See* page 142 of the 2011 SMFP.

There will be no change in the scope of services offered in Project I.D. No. G-8129-08. The capital costs to implement the PET/CT scanner as a mobile scanner will be significantly lower than originally proposed to develop the scanner inside Forsyth. One of the central purposes of the CON Law is cost control. *See* N.C. Gen. Stat. § 131E-175(2).

N.C. Gen. Stat. § 131E-189(b) allows the Agency to withdraw the CON if Novant and Forsyth fail to develop the service in a manner consistent with the representations made in the application or with any conditions that were placed on the CON. Novant and Forsyth will not be operating the project in a manner that is materially different from the representations made in the application, nor in a manner that is inconsistent with any of the conditions that were placed on the CON. Forsyth now provides PET/CT services to residents of Forsyth, Davidson and Rowan Counties on its existing PET/CT scanner, and that it is how it will use the mobile PET/CT scanner if this request is approved.

N.C. Gen. Stat. § 131E-176(16)s. states that a "new institutional health service" includes

> The furnishing of mobile medical equipment to any person to provide health services in North Carolina, which was not in use in North Carolina prior to the adoption of this provision, if such equipment would otherwise be subject to review in accordance with G.S. 131E1-76(16)(f1) or G.S. 131E-176(16)(p) if it had been acquired in North Carolina.

This provision of the CON Law is not applicable because Forsyth already has a CON for the PET/CT scanner. Further, this proposal differs from the scenario presented in *Hope-A Women's Cancer Center, P.A. v. NCDHHS*, -- N.C. App. –, 691 S.E.2d 421 (2010), in which a provider proposed to enter into a services agreement with an out of state corporation for the furnishing of various medical equipment, including a PET scanner. Here, Forsyth already has a CON for the PET/CT scanner and is simply proposing to use that scanner at Forsyth and at

other hospitals owned by Novant to serve patients that Novant already serves. This request is analogous to the many declaratory ruling requests that the Department has approved in the past to change the location of MRI scanners and linear accelerators. *See* Exhibits F through H. There is no provision of the CON Law that precludes a CON holder from proposing to convert fixed equipment to mobile equipment. On three prior occasions, the Department has approved another provider to convert a mobile MRI scanner to a fixed unit. *See* Exhibits I-K. The same logic should apply here – a fixed unit should be allowed to convert to a mobile unit.[2]

Novant and Forsyth are mindful of the fact that the 2011 SMFP does not provide for any additional mobile PET scanners. *See* 2011 SMFP, page 143. Novant and Forsyth respectfully submit that this provision of the SMFP does not apply here because they are simply proposing to take an already-approved PET/CT scanner and convert it to a mobile unit to serve certain Novant hospitals. This proposal is not a broad-based request to add another mobile PET/CT scanner to serve a range of host sites in North Carolina that are not affiliated with Novant.

DECLARATORY RULING REQUESTED

Novant and Forsyth request that the Department make the following declaration as to the applicability of the CON Law and the Department's rules to the foregoing stated facts.

Under the facts stated above, the conversion of the fixed PET/CT approved in Project I.D. No. G-008129-08 to a mobile PET/CT to serve Forsyth Medical Center, Kernersville Medical Center, Thomasville Medical Center and Rowan Regional Medical Center does not

[2]The fact that Exhibits I -K involve "grandfathered" MRI scanners does not affect the applicability of this precedent and is not a factor that the Department relied upon in making these rulings. Rather, the import of these rulings is that there is no provision of the CON Law that prevents an owner of mobile equipment from converting it to fixed equipment. Likewise, there is no provision in the CON Law that prevents an owner of fixed equipment from converting it to mobile equipment.

constitute a change in the scope of the project, would not violate N.C. Gen. Stat. § 131E-181, and would not constitute a failure to satisfy a condition of the certificate of need in violation of N.C. Gen. Stat. § 131E-189(b) or any of the rules of the Department.

This the 12th day of August, 2011.

NELSON MULLINS RILEY & SCARBOROUGH LLP

By: _____

Denise M. Gunter
380 Knollwood Street
Suite 530
Winston-Salem, North Carolina 27103

ATTORNEYS FOR NOVANT HEALTH, INC AND FORSYTH MEMORIAL HOSPITAL, INC d/b/a FORSYTH MEDICAL CENTER

STATE OF NORTH CAROLINA

Department of Health and Human Services
Division of Health Service Regulation

CERTIFICATE OF NEED

for

Project Identification Number #G-8129-08
FID#923174

ISSUED TO: Novant Health, Inc.
Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center
3333 Silas Creek Parkway
Winston-Salem, NC 27103

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/ Forsyth County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Forsyth Medical Center
3333 Silas Creek Parkway
Winston-Salem, NC 27103

MAXIMUM CAPITAL EXPENDITURE: $4,527,228

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: June 30, 2009

This certificate is effective as of the 13th day of November, 2008.

Lee B. Hoffman
Chief, Certificate of Need Section
Division of Health Service Regulation

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director
2701 Mail Service Center • Raleigh, North Carolina 27699-2701
http://www.ncdhhs.gov/dhsr

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

Drexdal Pratt, Director
Phone: 919-855-3750
Fax: 919-733-2757

FACSIMILE & CERTIFIED MAIL

Denise M. Gunter, Esq.
Nelson Mullins Riley & Scarborough LLP
380 Knollwood Street, Suite 530
Winston-Salem, NC 27103.

Re: Declaratory Ruling for Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center, Project I.D. No. G-8129-08

Dear Ms. Gunter:

Enclosed you will find the Declaratory Ruling which I am issuing in response to your written request received in my office on August 12, 2011.

If you believe you are aggrieved and choose to seek judicial review of this ruling, you must file a petition for judicial review in the Superior Court of Wake County or in the Superior Court of the county in which you reside. Your petition must be filed within 30 days of the date on which you were served your copy of this letter. Within 10 days after you file your petition with the court, you must serve copies of the petition by personal service or by certified mail upon the Department of Health and Human Services. You can only serve the petition on the Department of Health and Human Services by serving it on Emery B. Milliken, General Counsel, at the following address: Department of Health and Human Services, Office of Legal Affairs, 2001 Mail Service Center, Raleigh, North Carolina 27699-2001.

Sincerely,

Drexdal Pratt

DP:pcb

Enclosure

cc: David J. French, Consultant to Alliance Imaging Inc.
Terrill Johnson Harris, Smith Moore Leatherwood LLP
Jeff Horton, Chief Operating Officer, DHSR
Craig Smith, Chief, Certificate of Need Section, DHSR
Medical Facilities Planning Section
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section, DHSR
Mare Lodge, Special Deputy Attorney General, DOJ

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY RULING BY NOVANT HEALTH, INC. AND FORSYTH MEMORIAL HOSPITAL, INC. d/b/a FORSYTH MEDICAL CENTER Project ID No. G-8129-08	)))))	DECLARATORY RULING

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

Novant Health, Inc. ("Novant") and Forsyth Memorial Hospital, Inc., d/b/a Forsyth Medical Center ("Forsyth") (collectively "Petitioners") have requested a declaratory ruling that would allow the acquisition of a mobile positron emission tomography ("PET") / computed tomography ("CT") scanner rather than the originally proposed fixed site PET scanner, contending that such acquisition would not constitute a change in scope for purposes of N.C. Gen. Stat. § 131E-181 of the certificate of need ("CON") law, and that the location change would not affect Forsyth's material compliance with representations made in the CON application or the conditions imposed upon the CON. The CON law would require a full review of Forsyth's proposal if it represented a material change in the physical location or scope of the project. N.C. Gen. Stat. § 131E-181(a). This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the

statutes and regulations at issue in this Declaratory Ruling. Denise M. Gunter of Nelson Mullins Riley & Scarborough, LLP has requested this ruling on behalf of Novant and Forsyth, and has provided the material facts upon which this ruling is based.

Comments in opposition to this request were received by the following:

(1) Terrill Johnson Harris, of Smith Moore Leatherwood LLP, on behalf of Cone Health.

(2) David J. French on behalf of Alliance Imaging Inc.

STATEMENT OF THE FACTS

The 2008 State Medical Facilities Plan ("SMFP") contained two need determinations for fixed site PET scanners: one for Health Service Area ("HSA") II and one for HSA III. On November 13, 2008, the CON section issued a CON to Novant and Forsyth to acquire a fixed site PET/CT scanner to be installed at the Forsyth facility located at 3333 Silas Creek Parkway, Winston-Salem, NC 27103, known as Project ID No. G-8129-08. According to Novant and Forsyth, this project has not yet been implemented. Carolinas Medical Center – Union ("CMC – Union") received the CON allowing acquisition of a fixed site PET scanner for HSA III. The 2008 SMFP concluded there was no need for any mobile PET scanners anywhere in the state.

Rather than acquire a fixed site PET/CT scanner, Petitioners seek to acquire a mobile PET/CT scanner that would be operated at Forsyth as authorized by the previously issued CON, but, in addition, would be operated at Thomasville Medical Center ("Thomasville") located in Davidson County, Rowan Regional Medical Center ("Rowan") located in Rowan County, and Kernersville Medical Center ("Kernersville") located in Forsyth County, each of which is owned by Novant.

ANALYSIS

N.C. Gen. Stat. § 131E-181(a) provides that a CON "shall be valid only for the defined scope, physical location, and person named in the application." Petitioners' proposal to acquire a mobile PET/CT scanner must be denied based upon the provisions of N.C. Gen. Stat. § 131E-181(a).

The proposal constitutes a material change in the physical location and scope of the proposed project. As set forth in the factual statement above, Project ID No. G-8129-08 originally contemplated utilization of a fixed PET/CT scanner at the Forsyth facility located in Winston-Salem. Petitioners now propose utilization of a mobile scanner at the Forsyth facility in addition to the Thomasville, Rowan, and Kernersville facilities.

Pursuant to the 2008 SMFP, under which Petitioners originally acquired a fixed PET/CT scanner for HSA II, "there is no need for any additional mobile dedicated PET scanners anywhere in the state." 2008 SMFP at 117. In fact, there has not been a need for any additional mobile PET scanners anywhere in the state since Petitioners' application for the fixed PET/CT scanner. *See* 2009 SMFP at 133, 2010 SMFP at 139, 2011 SMFP at 143. Similarly, the proposed 2012 SMFP concludes there is no need for any additional mobile PET scanners in the state. In addition, CMC-Union was awarded the CON to acquire a fixed site PET scanner to serve the need identified in the 2008 SMFP for HSA III.

Not only does the methodology prevent additional acquisitions of mobile PET scanners, acquiring a mobile PET scanner would constitute a material change in the scope of the project as well as the physical location of the project given the proposed mobile sites. Petitioners' contention that the mobile scanner would simply serve the same population originally proposed for the fixed scanner is without merit. In the same manner that Petitioners anticipated that

residents of Rowan County would travel to the fixed scanner in Forsyth County, it is reasonable to anticipate that locating a mobile scanner in Rowan County would extend the radius of potential patients far beyond the borders of Rowan County into territory that was not included in Petitioners' original proposal.

Petitioners' proposal constitutes a material change in the physical location and scope of the project and must be denied.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the proposal to acquire a mobile PET/CT scanner rather than a fixed site PET/CT scanner constitutes a material change in the physical location and scope of the project, violates N.C. Gen. Stat. § 131E-181, and, therefore, must be denied.

This the 24 day of October, 2011.

Drexdal Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the agency party by facsimile and certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Denise M. Gunter
Nelson Mullins Riley & Scarborough LLP
380 Knollwood Street, Suite 530
Winston-Salem, NC 27103

Courtesy Copy:

David J. French
Consultant to Alliance Imaging, Inc.
Post Office Box 2154
Reidsville, NC 27323-2154

Terrill Johnson Harris (for Cone Health)
Smith Moore Leatherwood LLP
Post Office Box 21927
Greensboro, NC 27420

This the 24th day of October, 2011.

Jeff Herron
Chief Operating Officer

FILED

STATE OF NORTH CAROLINA

IN THE GENERAL COURT OF JUSTICE

2012 JUN -1 PM 12:35

COUNTY OF WAKE

SUPERIOR COURT DIVISION
11 CVS 18054

WAKE COUNTY, C.S.C.

NOVANT HEALTH, INC. and FORSYTH MEMORIAL HOSPITAL, INC. d/b/a FORSYTH MEDICAL CENTER,

Plaintiff-Petitioners,

v.

N.C., DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION,

Defendant-Respondent,

and

WAKE RADIOLOGY SERVICES, LLC and WAKE RADIOLOGY DIAGNOSTIC IMAGING, INC.,

Defendant-Respondent-Intervenors

NOTICE OF VOLUNTARY DISMISSAL WITH PREJUDICE

NOW COMES Plaintiff-Petitioners, Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center, and hereby gives notice of their voluntary dismissal with prejudice pursuant to Rule 41 of the North Carolina Rules of Civil Procedure.

EXHIBIT 3

This the 1st day of June, 2012.

NELSON MULLINS RILEY &
SCARBOROUGH LLP

Denise M. Gunter
N.C. State Bar No. 16695
Candace S. Friel
N.C. State Bar No. 36763

By: _____

Denise M. Gunter
380 Knollwood Street, Suite 530
Winston-Salem, NC 27103
Telephone: 336.774.3322
Facsimile: 336.774.3372

ATTORNEYS FOR NOVANT HEALTH, INC., AND FORSYTH MEMORIAL HOSPITAL, INC. d/b/a FORSYTH MEDICAL CENTER

CERTIFICATE OF SERVICE

This is to certify that I have this day served a copy of the foregoing pleading in a manner prescribed by Rule 5 of the Rules of Civil Procedure as follows:

____ By hand delivery to the following:

X By depositing in the United States mail, a copy of the same in an envelope with adequate postage thereon addressed as follows:

Joel L. Johnson
Assistant Attorney General
N.C. Department of Justice
PO Box 629
Raleigh, NC 27602-0629

Frank S. Kirschbaum
Nexsen Pruet, PLLC
4141 Parklake Ave.,
Suite 200
Raleigh, NC 27612

Joy Heath
Law Office of Joy Health
514 Daniels Street, #182
Raleigh, NC 27605

Terrill Johnson Harris
Smith Moore Leatherwood
LLP
Post Office Box 21927
Greensboro, NC 27420

____ By telefacsimile transmittal, which was received by 5:00 p.m. Eastern time, addressed as follows:

This the 1st day of June, 2012.

NELSON MULLINS RILEY & SCARBOROUGH LLP

By: Denise M. Gunter

Denise M. Gunter
Email: denise.gunter@nelsonmullins.com
380 Knollwood Street, Suite 530
Winston-Salem, NC 27103
Phone: 336.774.3322
Fax: 336.774.3372
Attorney for Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center

EXHIBIT 4

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ▪ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
Dempsey Benton, Secretary

www.ncdhhs.gov/dhsr

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

November 14, 2008

Joe Fiorenza, Director Facilities Planning
Novant Health Triad Region
1900 South Hawthorne Rd., Bldg. 7, Suite 718
Winston-Salem, NC 27103

RE: Transmittal of CON/ Project I.D. #G-8129-08/ Forsyth Medical Center/ Acquire a second PET/CT scanner/ Forsyth County
FID # 923174

Dear Mr. Fiorenza:

We are happy to transmit your certificate of need for the above referenced project. At this time, you should contact the Construction Section and the Licensure and Certification Section, regarding their procedures and requirements for the development of this project. The Certificate of Need Section will notify the other Sections that the certificate of need has been issued. However, please note that it is the responsibility of the holder of the certificate of need to contact these Sections concerning the next steps to follow in the development of the approved project.

Please be aware that pursuant to General Statute 131E-181(b), you are required to materially comply with the representations made in your application for a certificate of need, or with any conditions the department placed on the certificate of need. If you operate a service which materially differs from the representations made in your application for a certificate of need, or with any conditions the department placed on the certificate of need, including any increase in per diem reimbursement rates/charges, the department may bring remedial action against the holder of the certificate of need pursuant to General Statutes 131E-189 and 131E-190.

The holder of a certificate of need is obligated to submit progress reports to this Agency as required by 10A NCAC 14C .0209. The applicant shall notify the Agency of any variations from the schedule or the projected capital cost of the project. During the development of the project, the Agency may request any additional information pertinent to the project, including additional progress reports, to determine: 1) if the timetable specified on the certificate is being met; 2) if the amount of the capital expenditure obligated under the certificate has exceeded or can be expected to exceed the maximum amount under the certificate; 3) if the terms and conditions of the approval are being met; and 4) if the project is progressing as proposed in the application. The first progress report on this project is due June 30, 2009. Forms for the submittal of these reports are enclosed. Failure to submit any

scheduled or requested progress report in a timely manner may result in the agency withdrawing the certificate pursuant to G.S.131E-189 (a). If after reviewing the status of the project, the Certificate of Need Section determines that the holder of the certificate is not meeting the timetable and is not making a good faith effort to meet it, the Agency may withdraw the certificate in accordance with G.S. 131E-189.

Moreover, please be advised that this Agency may assess a civil penalty not to exceed $20,000 against any person who violates the terms of a certificate of need which has been issued each time the service provided is in violation of this provision (G.S. 131E-190(f)). If for some reason, the holder of a certificate of need determines it necessary to request an increase in a per diem charge or reimbursement rate over that which was stated in the application for the certificate of need, then the holder must first contact the Certificate of Need Section to obtain proper instructions for initiating such a request. The request for the increase will be considered by the department pursuant to G.S. 131E-181(b).

Please keep us informed of the progress in the development of this project. Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

Sincerely,

Martha J. Frisone

Martha J. Frisone, Team Leader

Lee B. Hoffman

Lee B. Hoffman, Chief
Certificate of Need Section

MJF:LBH: ly

Enclosures

cc: Medical Facilities Planning Section, DHSR
Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

Novant HEALTH®

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Received by the
CON Section

30 JUN 2009 02:46

June 29, 2009

Gebrette Miles, Project Analyst
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Progress Report No. 1

Project I.D. # G-8129-08/Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

Dear Ms. Miles:

Enclosed is Progress Report #1 for the above referenced project. Please contact me if you need further information.

Sincerely,

Mike Bolt, Director
Design & Construction

MB/bw

Enclosures

cc: Barbara Freedy
Paul Hammes
Laura MacFadden
Van Hauser
Roonie Saxon

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Forsyth
Facility: Forsyth Medical Center
Project I.D. #: G-8129-08
Date of Progress Report: #1 06/29/09
Facility I.D. #: 923174
Effective Date of Certificate: November 13, 2008

Project Description: Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

A. Status of the Project – Describe the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

We received capital approval to begin the design process and notified the architect to begin design. Design should be complete by October 30, 2009. The following timetable is our current best estimate for project completion.

Received by the CON Section
30 JUN 2009 02

October 30, 2009	Complete design
January 30, 2010	Obtain funds to construct project
February 28, 2010	Construction contract
October 30, 2010	Complete construction

B. Timetable

1. Complete the following. The first column must include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

	Projected Completion Date (from the Certificate of Need) Month/Day/Year	Actual Date Completed Month/Day/Year
Obtained Funds for the Project		
Approval of Final Drawings and Specifications		
Acquisition of land/facility		
Construction Contract Executed		
25% completion of construction		
50% completion of construction	09/01/2009	
75% completion of construction		
Completion of construction	12/01/2009	
Ordering of medical equipment		
Operation of medical equipment	01/01/2010	
Occupancy/offering of services		
Licensure		
Certification		

2. If the project is experiencing significant delays in development:

   a. explain the reasons for the delay; and
   b. provide a revised timetable for the CON Section to consider.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates

a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment.

a. Manufacturer
b. Model
c. Serial Number
d. Date acquired

D. Capital Expenditure

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fees		$ 3,538.80
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify) Filing Fee		$ 15,582.00
Subtotal Misc. Costs		**$ 19,120.80**
Total Capital Cost of the Project		**$ 19,120.80**

2. What do you project to be the remaining capital expenditure required to complete the project? 4,508,107.20

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference.

E. **CERTIFICATION** - - The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: _____

Name and Title of Responsible Officer Mike Bolt, Director Facilities Planning Design and Construction

Telephone Number of Responsible Officer (336) 718-0772

Effective date: 2/2/05

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ▪ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

July 8, 2009

Mike Bolt, Director
Design & Construction
Novant Health Triad Region
1900 S. Hawthorne Road, Suite 718
Winston-Salem, NC 27103

RE: Acknowledgment of Receipt of Progress Report/Project I.D. #G-8129-08/ Forsyth Medical Center/ Acquire a second PET/CT scanner/ Forsyth County
FID #923174

Dear Mr. Bolt:

Thank you for your recent progress report on the above referenced project. Your next progress report will be due October 1, 2009.

Please contact the Certificate of Need Section office if you have any additional delays or unexpected expenditures. Please do not hesitate to contact me if you have any questions regarding this project.

Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

Sincerely,

Gebrette Miles

Gebrette Miles, Project Analyst
Certificate of Need Section

GM:lmy

Attachment

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October 1, 2009

Received by the
CON Section

28 SEP 2009 10 : 25

Gebrette Miles, Project Analyst
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Progress Report No. 2

Project I.D. # G-8129-08/Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

Dear Ms. Miles:

Enclosed is Progress Report #2 for the above referenced project. Please contact me if you need further information.

Sincerely,

Mike Bolt, Director
Facilities Planning Design and Construction, Triad Region

MB/bw

Enclosures

cc: Barbara Freedy
Paul Hammes
Laura MacFadden
Cathy White
Roonie Saxon

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Forsyth
Facility: Forsyth Medical Center
Project I.D. #: G-8129-08

Date of Progress Report: #2 10/01/2009
Facility I.D. #: 923174
Effective Date of Certificate: November 13, 2008

Project Description: Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

A. Status of the Project – Describe the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

Our sourcing department is in the process of final negotiations with the vendor of choice. An architect has been awarded a design contract and will begin design immediately upon receipt of the final vendor drawings. We are hoping to have the final vendor drawings and begin design no later than October 15, 2009. Our revised project schedule estimate is as follows. We will update the project completion dates below as soon as possible after receipt of firm information.

December 31, 2009	*Complete design*
February 28, 2010	*Obtain funds to construct project*
March 31, 2010	*Construction contract*
December 31, 2010	*Complete construction*

Received by the CON Section
28 SEP 2009 10 : 25

B. Timetable

1. Complete the following. The first column must include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

	Projected Completion Date (from the Certificate of Need) Month/Day/Year	Actual Date Completed Month/Day/Year
Obtained Funds for the Project		
Approval of Final Drawings and Specifications		
Acquisition of land/facility		
Construction Contract Executed	06/01/2009	
25% completion of construction		
50% completion of construction	09/01/2009	
75% completion of construction		
Completion of construction	12/01/2009	
Ordering of medical equipment		
Operation of medical equipment	01/01/2010	
Occupancy/offering of services		
Licensure		
Certification		

2. If the project is experiencing significant delays in development:

   a. explain the reasons for the delay; and
   Final selection of equipment and negotiations with vendors to obtain best pricing.
   b. provide a revised timetable for the CON Section to consider.
   Revised timetable will provided as soon as a vendor purchase order is issued and we have architect input on design duration.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment.

a. Manufacturer
b. Model
c. Serial Number
d. Date acquired

D. Capital Expenditure

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fees		$ 3,538.80
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify) Filing Fee		$ 15,582.00
Subtotal Misc. Costs		$ 19,120.80
Total Capital Cost of the Project		$ 19,120.80

2. What do you project to be the remaining capital expenditure required to complete the project? **$4,508,107.20**

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference. No.

E. CERTIFICATION -- The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer:
Name and Title of Responsible Officer Mike Bolt, Director Facilities Planning Design and Construction
Telephone Number of Responsible Officer (336) 718-0777

Effective date: 2/2/05

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief
Phone: 919-855-3875
Fax: 919-733-8139

January 7, 2010

Mike Bolt, Director
Desgin & Construction
Novant Health Triad Region
1900 S. Hawthorned Road, Suite 718
Winston-Salem, NC 27103

RE: Acknowledgement of Receipt of Progress Report and Extension of Timetable/ Project I.D.#G-8129-08/ Forsyth Medical Center/ Acquire a second PET/CT scanner/ Forsyth County
FID #923174

Dear Mr. Bolt:

Thank you for your recent progress report on the above referenced project. Your next progress report will be due April 1, 2010.

The Certificate of Need Section has decided to extend the timetable for the above referenced project pursuant to N.C. Gen. Stat. §131E-189. The timetable for this project has been extended only for the period specified below.

Milestone	Completion Date
Contract Award	September 30, 2010
Ordering of Medical Equipment	September 30, 2010
50% completion of Construction	December 31, 2010
Completion of Construction	March 31, 2011
Operation of Medical Equipment	April 30, 2011

Please contact the Certificate of Need Section if you have any additional delays or unexpected expenditures.

Do not hesitate to contact me if you have any questions regarding this project. Refer to the Project I.D. # and Facility I.D. # in all future correspondence.

Sincerely,

Gebrette Miles

Gebrette Miles, Project Analyst
Certificate of Need Section

GM:vlw
Attachment

Novant HEALTH

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April 1, 2010

Gebrette Miles, Project Analyst
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Progress Report #3

Project I.D. #G-8129-08/Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

Dear Ms. Miles:

Enclosed is Progress Report #3 for the Project I.D. #G-8129-08 for the second PET/CT scanner. Please contact me if you need further information

Additionally, please send all correspondence on this project to me at 1980 S. Hawthorne Road, Suite 200, Winston-Salem, NC 27103.

Sincerely,

Laura MacFadden
Senior Director, Design & Construction

LM/cw

cc: Barbara Freedy

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Forsyth
Facility: Forsyth Medical Center
Project I.D. #: G-8129-08

Date of Progress Report: #3 04/01/2010
Facility I.D. #: 923174
Effective Date of Certificate: Nov. 13, 2008

Project Description: Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

A. Status of the Project

(a) Describe in detail the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

Design completed January 19, 2010. We expect to receive construction funding in third quarter 2010. On 1/7/2010, CON approved the extended timetable denoted below.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete **until** *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

State approved
01/7/2010

PROJECT MILESTONES	Projected Completion Date from certificate	Actual completion date	Proposed completion date
	Month/day/year	Month/day/year	Month/day/year
Obtained Funds for the Project			
Final Drawings and Specifications Sent to DHSR			
Acquisition of land/facility			
Construction Contract Executed	**9/30/2010**		
25% completion of construction			
50% completion of construction	**12/31/2010**		
75% completion of construction			
Completion of construction	**3/31/2011**		
Ordering of medical equipment	**9/30/2010**		
Operation of medical equipment	**4/30/2011**		
Occupancy/offering of services			
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and
   b. provide a revised timetable for the CON Section to consider.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

D. Capital Expenditure

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fees	$77,583.39	$81,122.19
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify) **Filing Fees**		$15,582.00
Subtotal Misc. Costs	$77,583.39	$96,704.19
Total Capital Cost of the Project	$77,583.39	$96,704.19

2. What do you project to be the remaining capital expenditure required to complete the project?
   $4,430,523.81

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference. NO

E. CERTIFICATION – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: [signature]
Name and Title of Responsible Officer: Laura MacFadden, Sr. Director, Design & Construction
Telephone Number of Responsible Officer: 336-718-0725

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ▪ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief
Phone: 919-855-3875
Fax: 919-733-8139

May 11, 2010

Laura MacFadden, Senior Director
Design & Construction
1980 S. Hawthorne Road, Suite 200
Winston-Salem, NC 27103

RE: Acknowledgment of Receipt of Progress Report/ Project I.D. #G-8129-08/ Forsyth Medical Center/ Acquire a second PET/CT scanner/ Forsyth County
FID #923174

Dear Ms. MacFadden:

Thank you for your recent progress report on the above referenced project. Your next progress report will be due October 15, 2010.

Please contact the Certificate of Need Section office if you have any additional delays or unexpected expenditures. Please do not hesitate to contact me if you have any questions regarding this project.

Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

Sincerely,

Gebrette Miles, Project Analyst
Certificate of Need Section

GM:vlw

Attachment

Novant HEALTH

Remarkable People. Remarkable Medicine.

Received by
CON Section

04 NOV 2010 09 : 37

November 3, 2010

Gebrette Miles, Project Analyst
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Progress Report 4

Project I.D. G-8129-08/Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

Dear Ms. Miles:

Enclosed is Progress Report #4 for the Project I.D. #G-8129-08 for a second PET/CT scanner at FMC. Please contact me if you need further information

Additionally, please send all correspondence on this project to me at 1980 South Hawthorne Road, Suite 200, Winston-Salem, NC 27103.

Sincerely,

Laura MacFadden
Senior Director, Design & Construction

LM/cw

cc: Barbara Freedy

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Forsyth
Facility: Forsyth Medical Center
Project I.D. #: G-8129-08
Date of Progress Report: #4 10/30/2010
Facility I.D. #: 923174
Effective Date of Certificate: Nov. 13, 2008
Project Description: Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

A. Status of the Project

(a) Describe in **detail** the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

We anticipate that further funding will be available to continue development of this PET/CT during the 4th Quarter 2010 or 1st Quarter 2011, so that we may purchase the equipment and move ahead with this project.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete **until** *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

State approved
01/7/2010

PROJECT MILESTONES	Projected Completion Date from certificate Month/day/year	Actual completion date Month/day/year	Proposed completion date Month/day/year
Obtained Funds for the Project			
Final Drawings and Specifications Sent to DHSR			
Acquisition of land/facility			
Construction Contract Executed	9/30/2010		
25% completion of construction			
50% completion of construction	12/31/2010		
75% completion of construction			
Completion of construction	3/31/2011		
Ordering of medical equipment	9/30/2010		
Operation of medical equipment	4/30/2011		
Occupancy/offering of services			
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and
   b. provide a revised timetable for the CON Section to consider.

C. Medical Equipment Projects -- If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

D. Capital Expenditure

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fees	**$16,054.88**	**$ 97,177.09**
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify) **Filing Fees**		**$ 15,582.00**
Subtotal Misc. Costs	**$16,054.88**	**$112,759.07**
Total Capital Cost of the Project	**$16,054.88**	**$112,759.07**

2. What do you project to be the remaining capital expenditure required to complete the project?
   $4,414,468.93

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference. **No**

E. CERTIFICATION – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer:
Name and Title of Responsible Officer: Jeffery T. Lindsay, President FMC/COO WS Market
Telephone Number of Responsible Officer: 336-718-2056

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ▪ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

December 6, 2010

Laura MacFadden, Senior Director
Design & Construction
Novant Health
1980 South Hawthorne Road, Suite 200
Winston-Salem, NC 27103

RE: Acknowledgment of Receipt of Progress Report/ Project I.D. # G-8129-08/ Forsyth Medical Center/ Acquire a second PET/CT scanner/ Forsyth County
FID #923174

Dear Ms. MacFadden:

Thank you for your recent progress report on the above referenced project. Your next progress report will be due March 31, 2011.

Please contact the Certificate of Need Section office if you have any additional delays or unexpected expenditures. Please do not hesitate to contact me if you have any questions regarding this project.

Please refer to the Project I.D. # and Facility I.D. # (FID) in all correspondence.

Sincerely,

Gebrette Miles, Project Analyst
Certificate of Need Section

GM:mw

Attachment

Novant HEALTH

Remarkable People. Remarkable Medicine.

April 1, 2011

Gebrette Miles, Project Analyst
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Progress Report #5

Project I.D. G-8129-08/Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

Dear Ms. Miles:

Enclosed is Progress Report #5 for the Project I.D. #G-8129-08 for a second PET/CT scanner at FMC. Please contact me if you need further information

Additionally, please send all correspondence on this project to me at 1980 South Hawthorne Road, Suite 200, Winston-Salem, NC 27103.

Sincerely,

Laura MacFadden
Senior Director, Design & Construction

LM/cw

cc: Barbara Freedy

CERTIFICATE OF NEED
PROGRESS REPORT FORM

Received by the CON Section

APR 2011

County: Forsyth
Facility: Forsyth Medical Center
Project I.D. #: G-8129-08

Date of Progress Report: #5 04/01/2011
Facility I.D. #: 923174
Effective Date of Certificate: Nov. 13, 2008

Project Description: Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

A. Status of the Project

(a) Describe in detail the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

FMC remains highly committed to this project and our need to have this scanner implemented still remains high due to our current scanner being one of the busiest in the State. However, with the opening of our newest hospital in Kernersville, the upcoming opening of BCH this summer, and the amount of resources needed to open those projects, some other priorities have had temporary delays.

Our plan is to complete the BCH project this summer, which should free up the resources and allow us to plan accurately for the implementation of this scanner. At that time, we would be able to submit to you an updated proposed completion date when we have more people committed towards this project.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete until *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

State approved
01/7/2010

PROJECT MILESTONES	Projected Completion Date from certificate Month/day/year	Actual completion date Month/day/year	Proposed completion date Month/day/year
Obtained Funds for the Project			
Final Drawings and Specifications Sent to DHSR			
Acquisition of land/facility			
Construction Contract Executed	9/30/2010		
25% completion of construction			
50% completion of construction	12/31/2010		
75% completion of construction			
Completion of construction	3/31/2011		
Ordering of medical equipment	9/30/2010		
Operation of medical equipment	4/30/2011		
Occupancy/offering of services			
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and
   b. provide a revised timetable for the CON Section to consider.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

D. Capital Expenditure

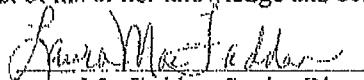
1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fees	$	$ 97,177.09
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify) **Filing Fees**		$ 15,582.00
Subtotal Misc. Costs	$	$112,759.07
Total Capital Cost of the Project	$	$112,759.07

2. What do you project to be the remaining capital expenditure required to complete the project? $4,414,468.93

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference. **NO**

E. CERTIFICATION -- The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: 
Name and Title of Responsible Officer Laura MacFadden, Senior Director, Design & Construction
Telephone Number of Responsible Officer 336-718-0725

Effective date: 4/24/09

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ▪ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

May 4, 2011

Laura MacFadden, Senior Director
Design & Construction
Novant Health
1980 South Hawthorne Road, Suite 200
Winston-Salem, NC 27103

RE: Acknowledgment of Receipt of Progress Report/ Project I.D. # G-8129-08/ Forsyth Medical Center/ Acquire a second PET/CT scanner/ Forsyth County
FID #923174

Dear Ms. MacFadden:

Thank you for your recent progress report on the above referenced project. Your next progress report will be due August 30, 2011.

Please contact the Certificate of Need Section office if you have any additional delays or unexpected expenditures. Please do not hesitate to contact me if you have any questions regarding this project.

Please refer to the Project I.D. # and Facility I.D. # (FID) in all correspondence.

Sincerely,

Gebrette Miles, Project Analyst
Certificate of Need Section

GM:mw

Attachment

Novant HEALTH

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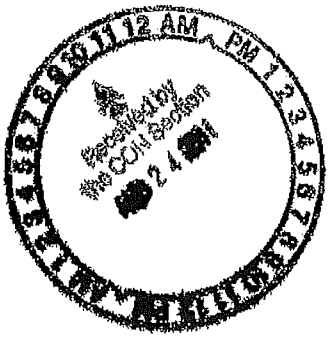


August 19, 2011

Gebrette Miles, Project Analyst
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Progress Report #6

Project I.D. G-8129-08/Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

Dear Ms. Miles:

Enclosed is Progress Report #6 for the Project I.D. #G-8129-08 for a second PET/CT scanner at FMC. Please contact me if you need further information

Additionally, please send all correspondence on this project to me at 1980 South Hawthorne Road, Suite 200, Winston-Salem, NC 27103.

Sincerely,

Laura MacFadden
Senior Director, Design & Construction

LM/cw

cc: Barbara Freedy

1980 S. Hawthorne Rd., Suite 200 | Winston-Salem, NC 27103 | 336-718-0725 |
www.novanthealth.org

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Forsyth
Facility: Forsyth Medical Center
Project I.D. #: G-8129-08
Date of Progress Report: #6 08/19/2011
Facility I.D. #: 923174
Effective Date of Certificate: Nov. 13, 2008
Project Description: Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

A. Status of the Project

(a) Describe in detail the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

Forsyth Medical Center (FMC) remains committed to this project and recently filed a Declaratory Ruling Request on August 12, 2011 in which we proposed that instead of implementing this machine as a fixed unit, this machine would become a mobile unit serving Forsyth Medical Center, Thomasville Medical Center, Kernersville Medical Center and Rowan Regional Medical Center. We believe that this proposal will allow us to meet the needs of cancer patients at FMC, and will also allow us to provide PET/CT services at our nearby sister hospitals in a cost-effective manner. We expect to receive a decision on this request by October 11, 2011.

When this regulatory request is approved, we will be able to provide an updated project timeline.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete **until** *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

State approved
01/7/2010

PROJECT MILESTONES	Projected Completion Date from certificate	Actual completion date	Proposed completion date
	Month/day/year	Month/day/year	Month/day/year
Obtained Funds for the Project			
Final Drawings and Specifications Sent to DHSR			
Acquisition of land/facility			
Construction Contract Executed	9/30/2010		
25% completion of construction			
50% completion of construction	12/31/2010		
75% completion of construction			
Completion of construction	3/31/2011		
Ordering of medical equipment	9/30/2010		
Operation of medical equipment	4/30/2011		
Occupancy/offering of services			
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and

b. provide a revised timetable for the CON Section to consider.

C. **Medical Equipment Projects** – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

D. **Capital Expenditure**

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	**Total Cumulative Capital Expenditure**
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fees	$	$ 97,177.09
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify) **Filing Fees**		$ 15,582.00
Subtotal Misc. Costs	$	$112,759.07
Total Capital Cost of the Project	$	$112,759.07

2. What do you project to be the remaining capital expenditure required to complete the project? $4,414,468.93

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference. **NO**

E. CERTIFICATION – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: Laura MacFadden

Name and Title of Responsible Officer: Laura MacFadden, Senior Director, Design & Construction

Telephone Number of Responsible Officer: 336-718-0725

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ▪ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief
Phone: 919-855-3875
Fax: 919-733-8139

September 22, 2011

Laura MacFadden, Senior Director
Design & Construction
Novant Health
1980 South Hawthorne Road, Suite 200
Winston-Salem, NC 27103

RE: Acknowledgment of Receipt of Progress Report/ Project I.D. # G-8129-08/ Forsyth Medical Center/ Acquire a second PET/CT scanner/ Forsyth County
FID #923174

Dear Ms. MacFadden:

Thank you for your recent progress report on the above referenced project. Your next progress report will be due December 31, 2011.

Please contact the Certificate of Need Section office if you have any additional delays or unexpected expenditures. Please do not hesitate to contact me if you have any questions regarding this project.

Please refer to the Project I.D. # and Facility I.D. # (FID) in all correspondence.

Sincerely,

Gebrette Miles, Project Analyst
Certificate of Need Section

GM:mw

Attachment

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center • Raleigh, North Carolina 27699-2704
http://www.ncdhhs.gov/dhsr/

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

February 17, 2012

Laura MacFadden, Director
Design & Construction
Novant Health
1980 South Hawthorne Road, Suite 200
Winston-Salem, NC 27103

RE: Request for Progress Report
Project I.D. #: G-8129-08
Project: Forsyth Medical Center/ Acquire a second PET/CT scanner/ Forsyth County
FID #: 923174

Dear Ms. MacFadden:

On November 13, 2008, this Department issued a Certificate of Need pursuant to Chapter 131E Article 9 of the General Statutes of North Carolina for the above captioned project. The certificate permits the named legal entity to develop the project for the defined scope and identified location within the timetable specified on the certificate. To determine whether the timetable is being met by the holder of the certificate and the project is being developed in accordance with representations made in the application and conditions imposed on the certificate, 131E-189 of Chapter 131E Article 9 of the General Statutes provides that this Agency is authorized to require the submission of periodic progress reports.

Accordingly, in furtherance of this authority, the Certificate of Need Section is hereby requesting a report to document progress made in offering the new institutional health service set forth in the certificate you have received. Please respond to the attached questions and provide the related documentation within 30 days of today's date. Your failure to respond in a timely and satisfactory manner may result in this Department's initiating proceedings to withdraw your certificate.

If you have any questions concerning this request, please contact me. Thank you for your cooperation.

Please refer to the Project I.D. # and Facility I.D. # (FID) in all correspondence.

Sincerely,

Gebrette Miles, Project Analyst
Certificate of Need Section

GM:mw

Novant HEALTH

Remarkable People. Remarkable Medicine.

March 15, 2012

Gebrette Miles, Project Analyst and
Craig R. Smith, Section Chief
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Progress Report #7

Project I.D. G-8129-08/Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

Dear Ms. Miles and
Mr. Smith:

In response to your letter dated February 17, 2012, requesting a progress report, I have attached Progress Report #7 for the Project I.D. #G-8129-08 for a second PET/CT scanner at FMC.

I apologize that this project report is late. We are reviewing our notification process in order to improve our timeliness of submission of Progress Reports. Please contact me if you need further information.

Additionally, please send all correspondence on this project to me at 1980 South Hawthorne Road, Suite 200, Winston-Salem, NC 27103.

Sincerely,

Laura MacFadden
Senior Director, Design & Construction

LM/cw

cc: Barbara Freedy

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Forsyth Date of Progress Report: #7 **03/15/2012**
Facility: Forsyth Medical Center Facility I.D. #: 923174
Project I.D. #: G-8129-08 Effective Date of Certificate: Nov. 13, 2008
Project Description: Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

A. Status of the Project

(a) Describe in **detail** the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

Forsyth Medical Center (FMC) remains committed to this project and plans to begin design and construction for this second PET/CT scanner to be installed at FMC as proposed in the CON application for Project I.D. G-8129-08 in January 2013. Listed below in Section B. Timetable is our proposed schedule[1].

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete **until** *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

State approved 01/7/2010

PROJECT MILESTONES	Projected Completion Date from certificate	Actual completion date	Proposed completion date
	Month/day/year	Month/day/year	Month/day/year
Obtained Funds for the Project			1/03/2013
Final Drawings and Specifications Sent to DHSR			4/01/2013
Acquisition of land/facility			N/A
Construction Contract Executed	9/30/2010		5/01/2013
25% completion of construction			6/01/2013
50% completion of construction	12/31/2010		7/01/2013
75% completion of construction			8/01/2013
Completion of construction	3/31/2011		9/01/2013
Ordering of medical equipment	9/30/2010		7/01/3013
Operation of medical equipment	4/30/2011		10/01/2013
Occupancy/offering of services			10/01/2013
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and

[1] As the Section is aware, Novant filed a declaratory ruling request in 2011 to convert this scanner to a mobile scanner and use it at various Novant hospitals, including Forsyth Medical Center. This declaratory ruling request was denied and is still under appeal. It remains Novant's desire to use this scanner in the manner described in the declaratory ruling request because Novant believes that is in the best interest of patient care. Nothing in this progress report should be construed as Novant's abandonment of the position it took in the declaratory ruling request. Novant does, however, want to offer the Department a schedule for implementation as set forth in this progress report in the event Novant does not prevail in litigation.

b. provide a revised timetable for the CON Section to consider. **Revised Timetable listed above, and submitted for the State's review and consideration.**

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

D. Capital Expenditure

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fees	$	$ 97,177.09
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify) **Filing Fees**		$ 15,582.00
Subtotal Misc. Costs	$	$112,759.07
Total Capital Cost of the Project	$ 0	$112,759.07

2. What do you project to be the remaining capital expenditure required to complete the project? $4,414,468.93

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference. **NO**

E. CERTIFICATION – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: Laura MacFadden

Name and Title of Responsible Officer: Laura MacFadden, Senior Director, Design & Construction

Telephone Number of Responsible Officer: 336-718-0725

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center • Raleigh, North Carolina 27699-2704
http://www.ncdhhs.gov/dhsr/

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

March 21, 2012

Laura McFadden, Senior Director
Design & Construction
Novant Health
1980 S. Hawthorne Road, Suite 200
Winston-Salem, NC 27103

RE: Acknowledgment of Receipt of Progress Report/ Project I.D. #G-8129-08/ Forsyth Medical Center/ Acquire a second PET/CT scanner/ Forsyth County
FID #923174

Dear Ms. MacFadden:

Thank you for your recent progress report on the above referenced project. Your next progress report will be due July 31, 2012.

Please contact the Certificate of Need Section office if you have any additional delays or unexpected expenditures. Please do not hesitate to contact me if you have any questions regarding this project.

Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

Sincerely,

Gebrette Miles

Gebrette Miles, Project Analyst
Certificate of Need Section

GM:mw

Attachment

Novant HEALTH

Remarkable People. Remarkable Medicine.

July 31, 2012

Lisa Pittman, Project Analyst
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Progress Report #8

Project I.D. G-8129-08/Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

Dear Ms. Pittman:

Attached is Progress Report #8 for the Project I.D. //G-8129-08 for a second PET/CT scanner at FMC.

Additionally, please note our office has relocated and all correspondence on this project should be sent to me at 3600 Country Club Road, Suite 201, Winston-Salem, NC 27104.

Sincerely,

Laura MacFadden
Senior Director, Design & Construction

LM/cw

cc: Barbara Freedy

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Forsyth
Facility: Forsyth Medical Center
Project I.D. #: G-8129-08
Date of Progress Report: #8 07/31/2012
Facility I.D. #: 923174
Effective Date of Certificate: Nov. 13, 2008
Project Description: Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

A. Status of the Project

(a) Describe in **detail** the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

Forsyth Medical Center (FMC) remains committed to this project. We are currently in the process of seeking internal Novant funding to support the commencement of design and construction for this second PET/CT scanner to be installed during 2013 at FMC's Radiology Department as proposed in the CON application for Project I.D. G-8129-08. See Section B for the timetable we reported in our last report, which remains our best estimate of a development timeline as of today.[1]

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete until *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

State approved 01/7/2010

PROJECT MILESTONES	Projected Completion Date from certificate Month/day/year	Actual completion date Month/day/year	Proposed completion date Month/day/year
Obtained Funds for the Project			1/03/2013
Final Drawings and Specifications Sent to DHSR			4/01/2013
Acquisition of land/facility			N/A
Construction Contract Executed	9/30/2010		5/01/2013
25% completion of construction			6/01/2013
50% completion of construction	12/31/2010		7/01/2013
75% completion of construction			8/01/2013
Completion of construction	3/31/2011		9/01/2013
Ordering of medical equipment	9/30/2010		7/01/3013
Operation of medical equipment	4/30/2011		10/01/2013
Occupancy/offering of services			10/01/2013
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and

[1] As the CON Section is aware, Novant filed a declaratory ruling request in 2011 to convert this scanner to a mobile scanner and use it at various Novant hospitals, including Forsyth Medical Center. This declaratory ruling request was denied and Novant's appeal was dropped in summer 2012.

b. provide a revised timetable for the CON Section to consider.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

D. Capital Expenditure

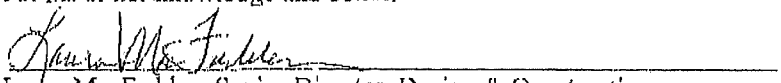
1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fees	$	$ 97,177.09
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify) **Filing Fees**		$ 15,582.00
Subtotal Misc. Costs	$	$112,759.07
Total Capital Cost of the Project	$ 0	$112,759.07

2. What do you project to be the remaining capital expenditure required to complete the project? $4,414,468.93

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference. NO

E. CERTIFICATION – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: 
Name and Title of Responsible Officer: Laura MacFadden, Senior Director, Design & Construction
Telephone Number of Responsible Officer: 336-277-8670

Effective date: 4/24/09

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center • Raleigh, North Carolina 27699-2704
http://www.ncdhhs.gov/dhsr/

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

August 8, 2012

Laura MacFadden, Senior Director
3600 Country Road, Suite 201
Winston-Salem, NC 27104

Acknowledgement of Receipt of Progress Report and Extension of Timetable

Project I.D. #:	G-8129-08
Facility:	Forsyth Medical Center
Project Description:	Acquire a second PET/CT scanner
County:	Forsyth
FID #:	923174

Dear Ms. MacFadden:

Thank you for your recent progress report on the above referenced project. Your next progress report will be due December 1, 2012.

Please notify the Project Analyst as soon as possible if development of the project may be delayed by more than three months or the total capital expenditure may exceed more than 110 percent of the approved capital expenditure. Extension of the timetable must be approved by the Certificate of Need Section. If the total capital expenditure will exceed 115 percent of the approved capital expenditure, a new certificate of need will be required for the cost overrun.

The Certificate of Need Section has decided to extend the timetable for the above referenced project pursuant to G.S. 131E-189. The timetable for this project has been extended only for the period specified below.

Milestone	Completion Date
Obtained Funds for the Project	January 3, 2013
Final Drawings and Specifications sent to Construction Section, DHSR	April 1, 2013
Construction Contract Executed	May 1, 2013
25% Completion of Construction	June 1, 2013
50% Completion of Construction	July 1, 2013
Ordering of Medical Equipment	July 1, 2013
75% Completion of construction	August 1, 2013
Completion of Construction	September 1, 2013
Operation of Medical Equipment	October 1, 2013
Occupancy/Offering of Service(s)	October 1, 2013

Novant HEALTH

Remarkable People. Remarkable Medicine.

November 30, 2012

Kimberly Randolph, Project Analyst and
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27699

Re: Progress Report #9

Project I.D. G-8129-08/Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

Dear Ms. Randolph:

Enclosed is Progress Report # 9 for the Project I.D. #G-8129-08 for Forsyth Medical Center second PET/CT scanner. Please contact me if you need further information.

Additionally, please send all correspondence on this project to me at 3600 Coutry Club Road, Suite 201, Winston-Salem, NC 27104.

Sincerely,

Ronald T. Eller
Senior Director, Design & Construction

RE/cw

cc: Barbara Freedy

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Forsyth
Facility: Forsyth Medical Center
Project I.D. #: G-8129-08
Date of Progress Report: #9 11/30/2012
Facility I.D. #: 923174
Effective Date of Certificate: Nov. 13, 2008
Project Description: Novant Health, Inc. and Forsyth Memorial Hospital, Inc, d/b/a Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

A. **Status of the Project**

(a) Describe in detail the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

Forsyth Medical Center (FMC) remains committed to this project. This project is part of the 2013 Capital Budget, with funding pending approval in January 2013 to support the beginning of design and then construction. The Revised Timetable, in the Proposed Completion Date column below in Section B, was approved by the CON Section on August 8, 2012 which remains as our best estimate of a development timeline as of today.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete until *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column must include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

State approved 01/7/2010

PROJECT MILESTONES	Projected Completion Date from certificate	Actual completion date	Proposed completion date
	Month/day/year	Month/day/year	Month/day/year
Obtained Funds for the Project			1/03/2013
Final Drawings and Specifications Sent to DHSR			4/01/2013
Acquisition of land/facility			N/A
Construction Contract Executed	9/30/2010		5/01/2013
25% completion of construction			6/01/2013
50% completion of construction	12/31/2010		7/01/2013
75% completion of construction			8/01/2013
Completion of construction	3/31/2011		9/01/2013
Ordering of medical equipment	9/30/2010		7/01/3013
Operation of medical equipment	4/30/2011		10/01/2013
Occupancy/offering of services			10/01/2013
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and

   b. provide a revised timetable for the CON Section to consider. **Revised Timetable listed above was approved by the CON Section on August 8, 2012.**

C. **Medical Equipment Projects** – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

D. **Capital Expenditure**

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fees	$	$ 97,177.09
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify) **Filing Fees**		$ 15,582.00
Subtotal Misc. Costs	$	$112,759.07
Total Capital Cost of the Project	$ 0	$112,759.07

2. What do you project to be the remaining capital expenditure required to complete the project? $4,414,468.93

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference. NO

E. CERTIFICATION – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: _____

Name and Title of Responsible Officer: Ronald T. Eller, Senior Director, Design & Construction

Telephone Number of Responsible Officer: 336-277-8670

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center • Raleigh, North Carolina 27699-2704
http://www.ncdhhs.gov/dhsr/

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

November 30, 2012

Laura MacFadden, Senior Director
3600 Country Road, Suite 201
Winston-Salem, NC 27104

Acknowledgement of Receipt of Progress Report and Next Progress Report Due

Project I.D. #:	G-8129-08
Facility:	Forsyth Medical Center
Project Description:	Acquire a second PET/CT scanner
County:	Forsyth
FID #:	923174

Dear Ms. MacFadden:

Thank you for your recent progress report on the above referenced project. Your next progress report will be due April 15, 2013.

Please notify the Project Analyst as soon as possible if development of the project may be delayed by more than three months or the total capital expenditure may exceed more than 110 percent of the approved capital expenditure. Extension of the timetable must be approved by the Certificate of Need Section. If the total capital expenditure will exceed 115 percent of the approved capital expenditure, a new certificate of need will be required for the cost overrun.

Do not hesitate to contact me if you have any questions regarding this project.

Refer to the Project I.D. # and Facility I.D. # in all future correspondence.

Sincerely,

Kim Randolph

Kim Randolph, Project Analyst
Certificate of Need Section

Attachment

NOVANT HEALTH

Novant Health
2985 Fronds Plaza Drive
Winston-Salem, NC 27103

April 30, 2013

Kimberly Randolph, Project Analyst
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27699

Re: Progress Report #10

Project I.D. G-8129-08/Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County

Dear Ms. Randolph:

Enclosed is Progress Report # 10 for the Project I.D. #G-8129-08 for Novant Health Forsyth Medical Center second PET/CT scanner. Please contact me if you need further information.

Additionally, please send all correspondence on this project to me at 3600 Coutry Club Road, Suite 201, Winston-Salem, NC 27104.

Sincerely,

Laura MacFadden

Senior Director, Design & Construction

LM/ss

cc: Barbara Freedy

1/1

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Forsyth
Facility: Novant Health Forsyth Medical Center
Project I.D. #: G-8129-08

Date of Progress Report: #10 04/30/2013
Facility I.D. #: 923174
Effective Date of Certificate: Nov. 13, 2008

Project Description: Novant Health, Inc. and Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center shall acquire a second PET/CT scanner/Forsyth County.

A. Status of the Project

(a) Describe in detail the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

Novant Health is committed to moving forward with this project and Novant Health intends to develop the project in accordance with the terms of the project's Certificate of Need ("CON"). In order to ensure that the greatest segment of the patient population in the service area can be served by the project, however, Novant Health is currently in the process of exploring options to implement this PET/CT Scanner in a different location within Forsyth County, including, but not limited to Novant Health Kernersville Medical Center and Novant Health Clemmons Medical Center. Novant Health expects to have the results of this inquiry within ninety (90) days of today's date, and will, at that point, submit a new Progress Report with a revised Project Timetable. We understand that any proposed re-location of this project would require the filing of an appropriate request with the State.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete until *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column must include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

State approved 08/08/2012

PROJECT MILESTONES	Projected Completion Date from certificate	Actual completion date	Proposed completion date
	Month/day/year	Month/day/year	Month/day/year
Obtained Funds for the Project	1/03/2013		
Final Drawings and Specifications Sent to DHSR	4/01/2013		
Acquisition of land/facility	N/A		
Construction Contract Executed	5/01/2013		
25% completion of construction	6/01/2013		
50% completion of construction	7/01/2013		
75% completion of construction	8/01/2013		
Completion of construction	9/01/2013		
Ordering of medical equipment	7/01/2013		
Operation of medical equipment	10/01/2013		
Occupancy/offering of services	10/01/2013		
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and **In order to ensure that the greatest segment of the patient population in the service area can be served by the project, however, Novant Health is currently in the process of exploring options to implement this PET/CT Scanner in a different location within Forsyth County, including, but not limited to Novant Health Kernersville Medical Center and Novant Health Clemmons Medical Center.**

   b. provide a revised timetable for the CON Section to consider.

C. **Medical Equipment Projects** – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

D. **Capital Expenditure**

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fees	$	$ 97,177.09
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify) Filing Fees		$ 15,582.00
Subtotal Misc. Costs	$	$112,759.07
Total Capital Cost of the Project	$ 0	$112,759.07

2. What do you project to be the remaining capital expenditure required to complete the project? $4,414,468.93

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference. NO

E. CERTIFICATION – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer:
Name and Title of Responsible Officer: Laura MacFadden, Senior Director, Design & Construction
Telephone Number of Responsible Officer: 336-277-8670

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

May 3, 2013

Laura MacFadden
3600 Country Club Road, Suite 201
Winston-Salem, NC 27104

Acknowledgement of Receipt of Progress Report and Next Progress Report Due

Project I.D. #:	G-8129-08
Facility:	Forsyth Medical Center
Project Description:	Acquire a second PET/CT scanner
County:	Forsyth
FID #:	923174

Dear Ms. MacFadden:

Thank you for your recent progress report on the above referenced project. Your next progress report will be due no later than August 1, 2013.

Please notify the Project Analyst as soon as possible if development of the project may be delayed by more than three months or the total capital expenditure may exceed more than 110 percent of the approved capital expenditure. Extension of the timetable must be approved by the Certificate of Need Section. If the total capital expenditure will exceed 115 percent of the approved capital expenditure, a new certificate of need will be required for the cost overrun.

Please do not hesitate to contact me if you have any questions regarding this project.

Please refer to the Project I.D. # and Facility I.D. # (FID) in all correspondence.

Sincerely,

Kim Randolph, Project Analyst
Certificate of Need Section

Attachment

KR:mw

Certificate of Need Section
www.ncdhhs.gov
Telephone 919-855-3873
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center •Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer

436 S.E.2d 390
112 N.C.App. 557, 436 S.E.2d 390
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Court of Appeals of North Carolina.
CATAWBA MEMORIAL HOSPITAL, Petitioner-Plaintiff,
v.
NORTH CAROLINA DEPARTMENT OF HUMAN RESOURCES, Respondent-Defendant
and
Ami Frye Regional Medical Center, Intervenor-Respondent-Defendant.
No. 9210SC821.

Nov. 16, 1993.

Hospital was advised by North Carolina Department of Human Resources that hospital needed to obtain **certificate** of need (CON) before developing its open heart surgery facility. Hospital petitioned for contested case hearing and requested declaratory ruling with regard to same issue. Agency rendered final decision concluding that CON was required and denied request for declaratory ruling. Hospital did not appeal CON decision but filed petition for judicial review of denial of request for declaratory ruling. The Superior Court, Wake County, Donald W. Stephens, J., reversed agency decision, reversed denial of request for declaratory ruling and dismissed hospital's request for declaratory judgment on ground that it was moot. All parties appealed. The Court of Appeals, Martin, J., held that: (1) good cause existed for denial of request for declaratory ruling, and (2) final agency decision on CON was judicial decision which barred, as res judicata, hospital's request for declaratory judgment.

Reversed in part and affirmed in part.

West Headnotes

[1] **Declaratory Judgment** 43
118Ak43 Most Cited Cases
Good cause existed for denial of request for declaratory ruling under North Carolina's Administrative Procedure Act where denial was based on existence of North Carolina Department of Human Resource's prior administrative agency ruling which necessarily required interpretation of same statute which was subject of request for declaratory ruling. G.S. § 150B-4.

[2] **Health** 245
198Hk245 Most Cited Cases
(Formerly 204k1 Hospitals)
Superior court had no jurisdiction to consider final administrative agency decision by North Carolina's Department of Human Resources requiring hospital to obtain **certificate** of need (CON) before developing open heart surgery facility where hospital's appeal to superior court only sought review of agency's refusal to issue declaratory ruling in response to hospital's request for declaratory ruling, and appeal from final agency decision regarding issuance of CON had to be filed in Court of Appeals, not superior court. G.S. § 131E-188.

[3] **Judgment** 540
228k540 Most Cited Cases
Final judgment, rendered on merits, by court of competent jurisdiction will bar subsequent action involving same issues between same parties.

[4] **Administrative Law and Procedure** 501
15Ak501 Most Cited Cases

[4] **Health** 240
198Hk240 Most Cited Cases
(Formerly 204k1 Hospitals)
Although contested case decision requiring hospital to obtain **certificate** of need (CON) before developing open heart surgery facility was administrative decision by North Carolina's Department of Human Resources, it could bar hospital's request for declaratory judgment on same issue under doctrine of res judicata.

[5] **Administrative Law and Procedure** 501
15Ak501 Most Cited Cases
As general rule, administrative decision denying or dismissing party's claim on merits precludes such party from obtaining, in judicial proceeding not designed for review of administrative decision, relief denied by administrative agency, whether upon same ground urged in administrative proceeding or upon another ground.

[6] **Administrative Law and Procedure** 501
15Ak501 Most Cited Cases

[6] **Health** 245
198Hk245 Most Cited Cases
(Formerly 204k1 Hospitals)
Final agency decision by North Carolina's

Department of Human Resources requiring hospital to obtain **certificate** of need (CON) to develop open heart surgery facility was judicial decision which barred, as res judicata, hospital's complaint in superior court for declaratory judgment with regard to same issue.

[7] Appeal and Error 854(2)
30k854(2) Most Cited Cases
Judgment which is correct must be affirmed even though reason stated for its entry is incorrect.
****391 *559** On 14 February 1990, petitioner Catawba Hospital (hereinafter Catawba) wrote respondent North Carolina Department of Human Resources (hereinafter the Agency) concerning Catawba's plans to develop an open heart surgery facility. The purpose of Catawba's letter to the Agency was to obtain a determination and affirmation that the hospital would not require a **certificate** of need (hereinafter CON) before commencing development of the new surgical facility.

G.S. § **131E**-178 requires issuance of a CON prior to construction or operation of a new health care facility where the capital expenditure for the new service will exceed $2,000,000, G.S. § **131E**-176(16)b, or the "annual operating costs" will exceed $1,000,000, G.S. § **131E**-176(16)f (repealed 1993). In response to Catawba's letter, the Agency asked Catawba to furnish specific financial and operating projections so that the Agency could determine whether Catawba's proposal would require issuance of a CON.

On 15 March 1990, Catawba wrote a letter to the Agency containing its projected operating expenses for the first three years of operation. Catawba's projected operating expenses were below the $1,000,000 threshold for each of the first three years. However, in evaluating Catawba's projections, the Agency found that the hospital had overlooked certain essential items of expense. Also, an Agency comparison of Catawba's financial projections to financial information from similar existing and proposed open heart surgery programs indicated that Catawba's operating expenses would exceed $1,000,000 in each year of operation.

Based on its evaluation of Catawba's financial projections, and its comparison of those projections with the expenses of other facilities, the Agency advised Catawba on 25 April 1990 that the hospital would be required to obtain a CON before proceeding with an open heart surgery program.

On 24 May 1990, Catawba petitioned the Office of Administrative Hearings for a contested case hearing and thereafter moved for a decision recommending summary judgment. In support of its motion, Catawba filed its 15 March 1990 letter to the Agency which contained its projected operating expenses. In opposition to the motion, the Agency offered the affidavits of its Project Analyst ***560** and its CON Section Chief. These affidavits concluded that Catawba's operating expenses would exceed the $1,000,000 threshold in each of the facility's first three years of operation.

The Administrative Law Judge, adopting Catawba's projected operating expenses, concluded that the surgical facility's operating expenses would not exceed the statutory threshold and would not require issuance of a CON. The Agency excepted to the recommended decision and filed its exceptions for review by the final agency decision maker.

On 12 April 1991, the case was called for hearing for a final agency decision before the Director of the Agency's Division of Facility Services, Mr. John Syria. During oral arguments, Catawba's counsel handed Mr. Syria a Request for Declaratory Ruling. The request sought, in pertinent part, a declaration that Catawba would not be required to obtain a CON if "the annual operating costs of the service [would] not exceed $1,000,000 in the first year[.]"

On 16 April 1991, the Agency rendered a final agency decision which concluded that Catawba's annual operating expenses ****392** would exceed $1,000,000 in each of the first three years of operation and that Catawba would be required to obtain a CON before commencing operation of the proposed open heart surgery facility. Catawba did not appeal this final agency decision.

On 3 May 1991, Mr. Syria responded by letter to Catawba's Request for Declaratory Ruling. Mr. Syria denied Catawba's request, explaining that Catawba's request was not filed until after the official record in the contested case had been closed. He further stated that although the facts set forth in a request for declaratory ruling are ordinarily taken as true, the facts in the instant case were established by the record in the contested case. Mr. Syria therefore declined to issue a declaratory ruling on the facts as set forth in the request.

On 5 June 1991, Catawba filed in the Wake County Superior Court a Petition for Judicial Review and

Complaint for Declaratory Judgment. The petition only sought review of the denial of its Request for a Declaratory Ruling. Additionally, Catawba sought, pursuant to G.S. § 1-253, a declaratory judgment interpreting former G.S. § **131E**-176(16)f. On 8 November 1991, AMI Frye Regional Medical Center was allowed to intervene.

***561** On 3 March 1992, the superior court issued an order reversing the final agency decision in the contested case. The court construed former G.S. § **131E**-176(16)f as requiring only that the facility's operating expenses not exceed $1,000,000 in the first year of operation. The court declared that the Agency exceeded its statutory authority by requiring that the facility's operating expenses not exceed $1,000,000 in the first three years of operation.

On 4 March 1992, the superior court issued an amended order reversing the Agency's 3 May 1991 denial of Catawba's request for declaratory ruling, and dismissing Catawba's complaint for a declaratory judgment on the ground that the complaint was rendered moot by the court's ruling with respect to Catawba's Petition for Judicial Review under G.S. § 150B-43, *et seq.* The superior court concluded that it had adequately declared Catawba's rights regarding its proposed surgical services. All parties appeal.

Petree Stockton by Noah H. Huffstetler, III, L. Elizabeth Henry, and Gary S. Qualls, Raleigh, for petitioner Catawba Memorial Hosp.

Atty. Gen. Lacy H. Thornburg by Associate Atty. Gen. Margaret C. Ciardella, and Associate Atty. Gen. Sherry L. Cornett, Raleigh, for respondent North Carolina Dept. of Human Resources.

Bode, Call & Green by Robert V. Bode, S. Todd Hemphill and Diana E. Ricketts, Raleigh, for intervenor-respondent AMI Frye Regional Medical Center.

MARTIN, Judge.

The parties raise numerous issues by this appeal. We find three to be dispositive and, in view of our decisions with respect thereto, conclude that it is unnecessary to address the remainder. For the reasons set forth herein, the decision below is reversed in part and affirmed in part.

RESPONDENTS' APPEAL

By their first assignment of error, respondents contend that the superior court erred by reversing the Agency's denial of Catawba's request for a declaratory ruling. Declaratory rulings under the Administrative Procedure Act are governed by G.S. § 150B-4, which provides in pertinent part:

> ***562** (a) On request of a person aggrieved, an agency shall issue a declaratory ruling as to the validity of a rule or as to the applicability to a given state of facts of a statute administered by the agency or of a rule or order of the agency, *except when the agency for good cause finds the issuance of a ruling undesirable.* (Emphasis added.)

Respondents argue that because the questions raised in Catawba's request to the Agency for a declaratory ruling were identical to the questions decided by the Agency in its final agency decision, the Agency had good cause to decline Catawba's request for a declaratory ruling. We agree.

****393** The issue addressed by the decision maker in the contested case was "[w]hether the annual operating costs of Catawba's proposed open heart surgical service will equal or exceed one million dollars, thus making it a new institutional health service, requiring it to obtain a **Certificate** of Need." The Agency concluded that Catawba would be required to obtain a CON and that under former G.S. § **131E**-176(16)f it was proper for the Agency to analyze the proposed service's annual operating costs for a three year period.

In its request for a declaratory ruling, Catawba sought,

> a declaration that it is entitled to offer open heart surgical services without obtaining a **certificate** of need so long as the capital expenditures associated with development of the service do not exceed $2,000,000, [and] the annual operating costs of the service will not exceed $1,000,000 in the first year.... In addition, Catawba requests a declaration that the three-year standard the Agency has applied to Catawba's proposal in determining the applicability of N.C.G.S. § **131E**-176(16)f is an invalid rule.

Clearly, the issues to be addressed in deciding the contested case were virtually identical to the issues which Catawba sought to have determined by way of its requested declaratory ruling. Both actions required the Agency to determine the applicability of former G.S. § **131E**-176(16)f to Catawba's proposed open heart surgery facility. As stated by Director Syria in his letter denying Catawba's request for a declaratory ruling, the interpretation sought by Catawba was included in the decision in the contested case. Furthermore, Catawba did not

approach the Agency for a declaratory ruling until after the official record in the contested case had ***563** been closed. Whereas a declaratory ruling by definition involves the application of a statute or agency rule to a given state of facts, the facts regarding Catawba's proposed surgical services were established by the record in the contested case.

[1] We hold good cause exists for denial of a request for a declaratory ruling where the denial is based on the existence of a prior agency ruling which necessarily required an interpretation of the same statute which is the subject of the request for declaratory ruling. To hold otherwise would be to require an agency to twice decide the same case, between the same parties, by applying the same statute to the same facts. We are convinced that the Administrative Procedure Act was not intended to allow such unnecessary repetition. Thus, the Agency's denial of Catawba's request was for good cause, and we must reverse that part of the superior court's order which reversed the Agency's denial of Catawba's request for declaratory ruling.

Respondents also assign error to that portion of the superior court's order which reversed the 16 April 1991 final agency decision. Respondents argue that the superior court lacked jurisdiction to enter an order reversing the final agency decision. We agree.

[2] The record shows, and the parties agree, that Catawba did not perfect an appeal of the final agency decision. Rather, Catawba's appeal to the superior court only sought review of the Agency's refusal to issue a declaratory ruling in response to Catawba's request. Moreover, G.S. § **131E**-188, which governs appeals from final agency decisions regarding the issuance of a CON, provides that such appeals are to be filed in this Court, not the superior court. N.C.Gen.Stat. § **131E**-188; *Iredell Mem. Hosp. v. N.C. Dept. of Human Resources,* 103 N.C.App. 637, 406 S.E.2d 304 (1991). Thus, the superior court had no jurisdiction to consider the final agency decision and that decision, not having been appealed, remains binding on the parties.

PETITIONER'S APPEAL

Catawba assigns error to the portion of the superior court's order which dismissed Catawba's complaint for declaratory judgment on the ground that it was moot. The superior court ruled that Catawba's complaint was moot on the ground that it had ****394** adequately determined Catawba's rights under former G.S. § **131E**-176(16)f when it reversed the final agency decision. Catawba ***564** argues that its complaint for a declaratory judgment will no longer be moot if we reverse the superior court's decision in favor of Catawba. Because we have reversed the superior court's decision in favor of Catawba, we must now determine whether dismissal of Catawba's complaint for declaratory judgment was proper. We hold that Catawba's complaint was properly dismissed, although on grounds other than mootness.

[3] As we have previously noted, Catawba failed to appeal the final agency decision in the contested case. "[A] final judgment, rendered on the merits, by a court of competent jurisdiction, is conclusive of rights, questions and facts in issue, as to the parties and privies, in all other actions involving the same matter." *Masters v. Dunstan,* 256 N.C. 520, 523, 124 S.E.2d 574, 576 (1962), (*quoting Bryant v. Shields,* 220 N.C. 628, 634, 18 S.E.2d 157, 161 (1942)). Such a final judgment will bar a subsequent action involving the same issues between the same parties. *Thomas M. McInnis & Assoc., Inc. v. Hall,* 318 N.C. 421, 349 S.E.2d 552 (1986); *see also, Cannon v. Cannon,* 223 N.C. 664, 28 S.E.2d 240 (1943).

Without question, Catawba's declaratory judgment action and the contested case involved the same parties: Catawba and the Agency. Likewise, we are persuaded that the issues addressed in the final agency decision are identical to the issues raised in Catawba's declaratory judgment action.

The central issue in both cases was whether, under former G.S. § **131E**-176(16)f, Catawba would be required to obtain a CON prior to offering its proposed open heart surgical services. A CON would be required if Catawba's "annual operating costs" exceeded $1,000,000. N.C.Gen.Stat. § **131E**-176(16) f (repealed 1993). However, the phrase "annual operating costs" is not defined by the statute. Thus, in rendering a decision in the contested case, the decision maker was required to interpret the meaning of the phrase "annual operating costs." The decision maker concluded that "the term 'annual operating costs' in the statute is not limited to annual operating costs in the first year."

In its complaint for declaratory judgment, Catawba prayed for a declaration that "[a]s a matter of law, the $1,000,000 limitation on operating costs set forth in N.C.G.S. § **131E**-176(16)f applies to the operating costs for the first year the service is offered...." Thus, Catawba was seeking a declaratory judgment regarding a matter which it previously litigated in the contested case and ***565** which was resolved against it in the final agency decision. As we have said, the

final agency decision was never appealed and remains binding on the parties.

[4][5] Although the contested case decision was an administrative decision, it may nevertheless bar Catawba's request for a declaratory judgment under the doctrine of *res judicata.* As a general rule, "[a]n administrative decision denying or dismissing a party's claim on the merits precludes such party from obtaining, in a judicial proceeding not designed for review of the administrative decision, the relief denied by the administrative agency, whether upon the same ground as urged in the administrative proceeding, or upon another ground." 2 Am.Jur.2d *Administrative Law* § 502. In *In re Mitchell,* 88 N.C.App. 602, 364 S.E.2d 177 (1988), this Court stated:

> Whether an administrative decision is *res judicata* depends upon its nature; decisions that are "judicial" or "quasi-judicial" can have that effect, decisions that are simply "administrative" or "legislative" do not. Though the distinction between a "quasi-judicial" determination and a purely "administrative" decision is not precisely defined, the courts have consistently found decisions to be quasi-judicial when the administrative body adequately notifies and hears before sanctioning, and when it adequately provides in the legislative authority for the proceeding's finality and review.

****395** *Id.,* at 605, 364 S.E.2d at 179. Thus, we examine the legislative authority which governs contested cases involving **certificates** of need to decide whether the final agency decision was a "judicial" decision.

G.S. § **131E**-188(a) provides:

> After a decision of the Department to issue, deny or withdraw a **certificate** of need or exemption or to issue a **certificate** of need pursuant to a settlement agreement with an applicant to the extent permitted by law, any affected person, ... shall be entitled to a contested case hearing....

G.S. § **131E**-188(b) provides that "[a]ny affected person who was a party to a contested case hearing shall be entitled to judicial review of all or any portion of any final decision of the department...."

***566** [6][7] Clearly, the foregoing sections adequately provide for the finality and review of the final agency decision in the present case. Thus, we conclude that the final agency decision was a judicial decision which barred, as *res judicata,* Catawba's complaint for declaratory judgment. Based on the foregoing conclusion, we hold that the superior court's dismissal of Catawba's declaratory judgment complaint was proper. A judgment which is correct must be affirmed even though the reason stated for its entry is incorrect. *Payne v. Buffalo Reinsurance Co.,* 69 N.C.App. 551, 317 S.E.2d 408 (1984).

In summary, we reverse that part of the order of the superior court which reversed the final agency decision of the respondent Agency requiring the petitioner to obtain a **certificate** of need before providing the proposed open heart surgical services, as well as the decision of the respondent Agency denying Catawba's request for a declaratory ruling. The order of the superior court dismissing Catawba's complaint for declaratory judgment is affirmed.

Reversed in part, and affirmed in part.

ARNOLD, C.J., and COZORT, J., concur.

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