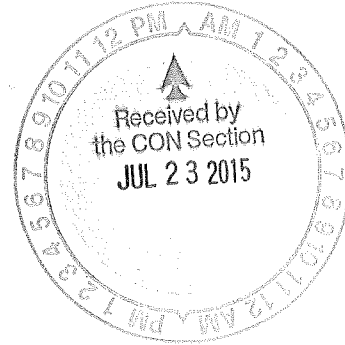




**Strategic
Healthcare
Consultants**



July 24, 2015

Ms. Martha Frisone, Assistant Chief
Health Planning and Certificate of Need Section
Division of Facility Services
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Alliance Healthcare Services Comments Regarding Novant Forsyth Medical
Center CON Application Project ID # G-011051-15

Dear Ms. Frisone:

I am writing on behalf of Alliance Healthcare Services. Please accept the attached written comments that were submitted regarding the above-referenced CON application. In addition, Alliance Healthcare Services requests that a public hearing be conducted regarding this proposed project.

Please do not hesitate to call me at 336 349-6250 if I can answer any questions.

Sincerely,

David J. French
Consultant

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Post Office Box 2154
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Alliance Healthcare Services Comments Regarding Novant Forsyth Medical Center CON Application Project ID # G-011051-15

As discussed in the comments that follow, the Novant Forsyth Medical Center CON application project ID # G-011051-15 fails to conform to the Certificate of Need ((CON) review criteria because the application is based on unreasonable utilization projections and incorrect financial forecasts.

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

The 2015 State Medical Facilities Plan (“SMFP”) shows a continuing decline in the total numbers of PET scans performed in North Carolina which does not generate an unmet need to convert a fixed PET scanner to become a mobile PET scanner. The 2015 SMFP includes no methodology to quantify an unmet need for additional mobile PET capacity. Excess capacity of fixed PET scanners exists in each of the six Health Service Areas. Tables 9N and 9O of the 2015 State Medical Facilities Plan include the following statements:

Table 9N: “It is determined that there is no need for additional fixed dedicated PET scanners anywhere else in the state and no other reviews are scheduled.”

Table 9O: “It is determined that there is no need for additional mobile dedicated PET scanners anywhere else in the state and no other reviews are scheduled.”

While the 2015 SMFP includes Policy TE-1 that allows for proposals to convert underutilized fixed PET scanners to become mobile PET scanners, this Policy does not generate a need determination for PET nor does it supersede the Certificate of Need Review Criteria 3.

The Novant application fails to demonstrate that the project’s total capital cost includes the actual and full cost to remove a fixed PET scanner from Novant Health Forsyth Medical Center. Without the removal of the fixed unit, the proposed acquisition of the mobile PET does not conform to Policy TE-1. The Siemens quote on page 317 includes “This quote includes the trade-in of the existing GE PET/CT.” However the value of the “trade-in” is not disclosed. Also, Siemens is not listed as a CON co-applicant. The term “trade-in” usually means the value of the equipment that would be taken by the seller as partial payment which would then reduce the amount to be paid. As a result, the CON project capital cost is understated because it fails to include the estimated fair market value that is represented by the trade-in equipment. Omitting the capital cost for the removal of the equipment is an error that cannot be remedied without amending the application.

The population that is served by Novant's existing fixed PET scanner is not the same population to be served by the proposed mobile PET scanner. The Novant application fails to show an unmet need the population has for additional mobile PET scanner services. Patient origin projections for the proposed host sites are based on unreasonable statistics because the methodology and assumptions overstated PET utilization. For example, it is absurd to project PET utilization at Novant Health Matthews Medical Center to increase 100 percent from 237 scans in Year 1 to 474 scans in Year 2. Furthermore, the application includes no letters of support from referring physicians that include PET scan projections and no documentation of extended patient waiting times to obtain PET scans at this location. Patient origin projections for the other proposed host sites are unreliable because the volume projections are overstated based on unreasonable growth assumptions.

Demand for PET scans in North Carolina shows a long term trend of declining utilization. The compound annual growth rate ("CAGR") for total combined fixed and mobile PET scans in North Carolina is -2.17 percent based on 41,760 total scans in 2009-10 which dropped to 38,215 total scans in 2013-14.

	2009-10	2010-11	2011-12	2012-13	2013-14
Fixed PET	36,622	34,900	32,729	33,553	32,381
Mobile PET	5,138	5,716	5,571	5,791	5,870
Totals	41,760	40,616	38,300	39,344	38,251

Sources: Tables 9L and 9M(1) of the 2015 SMFP and Proposed 2016 SMFP

For the most recent year, fixed PET scanners throughout the state reported a -3.49 percent decline in utilization and are underutilized at a combined 38.55 percent of capacity. While mobile PET utilization increased slightly last year, the total combined utilization for fixed and mobile PET fell -2.78 percent as seen in the following table.

	2012-13	2013-14	% Change
Fixed PET	33,553	32,381	-3.49%
Mobile PET	5,791	5,870	1.36%
Totals	39,344	38,251	-2.78%

Sources: Tables 9L and 9M(1) of the 2015 SMFP and Proposed 2016 SMFP

The low rate of fixed PET scanner utilization across the state, as well as decreasing utilization of PET services, demonstrates access and availability for PET scanning services for the citizens of the state. With declining total PET

utilization, there is no unmet need that the population has for a mobile PET scanner as a more effective alternate to a fixed PET scanner.

Historical fixed PET utilization for Novant Health Forsyth Medical Center and the fixed PET scanners at nearest hospitals are provided as follows:

	Current Inventory	2009-10	2010-11	2011-12	2012-13	2013-14	CAGR
Novant Health Forsyth Medical Center	2 Fixed PET	3,346	2,875	2,615	2,560	2,518	-6.86%
N.C. Baptist Hospital	2 Fixed PET	2,337	2,571	2,009	1,957	1,967	-4.22%
Cone Health	1 Fixed PET	2,014	1,829	1,801	1,612	1,463	-7.68%
High Point Regional	1 Fixed PET	1,049	794	601	583	592	-13.33%

Sources: Tables 9L and 9M(1) of the 2015 SMFP and

Table 9L reported at the June 3, 2015 SHCC Meeting

The negative CAGR for each of the fixed sites shown in the table above is greater than the statewide CAGR of -2.17 percent. In this region of declining fixed PET utilization, Novant Health proposes to convert one fixed PET scanner to become a mobile unit to provide mobile PET scanner service to Novant Health Kernersville Medical Center and multiple additional host sites.

The proposed mobile PET host site at Kernersville is clearly duplicative of the underutilized fixed PET scanners that are located within 20 miles. The population to be served by the proposed mobile PET host site at Kernersville already has access to multiple full-time fixed PET scanners.

	NC Baptist	Cone Health	High Point
Fixed PET 2014 Procedures as Percent of Capacity	32.78%	48.77%	19.73%
Novant Health Kernersville Medical Center Distances to Existing Fixed PET Facilities	11 miles	19 miles	13 miles

Sources: Proposed 2016 SMFP and MapQuest

Moreover, the projected mobile PET utilization at the Novant Health Kernersville Medical Center is based on unreasonable assumptions. The Novant application contends that population growth, aging and cancer incidence rates support an increased demand for PET. This contention is contradicted by the applicant's own historical utilization with the -6.86 percent CAGR based on 3,346 scans in 2009-10 decreasing to 2,518 scans in 2013-14.

From 2009 to 2014 Novant had one fixed PET scanner at Forsyth Medical Center; the applicant reports that Novant installed a new fixed PET scanner in November 2014 which increased capacity to two dedicated fixed PET scanners at Forsyth Medical Center. Even with this additional capacity the total number of PET

procedures for CY2014 is reported at 2,502, which is a decrease from the previous CY2013 of 2,567 and represents a loss of more than 5 scans per month.

The Novant application is nonconforming with Criterion 3 because the projected utilization is based on a flawed methodology and unreasonable assumptions.

In Step 1 of the methodology on page 61 of the application, Novant provides the projection of 2,700 scans for CY2015 based on only four months of 2015 data. This projection of 2,700 annual scans is not adequately supported because the five year trend shows a steady decline in the annual PET scans performed at Novant Health Forsyth Medical Center. Four months of utilization data is not sufficient to establish a trend or to make annualized projections. Therefore the 1.7% CAGR is not reasonable.

Looking at multiple years of actual data shows that a positive 1.7% CAGR is inconsistent with four consecutive years of negative annual percentages for PET utilization.

	Current Inventory	2009-10	2010-11	2011-12	2012-13	2013-14
Novant Health Forsyth Medical Center	2 Fixed PET	3,346	2,875	2,615	2,560	2,518
Annual Percentage Change from Previous Year			-14.08%	-9.04%	-2.10%	-1.64%

Sources: Tables 9L and 9M(1) of the 2015 SMFP and Proposed 2016 SMFP

In CON Findings for Project ID # F-10292-14 / Presbyterian Hospital Mint Hill, LLC d/b/a Novant Health Mint Hill Medical Center, the Agency determined that when multiple years of negative growth have occurred at a facility, it is unreasonable to assume a positive growth rate that only occurred in one brief time period. In CON Findings for Project ID # F-8792-12 / Caromont Health and Gaston Memorial Hospital's proposal for an MRI scanner, the Agency stated "A one year increase is not sufficient to establish a trend."

The Novant application provides inadequate documentation to show that "improvements in reimbursement and insurance approvals for PET procedures" has actually occurred anywhere in North Carolina. A recent article titled "Medicare is Scrutinizing Evidence More Tightly for National Coverage Determinations" documents that preauthorization for costly procedures has reduced utilization.¹ In addition, radiology management programs by companies like National Imaging Associates, HealthHelp, and CareCore National have been widespread for years and have strict preauthorization procedures for positron emission tomography procedures.

¹ Health Affairs, February 2015 vol. 34 no. 2 253-260

The applicant's projection in Step 2 that PET utilization will increase by 1.7 percent annually for the next four years is unreasonable due to the declining statewide PET utilization and the historical decreases for Forsyth Medical Center and all of the nearby fixed PET providers. For the last five years, PET utilization has simply not been increasing even though the population is aging and cancer incidence has increased.

Step 3 includes the unsupported assumption that 20 percent of the overstated PET utilization at Novant Health Forsyth Medical Center will shift to the Novant Health Kernersville Medical Center. Novant Health Kernersville Medical Center is a department of Novant Health Forsyth Medical Center based on the 2015 license renewal application.

The 20 percent assumption is unsupported and not credible because Novant Health Kernersville Medical Center only performed approximately 11.7 percent of the total linear accelerator ("LINAC") procedures reported for Forsyth Medical Center in 2013-14.

	2013-14
Kernersville LINAC Only	4513
Forsyth Medical Center LINACs + Kernersville LINAC	38547
Kernersville LINAC % of Total	11.71%

Source: Novant Health Forsyth Medical Center 2015 LRA

The application includes no letters of support from referring physicians with volume estimates and no documentation of extended patient waiting times to obtain PET scans at Kernersville.

In Step 4 the applicant wrongly assumes that the PET scans per day at existing mobile PET sites that were performed during the six month period from 10/1/2014 through 3/31/2015 is a reasonable statistic to predict future utilization. These figures are unreliable because the long-term trend for multiple PET sites has been negative CAGR and negative annual percentage of change.

	2010-11	2011-12	2012-13	2013-14	CAGR
Novant Health Rowan Medical Center	306	267	216	239	-7.91%
Rowan Annual Change from Previous Year		-12.75%	-19.10%	10.65%	NA
Novant Health Thomasville Medical Center	109	91	97	85	-7.96%
Thomasville Annual Change from Previous Year		-16.51%	6.59%	-12.37%	NA

Sources: Tables 9L and 9M(1) of the 2015 SMFP and Proposed 2016 SMFP

The application provides inadequate data to support the prediction that PET utilization at these facilities will increase or remain at current levels regardless of the numbers of days of service per week. Statewide utilization of PET continues

to decline. Novant's marketing of mobile PET services has no chance of increasing utilization at all of its host sites because physicians are increasingly discouraged from ordering PET procedures by the radiology benefits programs.

Steps 5 and 6 of the methodology include the unsubstantiated assumption that the scans per day at a given PET host site is a constant number and that increasing days of mobile PET service will result in increased annual utilization. These steps in the Novant methodology are irrational because a mobile PET scanner has no inherent ability to generate its own patients. The PET utilization projections provided on pages 65 and 66 of the application are not adequately supported by physician support letters with volume projections for each of the proposed host sites. No support letters from referring physicians are included for Lenoir Memorial Hospital. In the unlikely event that PET utilization at any of the proposed mobile host sites was to increase it would not be the result of increased demand but instead by a shift of procedures from other existing underutilized fixed scanners.

The applicant's projected PET utilization for Novant Health Matthews Medical center is extremely overstated because it is not reasonable for the Year 1 projection of 237 scans to increase by 100 percent to 474 scans in Year 2. The application fails to demonstrate that there is genuine demand for additional mobile PET at this location. PET utilization for the previous three years at the Novant Health Matthews facility has never exceeded 135 annual procedures. Furthermore, there are multiple underutilized full time fixed PET scanners located in Mecklenburg County and in Union County that are in close proximity to Matthews, NC. Carolinas Medical Center has two underutilized fixed PET scanners operating at 58.05 percent of capacity that are only 13 miles from Matthews, NC. Also, CMC Union Medical Center has one fixed PET operating at 11.63 percent of capacity that is only 16 miles from Matthews. With the full time availability of fixed PET scanners in these locations, the population of the Matthews area has no unmet need for additional mobile PET capacity.

On pages 65 and 66, Step 7 is totally omitted from the Novant methodology.

Step 8 provides the unreasonable projection that adding a half day of mobile PET service at Novant Health Huntersville Medical Center in Year 3 will boost the mobile PET utilization from 454 scans in Year 2 to 681 scans in Year 3. This projection is unreasonable because a mobile PET scanner has no ability to generate its own patients simply by adding a half day of service to the schedule. The table below provides the historical Huntersville PET utilization for this site.

	2010-11	2011-12	2012-13	2013-14
Novant Health Huntersville	221	211	197	218

Sources: Tables 9L and 9M(1) of the 2015 SMFP and Proposed 2016 SMFP

Novant's projected PET utilization for the Huntersville site is overstated because the dramatic 50 percent gain in Year 3 represents a numerical increase of 227 PET scans at this one location; this makes no sense when the utilization at all of the other proposed host sites remains the same as Year 2. The population in the Huntersville region is not projected to increase by 50 percent. Also there is no data to indicate that the cancer incidence rate is expected to skyrocket for this one population. Furthermore, the actual PET utilization data for all existing mobile and fixed PET sites in North Carolina demonstrates that no location has achieved a 50 percent increase in one year. In making its overstated growth projections, Novant fails to consider the available capacity of the full-time fixed PET scanner at CMC-Northeast in Concord that is within 23 miles from Huntersville and is operating at only 32.04 percent of capacity. This existing fixed PET site provides abundant access for the population of this region. Consequently there is no unmet need for additional mobile PET service in Huntersville.

Step 9 of the methodology includes the projections for the proposed new PET host site at Morehead Memorial Hospital in Eden, NC (Rockingham County). The projections of 77 scans in Year 1, 102 scans in Year 2 and 128 scans in Year 3 lack adequate justification. However, patients in Rockingham County have access to multiple fixed PET scanners in Guilford County that are underutilized. The majority of oncologists who treat Rockingham patients are located in Guilford County. Furthermore, the Novant application lacks physician letters of support to validate the projected numbers of patients that would be referred to the scanner at Morehead.

Step 10 combines the totals for all of the proposed host sites. These totals are overstated and unreasonable because the statewide utilization for PET is declining and no unmet need exists for the proposed mobile PET. The utilization projections for the individual host sites are overstated as discussed in the previous comments. Therefore the combined utilization for the proposed mobile PET is also overstated and unreasonable.

Novant's utilization projections are unreasonable because the methodology includes unsubstantiated assumptions that are contradicted by the historical PET utilization data. The statewide declining trend of PET utilization and decreases in utilization at multiple proposed host sites proves that the projected increases in PET utilization are unrealistic and unachievable. Consequently, the Novant application does not comply with Policy GEN-3.

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

As discussed in the comments regarding Criterion 3, the Novant mobile PET projections are unreasonable. Consequently the application fails to demonstrate there is an unmet need for the project. Therefore the application is also nonconforming to Criterion 3a because the applicant fails to demonstrate that the proposed conversion of a fixed PET to a mobile PET will more adequately serve the needs of the population presently served.

Page 17 of the application provides the projected hours of operation for the mobile PET scanner but omits the projected hours of operation of the one remaining fixed PET scanner at Novant Health Forsyth Medical Center. Without this information the application fails to demonstrate that one remaining fixed PET scanner can adequately serve the needs of the population.

According to the report, "*Forsyth County's Older Adults*", 82 percent of the adults over the age of 65 reside in Winston-Salem.² Reducing the availability of fixed PET access in Winston-Salem will cause hardship for low income and older persons who do not drive. Eliminating one of the fixed PET scanners at Novant Health Forsyth Medical Center will decrease scheduling options and limit patient access because two patients can no longer be scheduled for the same time. Also, Forsyth Medical Center will no longer have a back-up PET scanner on site when the one remaining unit requires maintenance.

(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.

The Novant application is nonconforming to Criterion 4 because the proposed project is not the least costly or most effective alternative. Novant's proposal fails to demonstrate that the population has a genuine need for the proposed conversion of a fixed PET scanner to a mobile scanner. The application unreasonably predicts that wherever it's proposed mobile PET scanner may be located, increased demand for PET scans results due to the growth and aging of the population and increasing cancer incidence rates. However, the growth and aging of the population and increasing cancer incidence rates are factors that have been present for the past five years while actual total PET utilization has decreased.

The Novant proposal is nonconforming to Criterion 4 because the application fails to demonstrate that the proposed project is the least costly or most effective alternative. In the financial pro forma, Novant reports that in 2014 its total expenses for the two fixed PET scanners were \$1,107,277. However, both PET scanners were not operational for the full year. For 2015 Novant projects total expenses for the two fixed scanners to be \$1,770,826. For Year 2 (2017-18) the total combined expenses for the one fixed PET and the one mobile PET are projected to be \$3,082,125. Therefore the total projected expenses for the one

² http://forsythaging.forsyth.cc/Documents/Older_Adults_Snapshot.pdf

fixed PET and one mobile PET scanner will be 74% higher than the 2015 expenses for two fixed PET scanners.

Comparison of Projected Expense	Direct Expenses	Indirect Expenses	Total Expenses
Two Fixed PET Scanners 2015 Expenses	\$697,323	\$1,073,504	\$1,770,826
One Fixed and One Mobile PET 2017-18 Combined Expenses	\$1,304,621	\$1,777,505	\$3,082,125
Percentage Increases for Proposed Project Over 2015 Expenses	87.09%	65.58%	74.05%

The Novant application also fails to demonstrate that the projected costs for operating the mobile PET scanner are based on reasonable utilization projections as discussed in the Criterion 3 comments. In addition, the Novant application fails to demonstrate that its proposal is an effective alternative because it is nonconforming to other CON review criteria. In previous CON Findings for Project ID # F-8792-12 / Caromont Health and Gaston Memorial Hospital, the Agency stated *“Moreover, the application is not conforming with all other applicable statutory and regulatory review criteria, and therefore, it is not approvable. An application that cannot be approved cannot be an effective alternative.”*

No capital costs are included for the conversion of existing facility space that was designed to house a fixed PET scanner. The application fails to explain how it is a cost effective alternative to create vacated space in a licensed healthcare facility. In addition, no funds are included in the capital cost for sales tax which may not be subject to refunds to non-profit organizations in future years. These errors make the project capital cost unreliable. The application fails to adequately demonstrate that the capital cost for the proposed mobile PET is reliable because the Siemens quote on page 317 includes “This quote includes the trade-in of the existing GE PET/CT.” However the value of the “trade-in” is not disclosed. The term “trade-in” usually means the value of the equipment that would be taken by the seller as partial payment which reduces the amount to be paid. As a result, Novant’s CON project capital cost is understated because it fails to include the estimated fair market value that is represented by the trade-in equipment. The hand written and unsigned footnote at the bottom of page 317 does not explain if the phrase “trade-in” means a credit or an additional charge that relates to the removal of the GE PET/CT. Thus, the Novant application does not adequately demonstrate that the projected capital cost is correct and sufficient to remove the existing fixed PET.

Novant is incorrect to assume that the Alliance mobile PET scanners do not have the capability to add host sites because mobile PET service was initiated at Maria Parham Hospital in 2014. With the Declaratory Ruling that was obtained in July 2015, the two existing mobile PET scanners are now allowed to serve all approved host sites in the statewide mobile PET service area. Consequently, Alliance can improve coordination and scheduling to the host sites to provide additional scanning capacity with no capital costs.

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

The application fails to conform to Criterion 5 because the capital cost for the proposed mobile PET is incorrectly calculated. The Siemens quote on page 317 includes "This quote includes the trade-in of the existing GE PET/CT." However the value of the "trade-in" is not disclosed. The term "trade-in" usually means the value of the equipment that would be taken by the seller as partial payment which reduces the amount to be paid. As a result, the CON project capital cost is understated and incorrect because it fails to include the market value that is represented by the trade-in PET CT equipment. The hand written and unsigned footnote at the bottom of page 317 does not explain if the phrase "trade-in" means a credit or an additional charge that relates to the removal of the GE PET/CT. The Novant application does not adequately demonstrate that the projected capital cost is correct and sufficient to remove the existing fixed PET.

The application fails to include the cost for converting the vacated space when a fixed PET scanner is removed from Forsyth Medical Center. This omitted capital cost could not be covered by the alleged "trade-in."

The applicant did not adequately demonstrate that projected revenues and operating costs are based on reasonable and adequately-supported assumptions, including projected utilization. Novant Health Kernersville Medical Center is a department of Novant Health Medical Center. Therefore, patients that utilize the proposed mobile PET host site at this location will be billed for these procedures. However, the CON financial pro forma does not include financial pro forma worksheets to show the gross revenue, net revenue and expenses for this host site as a department of Forsyth Medical Center. The applicant only shows the Forms D and E for the mobile PET scanner based on the "Fee for Service" charges that would be applicable to the other host sites that are not departments of Novant Health Forsyth Medical Center. Therefore, the financial statements are incomplete and fatally flawed due to the omission of patient revenues and operational expenses for Novant Health Kernersville Medical Center.

Financial projections for the fixed PET and the proposed mobile PET are incorrect for additional multiple reasons:

1. The CON application fails to show the actual cost for removal and disposal of PET equipment.
2. Utilization projections are overstated and unreasonable; financial projections for both PET scanners based on these unreasonable utilization projections are also flawed.

3. Section VII omits staffing information for the fixed PET scanner for Year 2; salary expenses that are shown are unreasonable.
4. Section VII staff salaries for the proposed mobile PET are unreasonable.
5. The 0.10 Driver position (4 hrs. / week) is inadequate to drive to the seven host sites.
6. Salaries and benefit expenses in the financial pro forma are not based on reasonable staffing assumptions regarding salaries and FTEs.
7. The expenses and the assumptions for the fixed PET scanner omit radiopharmaceuticals as seen on pages 136 and 148.
8. Expenses for the fixed PET are incorrect because the cost of PET equipment maintenance is omitted on page 137.
9. Page 137 shows that the depreciation expense for the fixed PET scanner unreasonably fluctuates from year to year without explanation.
10. Depreciation expenses are understated and incorrect because the capital cost incorrectly omits the "trade-in" value of the fixed PET equipment and the cost to convert the vacated space.

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

The Novant proposal is nonconforming to Criterion 6 because the proposed mobile PET is duplicative of existing fixed PET scanners in North Carolina and the Alliance Healthcare Services' mobile PET scanners. Tables 9N and 9O of the 2015 State Medical Facilities Plan include the following statements:

Table 9N: "It is determined that there is no need for additional fixed dedicated PET scanners anywhere else in the state and no other reviews are scheduled."

Table 9O: "It is determined that there is no need for additional mobile dedicated PET scanners anywhere else in the state and no other reviews are scheduled."

North Carolina has 28 existing fixed PET scanners that are operating at less than 39 percent of capacity. This low level of utilization and excess capacity exists in all six of the Health Service Areas. Patients throughout North Carolina have adequate access to these existing fixed PET scanners.

	2010-11	2011-12	2012-13	2013-14
28 Fixed PET Scanners in North Carolina	34,900	32,729	33,553	32,381
Total Procedures / 28 PET @ 3000 annual scans	41.55%	38.96%	39.94%	38.55%

Sources: Tables 9L and 9M(1) of the 2015 SMFP and Proposed 2016 SMFP

Total PET utilization in North Carolina shows a declining trend. The service area definition for Novant's existing fixed PET scanners is Health Service Area II that includes seven existing fixed PET scanners that are underutilized. The excess capacity of Novant's underutilized fixed PET scanners at Forsyth Medical Center is duplicative of the other fixed scanners that are located in this service area. The

proposed replacement mobile PET scanner would serve a statewide service area where there are 28 underutilized fixed PET scanners. Therefore, the proposed replacement mobile PET scanner will be duplicative of the excess capacity throughout all of the fixed PET service areas.

Over the past three years the two Alliance PET scanners provided a combined average of 5,744 annual scans or 2,872 procedures per unit. Alliance Healthcare Services currently utilizes the two mobile PET scanners to serve the eastern and western mobile PET service areas that were defined in the 2002 SMFP. Alliance recently received a Declaratory Ruling to utilize its two mobile PET scanners, which were approved for Project I.D. No. H- 6706-02 and Project I.D. No. H-6650-02, to serve any approved host site in the statewide service area. Allowing both Alliance mobile PET scanners to serve all of the approved host sites in North Carolina will coordinate scheduling to improve patient access and achieve operational efficiencies. Furthermore, the two mobile PET scanners will provide cross-coverage on an-as needed basis. With this change these two Alliance mobile PET scanners can increase annual capacity to exceed 3,000 procedures per scanner per year.

The next table shows the historical utilization of the PET host sites that are currently served by Alliance Healthcare Services that would be switched over to the proposed Novant mobile PET. The combined volumes of these five sites show no increases for the previous three year period.

	2011-12	2012-13	2013-14
Novant Health Huntersville	211	197	218
Novant Health Matthews	106	134	119
Novant Health Rowan	267	216	239
Novant Health Thomasville	91	97	85
Lenoir Memorial Hospital	150	170	154
Combined Totals	825	814	815

Sources: Tables 9L and 9M(1) of the 2015 SMFP and Proposed 2016 SMFP

As discussed in the Criterion 3 comments, the applicant's projections of increased PET demand in future years are unreasonable. Novant seeks to serve the above five host sites that averaged a combined 818 annual scans over the past three years. The Novant proposal is duplicative of existing Alliance mobile PET capacity because the proposal seeks to spend over \$2.5 million to acquire a mobile PET scanner to divert an average of 818 PET scans per year.

The following table illustrates the reduction in the utilization of the Alliance mobile PET scanners based on the three year historical average for the two mobile scanners and the proposed host sites.

	PET Scans
Three Year Average Combined Utilization for Alliance Mobile PET Scanners	5,744
Three Year Average Combined Utilization for four Novant Host Sites Plus Lenoir Memorial	818
Remaining Utilization for Alliance Mobile PET	4,926

Sources: Tables 9L and 9M(1) of the 2015 SMFP and Proposed 2016 SMFP

Alliance Healthcare Services' mobile PET scanners have available capacity for each of the following Novant host sites. As seen in the following table the PET scans per day for the Novant host sites are declining.

PET Scans per Day	2012	2013	2014	2015
Novant Health Huntersville	5.69	5.41	5.35	4.08
Novant Health Matthews	4.43	5.83	4.36	5.10
Novant Health Rowan	5.09	4.56	5.35	4.47
Novant Health Thomasville	3.43	3.96	2.96	3.00
Lenoir Memorial Hospital	6.61	6.88	5.96	6.13
Combined Totals	25.25	26.64	23.98	22.78
Annual Percentage Changes		5.50%	-9.98%	-5.00%

Source: Alliance Healthcare Services

Some of the Novant host sites have an alarming number of patients who do not show up for the scheduled procedures and/or have PET scans that could not be completed.

Time Period Jan 1, 2015 to May 30, 2015	Patient No Shows	Scan Not Completed	Combined
Novant Health Huntersville	7	5	12
Novant Health Matthews	3	1	4
Novant Health Rowan	3	9	12
Novant Health Thomasville	0	2	2
Lenoir Memorial Hospital	0	2	2
Combined Totals	13	19	32

Source: Alliance Healthcare Services

The above statistics prove that the Novant methodology that projects increased future PET scan volumes at these host sites is not credible.

Novant's proposal would result in unnecessary mobile PET capacity. The proposed increases in mobile PET service to Novant Health Huntersville Medical Center and Novant Health Matthews Medical Center will be duplicative of Novant Health Presbyterian Medical Center in Mecklenburg County. The fixed PET at Presbyterian operated at 54 percent capacity in 2014. Therefore the proposed increase in days of mobile PET service at the other Novant sites in Mecklenburg County would result in unnecessary duplication of services. In addition, the Novant CON application is consistent with the following statements included in § 131E-175 Findings of Fact:

"That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services."

"That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers."

(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.

The Novant proposal is nonconforming to Criterion 7 because Section VII of the application omits the Year 2 staffing for the fixed PET scanner that remains at Novant Forsyth Medical Center. The staffing projections and the average annual salary per FTE position for the proposed mobile PET scanner are inaccurate and unreasonable. Novant unreasonably projects that the driver position will require 0.10 FTE which is only 208 annual hours or 4 hours per week. It is impossible for a driver to transport the proposed PET scanner to six host sites weekly (and seven host sites on alternative weeks) due to the travel distances between these sites. The following table shows that the travel distances between the host sites with the shortest distances between two sites highlighted in green.

	Morehead	Lenoir	NHKMC	NHMMC	NHTMC	NHHMC	NHRMC
NHRMC	85	203	43	53	27	36	0
NHHMC	117	220	83	24	61	0	
NHTMC	59	185	22	73	0		
NHMMC	134	213	99	0			
NHKMC	41	179	0				
Lenoir	181	0					
Morehead	0						

Lenoir Memorial Hospital is 179 miles or at least three and a half hours' driving time one way. The shortest possible route to connect all seven sites is 508 miles which would take about 10 hours to drive assuming the truck would average 50 miles an hour. Additional time would be required for the driver to obtain fuel and inspect the equipment. It is clear that the 0.10 FTE driver's position that is budgeted at 4 hours per week is inadequate to serve these seven host sites. Given the fact that the mobile PET truck would have to be moved at least six days per week, a more reasonable staffing assumption would be 20 to 30 hours per week or a 0.50 FTE to 0.67 FTE.

The following staffing table is copied from page 104 of the Novant application:

TABLE VII.1(B): PROJECT YEAR 2 FOR NHFMC MOBILE PET/CT SCANNER IMAGING PROGRAM				
POSITION	TOTAL # OF FTE POSITIONS EMPLOYED	AVERAGE ANNUAL SALARY PER FTE POSITION	TOTAL # OF CONTRACT HOURS	AVERAGE HOURLY CONTRACT RATE
Nuclear Med/PET Technologist	2.50	\$ 73,118	N/A	N/A
Nuclear Medicine Supervisor	0.25	\$ 25,212	N/A	N/A
Manager Radiology	0.10	\$ 10,748	N/A	N/A
Senior Director Radiology	0.05	\$ 8,385	N/A	N/A
Radiation Safety Officer	0.20	\$ 40,453	N/A	N/A
Clinical Equipment Mgmt Staff	0.25	\$ 14,205	N/A	N/A
Tractor/Cab Driver	0.10	\$ 7,955	N/A	N/A
TOTAL FTEs	3.45	N/A	N/A	N/A

Current NHFMC Nuclear Medicine/PET staff will rotate time providing NucMed/PET Technologist coverage on the mobile PET/CT scanner. During PY 2 the NHFMC Mobile PET/CT Scanner is projected to be in operation 6.25 days per week. Assumes staffing for 7 host sites with the Mobile PET/CT Scanner in operation for an average of 10 hours per day

The salary figures in the column contain the "AVERAGE ANNUAL SALARY PER FTE POSITION" for Nuclear Medicine Supervisor, Manager Radiology, Senior Director Radiology, Radiation Safety Officer, Clinical Equipment Mgmt. These salaries are unreasonable because these senior level positions are paid less than the technologists they supervise.

As stated previously, the Driver FTE of 0.10 FTE is inadequate based on the travel distances between the host sites. Therefore the salary figure in the table for the driver is understated and inaccurate.

Section VII does not include a staffing table for the fixed PET scanner for Project Year 2 which makes it impossible to evaluate if there is adequate staffing for both

the proposed mobile PET and the remaining fixed PET. This omission is compounded by the applicant's statement "*Current NHFMC Nuclear Medicine/PET staff will rotate time providing NucMed/PET Technologist coverage on the mobile PET/CT scanner.*"

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

The Novant proposal fails to provide the operational expenses that will be incurred for ancillary and support services at Kernersville Medical Center which is a satellite of Forsyth Medical Center. Additional staff resources that will be required at Kernersville for patient scheduling and registration are omitted from the application. The applicant's Kernersville facility will incur additional utility and maintenance costs that are not included in the financial pro forma statements.

The proposal does not budget adequate staff to drive the vehicle to all of the host sites. No contract driver service is included in the proposal as a back-up resource. Based on this shortfall of resources, the proposed mobile PET cannot be coordinated with the host sites. In addition, the financial pro forma includes no expenses for Medical Director even though this resource is required by 10A NCAC 14C .3705.

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:

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

The Novant application does not conform to Criterion 13 (c) because reducing the availability of fixed PET access in Winston-Salem will cause hardship for low income and older persons who do not drive. Eliminating one of the two fixed PET scanners at Novant Health Forsyth Medical Center will decrease scheduling options and limit patient access because two patients can no longer be scheduled for the same time slot. Also, Forsyth Medical Center will no longer have a back-up PET scanner on site when its one remaining unit requires maintenance.

The Novant proposal would decrease access to PET services where the majority of older population and low income reside, in Winston-Salem, and adds mobile PET service in Kernersville where the population is more affluent.

The report, Forsyth County's Older Adults, reports that the overwhelming majority (82%) of the residents that are 65 years and older reside within the city limits of Winston-Salem.³ The US Census Quick Facts reports that the 2009-13 median family income for Winston-Salem is \$40,148 as compared to \$50,032 for Kernersville.

Pages 99, 100 and 101 of the Novant application show that the projected payor mix for the mobile PET service at Novant Health Kernersville Medical Center (NHKMC) is projected to be very different from the payor mix at Novant Health Forsyth Medical Center (NHFMC). Projected percentages of both Medicare and Medicaid are lower for NHKMC as compared to percentages for NHFMC. The Managed Care percentage at NHKMC is projected to be much higher than NHFMC.

	NHFMC Nuclear Medicine and Fixed PET	NHFMC Nuclear Medicine and Fixed PET	NHKMC Mobile PET
	CY 2014	FFY 2018	FFY 2018
Self Pay/Indigent/Charity	1.84%	1.84%	3.45%
Medicare/Medicare Managed Care	62.51%	62.51%	50.28%
Medicaid	5.40%	5.40%	3.21%
Commercial Insurance	0.24%	0.24%	0.00%
Managed Care	28.94%	28.94%	44.75%
Other Workers Comp and Other Gov't	1.07%	1.07%	0.55%
Totals	100.00%	100.00%	102.24%

Sources: Pages 99, 100 and 101 of the Novant Application

Having a projected payor mix for NHKMC that adds up to more than 100 percent indicates that the applicant's projections are inaccurate and unreasonable.

(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,

³ http://forsythaging.forsyth.cc/Documents/Older_Adults_Snapshot.pdf

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.

The Novant application is nonconforming to Criterion 18(a) because the utilization projections are overstated and unreasonable as discussed in the Criterion 3 comments. Tables 9N and 9O of the 2015 State Medical Facilities Plan document that there is no need for additional mobile dedicated PET scanners anywhere else in the state. Consequently there is no unmet need for the conversion of a fixed PET to a mobile PET.

Novant's proposal does nothing to enhance competition due to declining demand as seen in the declining PET scans per day for the Novant host sites.

PET Scans per Day	2012	2013	2014	2015
Novant Health Huntersville	5.69	5.41	5.35	4.08
Novant Health Matthews	4.43	5.83	4.36	5.10
Novant Health Rowan	5.09	4.56	5.35	4.47
Novant Health Thomasville	3.43	3.96	2.96	3.00
Lenoir Memorial Hospital	6.61	6.88	5.96	6.13
Combined Totals	25.25	26.64	23.98	22.78
Annual Percentage Changes		5.50%	-9.98%	-5.00%

Source: Alliance Healthcare Services

The project application fails to demonstrate that the proposed mobile PET scanner will be cost effective because the utilization projections are grossly overstated. Novant wrongly predicts that adding a half day of mobile PET service at Novant Health Huntersville Medical Center in Year 3 will boost the mobile PET utilization from 454 scans in Year 2 to 681 scans in Year 3. This projection is unreasonable because a mobile PET scanner has no ability to generate its own patients simply by adding a half day of service to the schedule of a host site.

Reducing the availability of fixed PET access in Winston-Salem will cause hardship for low income and older persons who do not drive. Eliminating one of the fixed PET scans at Novant Health Forsyth Medical Center will decrease scheduling options and limit patient access.

The proposed host site at Kernersville has overstated utilization projections that could only be achieved by shifting PET scan referrals from the existing underutilized fixed PET scanners at Cone Health, High Point Regional Medical Center and NC Baptist.

The Novant proposal will have a negative impact on quality by making it more financially difficult for existing providers to replace outdated equipment. According to Radiology Today, PET/CT manufacturers are implementing changes to the technology to reduce both the radiation dose and the image acquisition

time.⁴ These improvements are aimed at enhancing patient safety and image quality. The overall surplus of PET capacity in North Carolina will cause providers to delay upgrading their scanners. The additional mobile PET scanner proposed by Novant will draw patients away from existing fixed PET scanners, thereby causing facilities to delay replacing outdated fixed PET technology.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

The Novant application does not conform to Criterion 20 because the DHHS / CMS conducted a survey on February 2014 related to “deficient practice” at Novant Health Forsyth Medical Center on January 18, 2014 that resulted in the exposure of 18 neurosurgery patients to Creutzfeldt-Jakob disease. A copy of the survey is included in Attachment A and includes the statement “*The complaint allegation that facility staff failed to have systems in place to prevent exposure to Creutzfeldt-Jakob Disease (CJD) during surgery is substantiated.*” No descriptions of the corrective actions were included in the attached survey report that relate to the incident.

Novant contends that the PET administrative rules included in 10A NCAC.3700 are not applicable to the proposed project. This is in direct contrast to the two Alliance mobile PET scanners that are required to comply with the PET administrative rules to serve several of the same host sites that are proposed to be served by Novant. The informational responses provided by Novant in response to the performance standards are deficient and incorrect. As discussed in the Criterion 3 comments, the utilization projections are overstated and unreasonable. Staffing information for the existing fixed PET scanner in Year 2 is omitted in Section VII. Staffing and salary information for the proposed mobile PET is unreasonable and inadequate. For these reasons the Novant application should be denied.

§ 131E-183. Review criteria. (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.

The Novant application repeatedly contends that the .3700 Criteria and Standards for Positron Emission Technology are not applicable. However, there are numerous previous sets of findings where the Agency applied the administrative

⁴ Orenstein, Beth W., Reducing PET Dose, *Radiology Today* Vol. 17 No. 1 P. 22

rules for proposals to convert licensed beds and a proposal to convert a research PET scanner to a clinical PET scanner. Furthermore, Novant Health Forsyth Medical Center is not a designated academic medical center. The Novant application provided utilization projections for its existing fixed PET scanner and the proposed mobile PET that are not based on reasonable assumptions. The application also fails to meet the administrative rules 10A NCAC 14C .3703 a(1), a(2), a(3) and b.

Prior to the 2015 SMFP, there was no mechanism or policy to “convert” a fixed PET scanner that is assigned to a single fixed PET service area by replacing it with a mobile PET scanner with a statewide service area. In fact the word “convert” in the context of Policy TE-1 is not included in the CON definitions. Other policies in the 2015 SMFP that use the word “convert” relate to proposed changes in types of inpatient bed capacity at a facility that would not change the location of the health service. Given these circumstances, Policy TE-1 is ambiguous and unclear based on the previous different use of the word “convert” in other SMFP Policies.

After Policy TE-1 was approved by the State Health Coordinating Council to be included in the Proposed 2015 State Medical Facilities Plan, Alliance Healthcare Services submitted a written request on October 2014 to initiate changes to the PET administrative rules. No action has been taken by the Division of Health Service Regulation regarding this request. The fact that the PET administrative rules have not been amended following the adoption of Policy TE-1 is a quality concern because these rules provide the minimum standards of performance and staffing for a proposed PET provider. Even with the outdated administrative rules, the Novant application is nonconforming to multiple CON review criteria as explained previously.

For all of these reasons the Novant application should be denied.

ATTACHMENT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 07/21/2015
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 340014	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 02/20/2014
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NAME OF PROVIDER OR SUPPLIER NOVANT HEALTH FORSYTH MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 3333 SILAS CREEK PARKWAY WINSTON-SALEM, NC 27103
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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A 000	<p>INITIAL COMMENTS</p> <p>An on site complaint investigation was conducted February 18 through 20, 2014 as a result of a self reported incident that occurred on January 18, 2014 during a surgical procedure that resulted in exposure of eighteen patients to Creutzfeldt-Jakob Disease (CJD). Hospital staff self reported the incident to state agencies including Department of Public Health (DPH) and Division of Health Service Regulation (DHSR) and the Centers for Disease Control and Prevention (CDC). Corrective actions were taken as a result of the deficient practice that was found by the facility. Ongoing monitoring of corrective actions was verified during the complaint investigation. The complaint allegation that facility staff failed to have systems in place to prevent exposure to Creutzfeldt-Jakob Disease (CJD) during surgery is substantiated. Based on current practice during the complaint investigation, no deficiencies were found. NC00095175</p>	A 000		
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.