

Comments on Duke Raleigh Hospital

submitted by

Rex Hospital, Inc.

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Rex Hospital, Inc. (UNC REX) submits the following comments related to competing applications to develop an additional fixed PET scanner in Health Service Area IV. UNC REX's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards.*" See N.C. GEN. STAT. § 131E-185(a1)(1)(c). In order to facilitate the Agency's review of these comments, UNC REX has organized its discussion by issue, noting the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to Duke Raleigh Hospital Fixed PET-CT Scanner, Project ID # J-11384-17.

Duke Raleigh's application to develop a fixed PET scanner should not be approved as proposed. UNC REX identified the following specific issues, each of which contributes to Duke Raleigh's non-conformity:

- (1) Failure to demonstrate the need for the project**
- (2) Failure to meet performance standards**
- (3) Overstated utilization projections**
- (4) Failure to include all necessary costs**

Each of the issues listed above is discussed in turn below. Please note that relative to each issue, UNC REX has identified the statutory review criteria and specific regulatory criteria and standards creating the non-conformity.

FAILURE TO DEMONSTRATE THE NEED FOR THE PROJECT

On page 32 of its application, Duke Raleigh notes the collaboration between Duke Health and WakeMed Health and Hospitals to create *Cancer Care Plus+*

To further ensure access to top quality cancer care in Wake County and surrounding areas, Duke Health has also entered into collaboration with WakeMed Health & Hospitals to create *Cancer Care Plus+*. *Cancer Care Plus+* is designed to enhance the commitments of both organizations to population health management and delivery of easily accessible value-based cancer care throughout Wake County. *Cancer Care Plus+* will be anchored at Duke Raleigh Hospital and will combine a variety of Wake County-based Duke Cancer Institute specialty services, locations and cancer clinical research programs with the surgical cancer capabilities at WakeMed's hospitals in Raleigh and Cary.

In an April 2017 press release, the two systems stated: "*Cancer Care Plus+, a joint operating agreement, will establish a comprehensive cancer service throughout the WakeMed system that is fully integrated with Duke Cancer Institute locations in Wake County and anchored at Duke Raleigh Hospital . . . This agreement follows the February 2017 announcement of Heart Care Plus+, a similar collaboration between WakeMed and Duke that serves the cardiovascular needs of patients in Wake County, providing patients greater value and more options for quality heart care.*"

While Duke Raleigh notes its integration with WakeMed for oncology services, it fails to address - at all - WakeMed's ownership in Wake PET Services, an underutilized fixed PET scanner in Wake County (see Attachment 1 for the Wake PET Services Certificate). Given Duke Raleigh and WakeMed's affiliation and WakeMed's ownership interest in Wake PET Services, it is clear that Duke Raleigh and WakeMed have access to fixed PET scanner services. Given the commitment of the Cancer Care Plus+ partners to value-based cancer care, it seems reasonable that the utilization of the existing PET capacity at Wake PET Services should have been considered in the development of Duke Raleigh's proposed additional fixed PET scanner at a cost of \$7.9M. Yet, Duke Raleigh's application fails to explain why this obvious and logical alternative was not considered.

As noted in UNC REX's application on page 65, Wake PET Services is currently operating at less than 20 percent of standard capacity:

Utilization of Fixed PET in HSA IV

| County | Facility | PET Capacity @3,000 per Scanner | 2015 PET Procedures | 2015 PET Utilization as a % of Capacity | 2015 Additional Capacity in Procedures | 2016 PET Procedures | 2016 PET Utilization as a % of Capacity | 2016 Additional Capacity in Procedures |
|---------------|--------------------------|--|----------------------------|--|---|----------------------------|--|---|
| Wake | UNC REX | 3,000 | 2,085 | 69.5% | 915 | 2,231 | 74.4% | 769 |
| Durham | Duke University Hospital | 6,000 | 4,220 | 70.3% | 1,780 | 4,643 | 77.4% | 1,357 |
| Wake | Wake PET Services | 3,000 | 465 | 15.5% | 2,535 | 518 | 17.3% | 2,482 |
| Orange | UNC Hospitals | 6,000 | 3,702 | 61.7% | 2,298 | 3,934 | 65.6% | 2,066 |

Source: 2017 and Proposed 2018 SMFPs.

In fact, Wake PET Services operates at more than 2,400 procedures below standard capacity. As shown in the *Proposed 2018 SMFP*, Wake PET Services' fixed PET scanner has the third lowest utilization in the state, and the lowest among providers in urban Metropolitan Statistical Areas. As shown in the Criteria and Standards for Positron Emission Tomography Scanner, target utilization in the performance standard for PET scanners is 2,080 procedures annually. As such, Wake PET Services' scanner has sufficient unused capacity to provide its co-owner, WakeMed, and integrated partner, Duke Raleigh, with more than 80 percent of the capacity of a fixed PET scanner.

While the need determination in the *2017 SMFP* was generated based on Duke Raleigh's linear accelerator utilization and lack of a fixed PET scanner, since the need determination was approved in the *2017 SMFP* Duke Raleigh commenced its joint operating agreement with WakeMed. As Duke Raleigh's oncology service is fully integrated with WakeMed, their patients can access Wake PET Services and remain within their system of care. While Duke Raleigh does not have fixed PET services on its hospital campus, its cancer services are geographically distributed across Wake County. As such, no single location for fixed PET services (at Duke Raleigh Hospital or elsewhere) could provide co-located access to all of Duke Raleigh's cancer services. Nonetheless, all of Duke Raleigh's linear accelerator locations (Duke Cancer Center Macon Pond Road, Duke Cancer Center Cary, and Duke Raleigh Hospital) currently have convenient access to PET services, as described in UNC REX's application.

As noted in its application, Duke Raleigh proposes to perform 2,211 PET procedures by the third year of operation. As such, Wake PET Services’ scanner has sufficient capacity to serve all of Duke Raleigh’s proposed procedures. Duke Raleigh’s application fails to demonstrate the need for its proposed project given the capacity at Wake PET Services, an existing provider, co-owned by its oncology partner, WakeMed.

While Duke Raleigh’s application has an extensive discussion of its existing mobile PET services provided by Alliance, it fails to mention that the Alliance II unit that serves Duke Raleigh was recently approved to be replaced. As shown in Attachment 2, Alliance was approved to replace its 2006 Siemens Biograph PET-CT with a 2016 GE Discovery IQ PET-CT. Based on UNC REX’s clinical experience, this change to newer, more advanced equipment will result in significantly decreased patient scan times. UNC REX estimates that the historical Alliance equipment would require approximately 35 minutes per scan and that the replacement equipment would require only 20 minutes per scan. As a result of this lowered scan time, the capacity of the Alliance scanner that serves Duke Raleigh will effectively increase by 75 percent¹. Duke Raleigh’s application does not address the need for its proposed project given this expected increase in its PET capacity.

In summary, Duke Raleigh fails to adequately demonstrate the need the population projected to be served has for the proposed fixed PET scanner given additional capacity available. **As such, Duke Raleigh’s application is non-conforming with Criteria 3, 4, and 6.**

FAILURE TO MEET PERFORMANCE STANDARDS

The Hospital License Renewal Applications (HLRA) clearly states that a PET procedure is “a single discrete study of one patient involving one or more PET scans” (emphasis added) and that the number of PET procedures reported in Table 10h should match the number of patients reported on the PET Patient Origin Table. In other words, the HLRA expects the number of PET procedures to equal the number of PET patients.

As shown in the excerpts from their 2017 Hospital License Renewal Applications (HLRAs) included in Attachment 3, Duke University Hospital and Duke Raleigh have historically reported a higher number of PET procedures, as reported on Table 10h, than PET patients, as reported on the PET Patient Origin Table. In fact, Duke Raleigh and Duke University Hospital report 1.2 to 1.4 times as many PET procedures as PET patients, as summarized below.

Duke Health PET Procedures and Patients

| | <i>PET Procedures per Table 10h</i> | <i>PET Patients</i> | <i>Ratio</i> |
|--------------------------|-------------------------------------|---------------------|--------------|
| Duke University Hospital | 4,643 | 3,351 | 1.39 |
| Duke Raleigh Hospital | 951 | 784 | 1.21 |

Source: 2017 HLRAs.

In the footnote provided by Duke University Hospital for the PET Patient Origin Table, it states “PET Scanner patients by zip code do not tie to section 10d [sic, 10h] as patients may receive more than one

¹ At 35 minutes per scan, the historical Alliance unit could perform 1.7 procedures per hour. At 20 minutes per scan, the replacement Alliance unit can perform 3.0 procedures per hour, a 75 percent increase per hour (75 percent = (3.0 ÷ 1.71) - 1).

PET scan” (*emphasis added*). Based on this statement, it is obvious that Duke University Hospital and Duke Raleigh have historically reported PET scans, rather than PET procedures or patients, when reporting their total utilization on Table 10h. Importantly, the *SMFP* uses the PET utilization data reported on Table 10h in the standard methodology to determine need for fixed PET scanners.

Based on the relative consistency of these HLRA statistics with the utilization reported in Duke Raleigh’s application, it appears that Duke Raleigh’s application also provides PET scans as its utilization statistic, rather than PET procedures or patients. As demonstrated below, the Duke Raleigh application provides PET utilization for its facility and Duke University Hospital that is nearly identical to its historical reporting of PET scans at those facilities on its HLRAs.

Duke Raleigh PET Utilization Comparison

| | <i>FY14</i> | <i>FY15</i> | <i>FY16</i> |
|--|-------------|-------------|-------------|
| Duke Raleigh per Form C Assumptions and Methodology, Step 4b | 488 | 670 | 947 |
| Duke Raleigh per HLRAs | 493 | 675 | 951 |

Duke University Hospital PET Utilization Comparison

| | <i>FY14</i> | <i>FY15</i> | <i>FY16</i> |
|--|-------------|-------------|-------------|
| Duke Univ. per Form C Assumptions and Methodology, Step 4b | 4,084 | 4,220 | 4,643 |
| Duke Univ. per HLRAs | 4,084 | 4,220 | 4,643 |

Given this comparison, it is clear that the utilization projections included in Duke Raleigh’s application are based on PET scans and not PET procedures or patients and therefore, do not conform with the CON rules as discussed below. Moreover, it is not reasonable to assume that Duke Raleigh’s reported utilization in its application (947 in FY 2016) are PET procedures as PET procedures equal PET patients by definition and Duke Raleigh’s historical PET patients have historically been much lower (784 PET patients in FY 2016) based on its HLRA, and the application contains no explanation for this discrepancy.

As stated in the HLRA, a single PET procedure may include more than one PET scan. However, the *State Medical Facilities Plan* and more importantly the Criteria and Standards for Positron Emission Tomography Scanner (10A NCAC .3700) assess utilization based on PET procedures not scans. The performance standard at 10 NCAC .3703 (a)(1) states that “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” (*emphasis added*). While Duke Raleigh states in its application that it is reporting PET procedures, the historical discrepancy between its PET procedures and patients suggests that it has reported PET scans. If so, Duke Raleigh’s representations about its PET procedure utilization are overstated. Specifically, while Duke Raleigh states in its application that it has historically performed over 1,000 PET procedures, the above evidence suggests that it has, in fact, performed over 1,000 PET scans and that its number of PET procedures is lower (based on the 1 procedure/patient to 1.2 scan ratio in ratio indicated in its HLRA). Similarly, the historical utilization data provided for Duke University Hospital appears to also be overstated by presenting PET scans rather the procedures (based on the 1 procedure/patient to 1.4 scan ratio in ratio indicated in its HLRA).

In its application, Duke Raleigh provides its utilization projections in demonstrating conformity with the performance standards for PET scanners as shown below:

(b) **Document that the proposal is consistent with the applicable Rules.**

The following is required under the Criteria and Standards for PET scanner projects:

10A NCAC 14C .3700

(a) *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;*

As set forth in Form C, DUHS projects that the proposed fixed unit at Duke Raleigh Hospital shall be utilized at an annual rate of 2211 procedures by the end of the third full fiscal year following completion of the project (FY 2022).

(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; and*

Duke University Hospital performed 4774 PET procedures on 2 fixed PET scanners in FY 17 (July 2016-June 2017), for an average of 2387 procedures per scanner.

(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.*

DUHS projects that its three machines (existing and approved) at Duke University Hospital and Duke Raleigh Hospital shall perform a total of 7774 PET procedures in FY 2022, for an average of 2591 procedures per scanner.

However, as it appears that Duke Raleigh and Duke University Hospital’s utilization data is, in fact, PET scans, and not PET procedures, then each of these historical and projected utilization statistics are overstated. In order to convert Duke Raleigh and Duke University Hospitals’ PET scan utilization data to PET procedures, UNC REX divided by each facility’s historical ratio of PET scans to PET procedures or 1.2 and 1.4, respectively. As shown below, when corrected to comply with the definitions in the CON rules, Duke Raleigh and Duke University Hospital fail to meet the historical performance standard of 2,080 PET procedures per scanner in the most recent 12 month period and the projected performance standard of 2,080 PET procedures per scanner in the third year following completion of the project.

Non-Conformity with Historical Performance Standard

| | FY17 |
|---|-------------|
| Duke University Hospital PET Scans as reported in Application | 4,774 |
| <u>Divide</u> by Ratio of PET Scans to PET Procedures | 1.39 |
| Duke University Hospital PET Procedures | 3,446 |
| # of Fixed PET Scanners | 2 |
| FY22 PET Procedures per Scanner | 1,723 |

Non-Conformity with Projected Performance Standard

| | <i>Duke Raleigh</i> | <i>Duke University Hospital</i> | <i>Combined Total</i> |
|---|---------------------|---------------------------------|-----------------------|
| FY22 PET Scans as reported in Application | 2,211 | 5,563 | 7,774 |
| <u>Divide</u> by Ratio of PET Scans to PET Procedures | 1.21 | 1.39 | |
| FY22 PET Procedures | 1,843 | 4,015 | 5,857 |
| PET Units | 1 | 2 | 3 |
| FY22 PET Procedures per Unit | 1,843 | 2,007 | 1,952 |

Based on this apparent misrepresentation of its utilization, Duke Raleigh’s application is non-conforming with performance standards in the PET scanner rules (10A NCAC 14C .3700). As a result, Duke Raleigh’s application fails to demonstrate the need for the project and is non-conforming with Criteria 3, 4, 5, and 6.

OVERSTATED UTILIZATION PROJECTIONS

Duke Raleigh’s assumes that its projected PET utilization will be comprised over several patient cohorts as summarized in its Form C methodology and assumptions in the table excerpted below:

DRaH PET Total Volumes by Project Year

| | 2019 | 2020 | 2021 | 2022 |
|-------------------------------|--------------|--------------|--------------|--------------|
| Existing Service Area Volumes | 924 | 965 | 1,008 | 1,053 |
| Shift from DUHS | 155 | 198 | 244 | 255 |
| Market Share Increase | 302 | 430 | 562 | 571 |
| Inmigration | 153 | 228 | 320 | 332 |
| Total | 1,535 | 1,821 | 2,134 | 2,211 |

As detailed below, Duke Raleigh’s projections for “Existing Service Area Volumes”, “Shift from DUHS”, and “Market Share Increase” are based on unsupported and unreasonable assumptions. Please note that UNC REX has addressed these patient cohorts in reverse order for clarity purposes.

Market Share Increase

In Step 3 of its Form C Methodology and Assumptions for Projecting Utilization, Duke Raleigh projects the patients related to its “Market Share Increase.” Duke Raleigh first projects the total number of PET procedures to be generated for patients in HSA IV from 2016 to 2025, as shown below. Of note, Duke Raleigh projects that PET volumes will grow annually based on projected population growth rates by county which range from negative 0.3 percent to 1.7 percent.

Projected Total PET Procedures in HSA IV Counties based on Statewide PET Use Rate

| County | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | CAGR |
|----------------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|-------------|
| Chatham County, NC | 216 | 218 | 221 | 223 | 226 | 229 | 232 | 235 | 237 | 240 | 1.2% |
| Durham County, NC | 1,204 | 1,220 | 1,238 | 1,256 | 1,275 | 1,295 | 1,315 | 1,335 | 1,356 | 1,378 | 1.5% |
| Franklin County, NC | 237 | 239 | 242 | 245 | 247 | 250 | 253 | 256 | 258 | 261 | 1.1% |
| Granville County, NC | 213 | 214 | 215 | 216 | 217 | 219 | 219 | 220 | 221 | 222 | 0.5% |
| Johnston County, NC | 629 | 636 | 644 | 652 | 660 | 669 | 677 | 686 | 694 | 704 | 1.2% |
| Lee County, NC | 301 | 305 | 308 | 311 | 315 | 318 | 322 | 326 | 329 | 333 | 1.1% |
| Orange County, NC | 614 | 620 | 628 | 635 | 644 | 653 | 661 | 669 | 678 | 687 | 1.3% |
| Person County, NC | 186 | 186 | 187 | 187 | 188 | 188 | 189 | 189 | 189 | 190 | 0.2% |
| Vance County, NC | 189 | 189 | 189 | 189 | 189 | 190 | 190 | 189 | 189 | 189 | 0.0% |
| Wake County, NC | 4,486 | 4,554 | 4,627 | 4,705 | 4,788 | 4,875 | 4,961 | 5,051 | 5,144 | 5,241 | 1.7% |
| Warren County, NC | 72 | 72 | 72 | 72 | 71 | 71 | 71 | 71 | 70 | 70 | -0.3% |
| Total HSA IV | 8,347 | 8,454 | 8,569 | 8,690 | 8,820 | 8,957 | 9,089 | 9,225 | 9,368 | 9,517 | 1.5% |

Formula: Population/(1,000) x FY2015 State PET Use Rate
 Totals may not foot due to rounding

The methodology is clearly invalid, however, when the results are compared with actual data for 2016, which Duke Raleigh did not use. Specifically, based upon a review of data submitted on annual licensure applications by North Carolina PET providers, Duke Raleigh’s projected PET procedures are significantly overstated. As shown below, PET data from the databases developed by the Healthcare Planning and Certificate of Need Section for fixed and mobile PET providers (including hospital and freestanding sites) shows significantly fewer PET procedures in HSA IV.

Utilization of Fixed PET in HSA IV

| | 2015 Actual | 2016 Actual | 2016 Projected by Duke Raleigh | % Overstated/ (Understated) |
|---------------------|--------------------|--------------------|---------------------------------------|------------------------------------|
| Chatham | 374 | 353 | 216 | (39%) |
| Durham | 796 | 833 | 1,204 | 45% |
| Franklin | 181 | 229 | 237 | 3% |
| Granville | 196 | 184 | 213 | 16% |
| Johnston | 642 | 672 | 629 | (6%) |
| Lee | 360 | 385 | 301 | (22%) |
| Orange | 639 | 698 | 614 | (12%) |
| Person | 184 | 228 | 186 | (18%) |
| Vance | 194 | 168 | 189 | 13% |
| Wake | 3,225 | 3,438 | 4,486 | 30% |
| Warren | 30 | 46 | 72 | 57% |
| HSA IV Total | 6,821 | 7,234 | 8,347 | 15% |

Source: 2017 and Proposed 2018 SMFPs.

Duke Raleigh’s utilization projections rely on these overstated projections of the number of PET procedures in HSA IV shown in Step 3 of its methodology. In Step 5, “Project Incremental PET Market Share for DRaH”, Duke Raleigh projects that “with the development of a fixed PET scanner, DRaH will gain incremental market share in PET services in Wake and the adjacent counties” and that “PET procedures based in incremental market gain in the service area [are calculated by] applying the percentages set forth above to the projected total HSA volumes from Step 3.”

In order to determine the impact of Duke Raleigh’s overstated market volumes, UNC REX revised Duke Raleigh’s utilization projections for those counties where incremental market share was assumed using actual 2016 PET procedures for HSA IV, projected forward at population growth rates consistent with those assumed by Duke Raleigh, and applied the assumed incremental market share gains, as shown in the tables below. In other words, UNC REX applied Duke Raleigh’s own assumptions for growth, but to more reasonable base year 2016 figures based on actual data.

Revised Projected Utilization of Fixed PET in HSA IV

| | 2016 Actual | Revised 2019 Projected | Revised 2020 Projected | Revised 2021 Projected | Revised 2022 Projected | Pop. CAGR per Duke Raleigh |
|----------|--------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---|
| Chatham | 353 | 366 | 370 | 375 | 379 | 1.2% |
| Franklin | 229 | 237 | 239 | 242 | 244 | 1.1% |
| Johnston | 672 | 697 | 706 | 714 | 723 | 1.2% |
| Lee | 385 | 398 | 402 | 407 | 411 | 1.1% |
| Wake | 3,438 | 3,614 | 3,675 | 3,736 | 3,799 | 1.7% |

Duke Raleigh Assumed Incremental Market Share

| | 2019 | 2020 | 2021 | 2022 |
|----------|-------------|-------------|-------------|-------------|
| Chatham | 3% | 4% | 5% | 5% |
| Franklin | 5% | 7% | 9% | 9% |
| Johnston | 5% | 7% | 9% | 9% |
| Lee | 5% | 7% | 9% | 9% |
| Wake | 5% | 7% | 9% | 9% |

Revised Incremental PET from Market Share

| | Revised 2019 Projected | Revised 2020 Projected | Revised 2021 Projected | Revised 2022 Projected |
|--------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| Chatham | 11 | 15 | 19 | 19 |
| Franklin | 12 | 17 | 22 | 22 |
| Johnston | 35 | 49 | 64 | 65 |
| Lee | 20 | 28 | 37 | 37 |
| Wake | 181 | 257 | 336 | 342 |
| Total | 258 | 366 | 478 | 485 |

Based on these revised “Market Share Increase” volumes alone, Duke Raleigh is projected to provide approximately 86 fewer PET procedures in 2022 as shown below.

Revised Duke Raleigh PET Utilization

| | 2019 | 2020 | 2021 | 2022 |
|--|-------------|-------------|-------------|-------------|
| Market Share Increase As Projected by Duke Raleigh | 302 | 430 | 562 | 571 |
| Revised Market Share Increase | 258 | 366 | 478 | 485 |
| Difference | -44 | -64 | -84 | -86 |

Shift from DUHS (Duke University Hospital)

In Step 4c of its Form C Methodology and Assumptions for Projecting Utilization, Duke Raleigh projects a shift of Duke University Hospital outpatient PET patients that will shift from Duke University Hospital to Duke Raleigh during the three project years. Duke Raleigh “expects that some percentage of patient volume who have historically received PET services at Duke University Hospital would choose to receive those services at Duke Raleigh instead, when Duke Raleigh Hospital has a fixed PET scanner.” Duke Raleigh includes the following table demonstrating the percentage of Duke University Hospital PET volumes that will shift to Duke Raleigh.

Percent of Outpatient PET Volumes projected to shift from DUH to DRaH

| HSA IV Counties | Project Year 1 | Project Year 2 | Project Year 3 | Project Year 4 |
|-----------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Chatham County, NC | 30% | 35% | 40% | 40% |
| <i>Durham County, NC</i> | 0% | 0% | 0% | 0% |
| Franklin County, NC | 30% | 35% | 40% | 40% |
| <i>Granville County, NC</i> | 0% | 0% | 0% | 0% |
| Johnston County, NC | 30% | 35% | 40% | 40% |
| Lee County, NC | 30% | 35% | 40% | 40% |
| <i>Orange County, NC</i> | 0% | 0% | 0% | 0% |
| <i>Person County, NC</i> | 0% | 0% | 0% | 0% |
| <i>Vance County, NC</i> | 0% | 0% | 0% | 0% |
| Wake County, NC | 20% | 25% | 30% | 30% |
| <i>Warren County, NC</i> | 0% | 0% | 0% | 0% |

***In these tables, Project Year 1 refers to FY 19, during which the fixed PET scanner will begin operation. Project Year 4 (FY 22) is the third full fiscal year of operation after project development.**

However, Duke Raleigh’s methodology assumes growing market share for Duke University Hospital, which is completely unstated and without basis or support, and applies the assumed shift of PET utilization from Duke University Hospital to Duke Raleigh. Specifically, Duke Raleigh assumes that Duke University Hospital’s PET volume in each of the counties identified above will grow 4.5 percent annually when in Step 3 of its methodology, as noted above, it assumes that PET volume in each county will grow at the projected population growth rate. Because Duke University Hospital’s projected volume in each county is expected to grow faster (4.5 percent annually) than the county as a whole, Duke Raleigh assumes, without basis and entirely unstated, that Duke University Hospital’s market share will grow in every county in HSA IV.

In order to determine the impact of Duke Raleigh’s unsupported assumption of market share gain for Duke University Hospital, UNC REX revised Duke Raleigh’s utilization projections for those counties where a shift of PET utilization from Duke University Hospital to Duke Raleigh was assumed using Duke Raleigh’s projected growth rates for PET volume for each county, as shown in the tables below.

Revised Projected Utilization of Duke University Hospital

| | 2017 Actual | Revised 2019 Projected | Revised 2020 Projected | Revised 2021 Projected | Revised 2022 Projected | Pop. CAGR per Duke Raleigh |
|----------|--------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-----------------------------------|
| Chatham | 37 | 37 | 38 | 38 | 39 | 1.2% |
| Franklin | 37 | 37 | 38 | 38 | 39 | 1.1% |
| Johnston | 62 | 63 | 64 | 64 | 65 | 1.2% |
| Lee | 23 | 23 | 24 | 24 | 24 | 1.1% |
| Wake | 473 | 481 | 489 | 497 | 506 | 1.7% |

Assumed Shift from Duke University Hospital to Duke Raleigh

| | 2019 | 2020 | 2021 | 2022 |
|----------|-------------|-------------|-------------|-------------|
| Chatham | 30% | 35% | 40% | 40% |
| Franklin | 30% | 35% | 40% | 40% |
| Johnston | 30% | 35% | 40% | 40% |
| Lee | 30% | 35% | 40% | 40% |
| Wake | 20% | 25% | 30% | 30% |

Revised Shift of PET Utilization

| | Revised 2019 Projected | Revised 2020 Projected | Revised 2021 Projected | Revised 2022 Projected |
|--------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Chatham | 11 | 13 | 16 | 16 |
| Franklin | 11 | 13 | 15 | 16 |
| Johnston | 19 | 23 | 26 | 26 |
| Lee | 7 | 8 | 10 | 10 |
| Wake | 98 | 124 | 152 | 154 |
| Total | 147 | 182 | 218 | 222 |

Based on these revised “Shift from DUHS” volumes alone, Duke Raleigh is projected to provide approximately 34 fewer PET procedures in 2022 as shown below.

Revised Duke Raleigh PET Utilization

| | 2019 | 2020 | 2021 | 2022 |
|--|-------------|-------------|-------------|-------------|
| Shift from DUHS As Projected by Duke Raleigh | 155 | 198 | 245 | 256 |
| Revised Shift from DUHS | 147 | 182 | 218 | 222 |
| Difference | -9 | -17 | -27 | -34 |

Existing Service Area Volumes

In Step 4b of its Form C Methodology and Assumptions for Projecting Utilization, Duke Raleigh projects the growth of its existing PET volume from HSA IV. Duke Raleigh assumes a 4.5 percent annual growth rate of these patients which “reflects Sg2’s projected outpatient PET volumes CAGR for the HSA IV service area.” The only basis provided for this growth rate is a listing of Sg2’s expertise. Duke Raleigh provides no supporting data to indicate that this growth rate is reasonable or based on valid assumptions. More importantly (as noted above with regard to the “Shift from DUHS” assumptions), this assumed growth rate is not consistent with Duke Raleigh’s assumed growth in PET utilization for the market based on county-specific population growth rates between negative 0.3 and 1.7 percent annually. As such, it is not clear if the assumed 4.6 percent growth rate includes an increase in market share for Duke Raleigh. However, this is not stated and would be duplicative of its assumptions under its “Revised Market Share Increase” utilization. For these reasons, Duke Raleigh’s “Existing Service Area Volumes” utilization is unsupported.

Summary

Based on the foregoing revised “Market Share Increase” and revised “Shift from DUHS” and assuming Duke Raleigh’s “Existing Service Area Volumes” and immigration assumptions remain unchanged, UNC REX calculated Duke Raleigh’s revised total PET utilization, as shown below.

Revised Duke Raleigh PET Utilization

| | <i>Revised 2019 Projected</i> | <i>Revised 2020 Projected</i> | <i>Revised 2021 Projected</i> | <i>Revised 2022 Projected</i> |
|--|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| Existing Service Area Volumes per Form C Assumptions | 924 | 965 | 1,008 | 1,053 |
| Shift from DUHS per Form C Assumptions | 147 | 182 | 218 | 222 |
| Revised Market Share Increase | 258 | 366 | 478 | 485 |
| Inmigration % per Form C Assumptions | 10.0% | 12.5% | 15.0% | 15.0% |
| Inmigration | 148 | 216 | 301 | 311 |
| Total | 1,477 | 1,730 | 2,005 | 2,070 |

Based on these revised utilization projections, Duke Raleigh is projected to provide approximately 141 fewer PET procedures in 2022 as shown below. Moreover, Duke Raleigh fails to meet the projected performance standard of 2,080 PET procedures per scanner in the third year following completion of the project, even without adjusting for the errors made in reporting scans rather than procedures, as discussed above.

Revised Duke Raleigh PET Utilization

| | <i>2019</i> | <i>2020</i> | <i>2021</i> | <i>2022</i> |
|------------------------------------|-------------|-------------|-------------|-------------|
| Total As Projected by Duke Raleigh | 1,535 | 1,821 | 2,134 | 2,211 |
| Revised Total | 1,477 | 1,730 | 2,005 | 2,070 |
| Difference | -58 | -91 | -129 | -141 |

As a result of these issues with its projection methodology, Duke Raleigh’s projected utilization is overstated and unsupported. **As such, Duke Raleigh is non-conforming with the performance standards in the PET scanner rules (10A NCAC 14C .3700) and failed to demonstrate the need for the proposed project and is non-conforming with Criteria 3, 4, 5, and 6.**

FAILURE TO INCLUDE ALL NECESSARY COSTS

It is clear from Duke Raleigh’s application that its pro forma financial statement for its PET service (Form F.4) does not include all appropriate costs. In its Form F.4-6 Assumptions, Duke Raleigh states:

Depreciation expense includes capital costs for construction, equipment, furniture, IT, and other support. Equipment/furniture assumes a 5 year useful life; all other capital costs assuming a 15 year useful life. Depreciation does not include capital costs for the construction of the connector building which will house the PET scanner, as that construction is anticipated to occur independent of the approval of this application for other operational reasons, and the costs are therefore not internally allocated to the PET scanner project. These costs are reflected, however, in the system P&L in Form F.3, Line 20.

Duke Raleigh states clearly that depreciation expense for the fixed PET scanner does not reflect the capital costs for construction of the building which will house the PET scanner. There is no other service proposed for this building and its construction is subject to approval of Duke Raleigh’s application as the cost for this construction appears to be included in the capital cost for which Duke Raleigh is seeking a CON. Duke Raleigh’s total capital cost is stated to be \$7,902,157 and Duke Raleigh’s depreciation expense for the PET service reflects a capital cost of \$6,602,157, or \$1.3M less than the total project, as shown on the second page of its Form F.4-6 Assumptions and excerpted below.



| DRAH PET CT | Equipment & | Construction | Total |
|---------------------|-------------|--------------|------------------|
| | FF&E | Costs | |
| Capital Costs | 3,199,247 | 3,402,910 | 6,602,157 |
| Useful Life | 5 | 15 | |
| Annual Depreciation | 639,849 | 226,861 | 866,710 |

Assuming a uselife of 15 years, this excluded \$1.3M in capital costs reflects an additional \$86,667 in expenses annually for the PET service.

In addition to excluding this depreciation expense, Duke Raleigh’s Form F.4 for its PET service includes only depreciation expense in its indirect expenses. As such, no costs are included for scheduling, medical records, billing, human resources, information technology, or any other corporate services.

Given these issues, it is clear that Duke Raleigh has understated expenses for its proposed fixed PET service. As such, Duke Raleigh has failed to demonstrate that the financial feasibility of the proposal is based upon reasonable projections of the costs.

As such, Duke Raleigh’s application is non-conforming with Criterion 5.

COMPARATIVE ANALYSIS

The Duke Raleigh and UNC REX applications each propose to develop a fixed PET scanner in response to the 2017 SMFP need determination for HSA IV. UNC REX acknowledges that each review is different and, therefore, that the comparative review factors employed by the Project Analyst in any given review may be different depending upon the relevant factors at issue. Given the nature of the review, the Analyst must decide which comparative factors are most appropriate in assessing the applications.

In order to determine the most effective alternative to meet the identified need for a fixed PET scanner in HSA IV, UNC REX reviewed and compared the following factors in each application:

- Geographic Distribution
- Populations to be Served
- Demonstration of Need
- Access by Underserved Groups
- Access to Diverse Patient Population/Diverse Specialties
- Physician Support
- Revenues
- Operating Expenses

UNC REX believes that the factors presented above and discussed in turn below should be used by the Analyst in reviewing the competing applications. The factors are appropriate and/or have been used in previous competitive fixed PET review findings including the 2014 HSA II and the 2008 HSA III fixed PET reviews.

Geographic Distribution

The following table shows the locations of the existing fixed PET scanners in HSA IV.

| County | Facility | Existing Fixed PET Scanners |
|---------------|--------------------------|------------------------------------|
| Durham | Duke University Hospital | 2 |
| Orange | UNC Hospitals | 2 |
| Wake | UNC REX | 1 |
| Wake | Wake PET Services | 1 |

Source: 2017 SMFP.

As shown in the table above, there are six existing fixed PET scanners in HSA IV, including two in Wake County, two in Durham County, and two in Orange County. There are no existing or approved fixed PET scanners in any of the other counties in HSA IV. Both Duke Raleigh and UNC REX propose to develop a fixed PET scanner in Wake County. Therefore, with regard to geographic distribution, both applications are comparable.

Populations to be Served

The following table shows the projected number of patients to be served in third project year (Fiscal Year 2022) based on the information provided in applicants' response to Section C.3.(a).

Projected Patients by County – FY 2022

| | <i>UNC REX</i> | <i>Duke Raleigh</i> |
|-------------|----------------|---------------------|
| Wake | 3,179 | 1,230 |
| Johnston | 348 | 168 |
| Franklin | 228 | 84 |
| Harnett | 185 | NA |
| Sampson | 102 | NA |
| Nash | 59 | NA |
| Wayne | 52 | NA |
| Wilson | 47 | NA |
| Granville | 46 | 10 |
| Vance | 30 | 4 |
| Cumberland | 26 | NA |
| Durham | 24 | 16 |
| Edgecombe | 17 | NA |
| Duplin | 16 | NA |
| Orange | 12 | 1 |
| Lee | 11 | 37 |
| Chatham | 11 | 27 |
| Lenoir | 9 | NA |
| Robeson | 7 | NA |
| Onslow | 6 | NA |
| Warren | 5 | 4 |
| Halifax | 4 | NA |
| Carteret | 4 | NA |
| Moore | 4 | NA |
| New Hanover | 4 | NA |
| Northampton | 4 | NA |
| Person | 4 | 3 |
| Burke | 3 | NA |
| Iredell | 3 | NA |
| Alamance | 3 | NA |
| Beaufort | 1 | NA |
| Columbus | 1 | NA |
| Craven | 1 | NA |
| Guilford | 1 | NA |

| | UNC REX | Duke Raleigh |
|--------------------|----------------|---------------------|
| Mecklenburg | 1 | NA |
| Watauga | 1 | NA |
| Wilkes | 1 | NA |
| Other States/Other | 28 | 280 |
| Total | 4,490 | 1,864 |

Source: Section C.3.(a) for each applicant.

Both applicants project to serve patients in all counties in HSA IV. In total, UNC REX projects to serve 37 counties in North Carolina. By comparison, Duke Raleigh projects to serve the 11 counties in HSA IV and does not identify any other counties. Therefore, with regard to populations to be served, UNC REX is the more effective applicant.

Demonstration of Need

As noted above, Duke Raleigh fails to adequately demonstrate that the projected number of PET procedures to be performed was based on reasonable, credible or supported assumptions. In addition, Duke Raleigh did not adequately demonstrate the need for a fixed PET scanner when taking into account the Wake PET Services fixed PET scanner. Further, as noted in its application and summarized below, UNC REX is more effective than Duke Raleigh across numerous comparative factors related to the development of additional capacity.

Comparison of Factors Demonstrating Need for Additional PET Capacity

| | UNC REX | Duke Raleigh/ Wake PET Services |
|---|----------------|--|
| Least available additional fixed PET capacity in procedures | ✓ | |
| Highest fixed PET utilization | ✓ | |
| Highest growth in fixed PET utilization | ✓ | |
| Provider of Oncology PET | ✓ | ✓ |
| Provider of Cardiac PET | ✓ | |
| Lowest cost PET procedures | ✓ | |
| Highest volume cardiac catheterization provider | ✓ | |
| Highest volume linear accelerator provider | ✓ | |
| Greatest number of linear accelerators at or adjacent to site | ✓ | |

Therefore, with regard to demonstration of need, UNC REX is the more effective applicant.

Access by Underserved Groups

The following table illustrates each applicants' projected percentage of fixed PET procedures to be provided to Medicaid and Medicare recipients in the third year of operation following completion of the project.

Access by Underserved Groups

| | <i>Duke Raleigh</i> | <i>UNC REX</i> |
|--------------|---------------------|----------------|
| Medicaid | 3.3% | 3.3% |
| Medicare | 58.5% | 62.1% |
| Total | 61.8% | 65.4% |

Source: Section L.3.(a) for each applicant.

As shown in the table above, UNC REX and Duke Raleigh project the same percentage of Medicaid procedures as a percent of total while UNC REX project the highest percentage of Medicare procedures as a percent of total. UNC REX projects a higher percentage of combined Medicaid/Medicare procedures as a percent of total than the Duke Raleigh project. Therefore, with regard to access to the underserved, UNC REX is the more effective applicant.

Access to a Diverse Patient Population/Diverse Specialties

UNC REX provides fixed PET services to oncology, cardiology, and other patients. Duke Raleigh proposes to provide fixed PET services to oncology patients. Duke Raleigh’s application makes no mention of its intention to provide cardiac PET services. Further, Duke Raleigh’s application does not include the appropriate equipment to provide cardiac PET services. Therefore, with regard to providing access to a diverse patient population and diverse specialties, UNC REX is the more effective applicant.

Physician Support

While each of the applications includes letters of support from physicians, the amount of support from physicians that can drive the success of the project is different among applications, as shown in the following table:

Physician/Provider Support Letters

| | <i>Duke Raleigh</i> | <i>UNC REX</i> |
|--------------------|---------------------|----------------|
| Letters of Support | 46 | 84 |

Source: Duke Raleigh, Exhibit C-4; UNC REX, Exhibit I.2.

Based on the letters of physician support included in the application, UNC REX is a more effective applicant with regard to documentation of physician support. Similarly, while each of the applications includes letters of support from other hospitals in HSA IV, the amount of other hospital support is different among the applications, as shown in the following table:

Other HSA IV Hospital Support Letters

| | <i>Duke Raleigh</i> | <i>UNC REX</i> |
|--------------------|---------------------|----------------|
| Letters of Support | 1 | 3 |

Source: Duke Raleigh, Exhibit C-4; UNC REX, Exhibit I.2.

Based on the letters of support from other hospitals in HSA IV included in the application, UNC REX is a more effective alternative with regard to documentation of support.

Revenues

The following table shows projected gross revenue per fixed PET procedure in 2022 based on the information provided in the applicants' pro forma financial statements.

Gross Revenue per Procedure - 2022

| | <i>Duke Raleigh</i> | <i>UNC REX</i> |
|------------------------------------|---------------------|----------------|
| Fixed PET Procedures | 2,211 | 4,490 |
| Total Gross Revenue | \$15,949,023 | \$29,409,142 |
| Gross Revenue per Procedure | \$7,213 | \$6,550 |

Source: Pro Forma Financial Statements for each applicant.

Of note, Duke Raleigh projects no increase in charges to account for annual inflation. The following table shows historical gross revenue per fixed PET procedure in 2017 based on the information provided in the applicants' pro forma financial statements.

Gross Revenue per Procedure - 2017

| | <i>Duke Raleigh</i> | <i>UNC REX</i> |
|------------------------------------|---------------------|----------------|
| Fixed PET Procedures | 1,086 | 2,776 |
| Total Gross Revenue | \$7,833,944 | \$15,684,579 |
| Gross Revenue per Procedure | \$7,214 | \$5,650 |

Source: Pro Forma Financial Statements for each applicant.

As shown in the table above, UNC REX projects the lowest gross revenue per fixed PET procedure even though Duke Raleigh projects zero annual inflation of its charges over the five year projection period and UNC REX projects three percent annually to account for inflation. UNC REX believes an annual inflation is reasonable for this service and should be included for both revenues and expenses. Of note, Duke Raleigh assumes inflation for all of its expense line items ranging from 2.0 to 7.5 percent as shown in the excerpt below from its Form F.4-6 Assumptions.

Inflation Factors Per FY2018 DUHS Financial Plan

| | Current | FY2019-FY2020 | |
|-----------------------|---------|---------------|------|
| Drugs | 7.0% | 7.0% | 7.5% |
| Medical Supplies | 2.5% | 2.5% | 2.5% |
| Non-Medical Supplies | 2.0% | 2.0% | 2.0% |
| Machinery & Equipment | 2.0% | 2.0% | 2.0% |
| Other Expenses | 2.0% | 2.0% | 2.0% |
| P&PS | 2.5% | 2.5% | 2.5% |
| Bldg MR&Rent | 2.5% | 2.5% | 2.5% |

Given Duke Raleigh's expense inflation assumptions, UNC REX believes that it is unreasonable for Duke Raleigh to assume no inflation of its revenues for PET services.

The following table shows projected net revenue per fixed PET procedure in 2022 based on the information provided in the applicants' pro forma financial statements. Note, UNC REX's net revenue does not include Other Revenue as shown on its pro forma financial statement which is based on pass-through Medicare reimbursement for the expense of a new tracer, Axumin. The impact of this tracer is expected to be budget neutral with an equal offsetting expense. Exclusion of this revenue is essential to provide a reasonable comparison between the applicants as Duke Raleigh does not include this revenue.

Such an exclusion is comparable to the Agency’s practice of excluding professional fee revenue, when applicable, in competitive reviews of fixed MRI applications.

Net Revenue per Procedure - 2022

| | <i>Duke Raleigh</i> | <i>UNC REX</i> |
|----------------------------------|---------------------|----------------|
| Fixed PET Procedures | 2,211 | 4,490 |
| Total Net Revenue | \$4,190,474 | \$8,698,812 |
| Net Revenue per Procedure | \$1,895 | \$1,937 |

Source: Pro Forma Financial Statements for each applicant.

Of note, Duke Raleigh projection methodology results in almost zero increase in net revenue per procedure as a result of its assumption of zero inflation for charges. The following table shows historical net revenue per PET procedure in 2017 based on the information provided in the applicants’ pro forma financial statements.

Net Revenue per Procedure - 2017

| | <i>Duke Raleigh</i> | <i>UNC REX</i> |
|----------------------------------|---------------------|----------------|
| PET Procedures | 1,086 | 2,776 |
| Total Gross Revenue | \$2,026,011 | \$4,639,279 |
| Net Revenue per Procedure | \$1,866 | \$1,671 |

Source: Pro Forma Financial Statements for each applicant.

As shown above, UNC REX has historically demonstrated the lowest net revenue per procedure. According to each applicants’ projected 2022 financial results, UNC REX and Duke Raleigh project comparable net revenue per fixed PET procedure. However, Duke Raleigh projects almost no inflation of its net revenue per procedure and UNC REX projects three percent annually. UNC REX believes any comparison of revenues between the applicants should consider this difference in assumed inflation rates. If the applicants were to experience equal inflation rates over the five year projection period, UNC REX would have the lowest projected net revenue per procedure. Therefore, with regard to revenues, UNC REX is the more effective applicant.

Operating Expenses

The following table shows projected total expense per fixed PET procedure in 2022 based on the information provided in the applicants’ pro forma financial statements. Note, UNC REX’s expense has been reduced to exclude Other Supplies-Axumin Tracer as shown on its pro forma financial statement. The impact of this tracer is expected to be budget neutral with an equal offsetting Medicare pass-through reimbursement, which is excluded from the revenue comparative factor analysis above. Exclusion of this expense is essential to provide a reasonable comparison between the applicants as Duke Raleigh does not include this expense. Such an exclusion is comparable to the Agency’s practice of excluding professional fee expense and revenue attributable to professional fees, when applicable, in competitive reviews of fixed MRI applications.

Total Expense per Procedure – 2022

| | <i>Duke Raleigh</i> | <i>UNC REX</i> |
|--------------------------------------|---------------------|----------------|
| PET Procedures | 2,211 | 4,490 |
| Total Operating Costs | \$1,905,577 | \$3,801,112 |
| Operating Costs per Procedure | \$862 | \$847 |

Source: Pro Forma Financial Statements for each applicant.

As shown in the table above, UNC REX projects the lowest total expense per fixed PET procedure. Further, as noted above, the depreciation expense on Duke Raleigh’s Form F.4 financial statement for PET services fails to reflect \$1.3M in capital cost or \$86,667 in additional expense. Moreover, Duke Raleigh’s Form F.4 financial statement for PET services includes only depreciation expense in its indirect expenses. As such, no costs are included for scheduling, medical records, billing, human resources, information technology, or any other corporate services. By comparison, UNC REX’s Form F.4 financial statement includes Other Indirect Expenses which reflect an allocation of corporate overhead for these services and totals \$770,268 in 2022. The table below provides a reasonable comparison of operating costs per procedure by adjusting Duke Raleigh’s operating expense to include the additional \$86,667 annually in inappropriately excluded depreciation expense and adjusting UNC REX’s operating expense to exclude its Other Indirect Expense line item.

Adjusted Total Expense per Procedure – 2022

| | <i>Duke Raleigh</i> | <i>UNC REX</i> |
|--------------------------------------|---------------------|----------------|
| PET Procedures | 2,211 | 4,490 |
| Adjusted Total Operating Costs | \$1,992,244 | \$3,030,844 |
| Operating Costs per Procedure | \$901 | \$675 |

Source: Pro Forma Financial Statements for each applicant.

As shown in the table above, UNC REX projects the lowest total expense per fixed PET procedure when operating costs are adjusted to provide a reasonable comparison. Therefore, with regard to operating expenses, UNC REX is the more effective applicant.

SUMMARY

As noted previously, UNC REX maintains that the Duke Raleigh application cannot be approved as proposed. As such, UNC REX maintains that it has the only approvable application based on its comments. Based on both its comparative analysis and the comments on the competing application, UNC REX believes that its application represents the most effective alternative for meeting the need identified in the 2017 SMFP for an additional fixed PET scanner in HSA IV. As such, the CON Section can and should approve the UNC REX application.

Please note that in no way does UNC REX intend for these comments to change or amend its applications as filed on August 15, 2017. If the Agency considers any statements to be amending UNC REX’s application, those comments should not be considered.

Attachment 1

STATE OF NORTH CAROLINA
Department of Health and Human Services

Division of Facility Services

CORRECTED COPY

CERTIFICATE OF NEED

for

Project Identification Number J-7103-04

FID# 041022

ISSUED TO: Wake PET Services LLC, WakeMed, Wake Radiology Oncology Services, PLLC and Wake Radiology Services, LLC
2418 Blue Ridge Road
P. O. Box 19766
Raleigh, NC 27607

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: Wake PET Services LLC, WakeMed, Wake Radiology Oncology Services, PLLC and Wake Radiology Services, LLC shall acquire a fixed PET scanner/Wake county

CONDITIONS: See Reverse Side

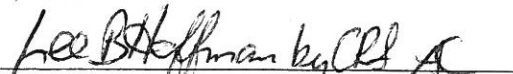
PHYSICAL LOCATION: 1900 Kildaire Farm Road
Cary, NC 27511

MAXIMUM CAPITAL EXPENDITURE: \$2,457,073

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: April 1, 2006

This certificate is effective as of the 18th day of November, 2005.


Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS:

1. Wake PET Services, LLC, WakeMed, Wake Radiology Services, LLC, and Wake Radiology Oncology Services, PLLC (collectively "Wake") shall materially comply with all representations made in its certificate of need application, identified as Project I.D.#J-7103-04, and the Supplemental information provided to the Agency on August 1, September 30, and October 19, 2005. In those instances in which any of these representations conflict, Wake shall materially comply with the last-made representations.
2. WakeMed 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. The approved capital expenditure shall be \$2,457,073.
4. Wake PET Services, LLC shall acquire the PET/CT scanner and provide the equipment to WakeMed pursuant to a lease and services agreement.
5. The PET/CT scanner, shall be physically located in WakeMed's licensed hospital space and the service shall be provided under WakeMed's License and billed under WakeMed's Hospital Provider Number.

TIMETABLE:

| | |
|-------------------------------------|-------------------|
| 25% completion of renovations ----- | February 15, 2006 |
| Completion of Renovations ----- | June 1, 2006 |
| Ordering of Equipment ----- | April 1, 2006 |
| Operation of Equipment ----- | October 2, 2006 |

Attachment 2



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

April 12, 2017

David French
P.O. Box 2154
Reidsville, NC 27323

Exempt from Review – Replacement Equipment

Record #: 2222
Business Name: Alliance Healthcare Services, Inc.
Business #: 60
Project Description: Replace mobile PET/CT scanner
County: Johnston, Lenoir, Dare, Scotland, Robeson, Wayne, Wilson, Carteret, Onslow and Vance

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of March 6, 2017 and supplemental information of March 15, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, Alliance Healthcare Services, Inc. may proceed to acquire without a certificate of need the PET/CT 171 to replace the existing PET/CT Unit 44. This determination is based on your representations that the existing unit will be disposed of by removing it from North Carolina and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency's position is based solely on the facts represented by you and

HEALTHCARE PLANNING AND 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

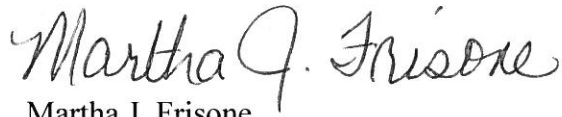


that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,



Tanya S. Rupp
Project Analyst



Martha J. Frisone
Assistant Chief, Certificate of Need

cc: Paige Bennett, Assistant Chief, Healthcare Planning, DHR
Acute and Home Care Licensure and Certification Section, DHR

Rupp, Tanya

From: David French <djfrench45@gmail.com>
Sent: Thursday, April 06, 2017 4:48 PM
To: Rupp, Tanya
Subject: Re: question re: exemption PET/CT replacement

Hi
Thanks for the email. The purchase cost was \$1,531,790.

David French
336 349-6250 office
336 432-8308 cell

On Thu, Apr 6, 2017 at 4:42 PM, Rupp, Tanya <tanya.rupp@dhhs.nc.gov> wrote:

Hi David,

I have drafted a response to your exemption request on behalf of Alliance Healthcare Services, Inc. but have one question:

1. You state the capital cost is “less than \$2,000,000. Please provide the actual cost of the replacement equipment.

You may email the response simply as a response to this email.

Thank you in advance for your assistance; have a great day.

Tanya S. Rupp, JD

Project Analyst

Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section

North Carolina Department of Health and Human Services

919-855-3873 office

Tanya.rupp@dhhs.nc.gov

809 Ruggles Drive
2704 Mail Service Center
Raleigh, NC 27699-2704



Nothing Compares

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Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

Rupp, Tanya

From: David French <djfrench45@gmail.com>
Sent: Wednesday, March 15, 2017 10:01 AM
To: Rupp, Tanya
Subject: Alliance PETCT Replacement Exemption
Attachments: Replacement Notice for PET CT 44 3_06_2017.pdf



Good morning,

I am writing to confirm that the Alliance request to replace PETCT 44 with the new unit PETCT 171 is a permanent replacement. With the delivery of PETCT 171, the existing PETCT 44 will be removed from North Carolina. Attached is a copy of the request that was previously submitted.

Please let me know if you have any questions.

David French
Consultant to Alliance Healthcare
336 349-6250

Bus id 60
ALLIANCE HEALTHCARE SERVICES
c/o Rodney Skelding
8390 Hunting Court
Stokesdale, NC 27357



March 6, 2017

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

RE: Alliance Imaging Inc. - Written Notice for Exemption from CON Review for Replacement PET/ CT Equipment for the Mobile PET/ CT 44 Scanner NR 2222

Dear Ms. Frisone:

I am writing on behalf of my client Alliance Healthcare Services d/b/a/Alliance Imaging Inc. regarding the need to replace the mobile PET CT Unit 44, Serial Number 1M9A6A8256H022243 that is utilized in North Carolina

In 2003, Alliance Imaging Inc. obtained approval for project application # F-6706-02 to implement a mobile PET scanner to serve sites in North Carolina. In 2006, Alliance obtained an equipment replacement exemption to replace the PET scanner equipment with a PET/CT scanner. The unit that is currently in use is PET/ CT 44 Serial Number 1M9A6A8256H022243.

Please accept this notice of exemption to replace the above unit with PETCT 171, Serial Number 1S9SC4826FS834422 which is a scanner that is currently owned by Alliance. This letter provides justification and written notice regarding the replacement equipment in accordance with NCGS 131 E-184. Alliance Imaging Inc. also provides documentation that the replacement equipment conforms to the Certificate of Need laws and Administrative rules:

G.S. 131E-176 (22a) Replacement equipment definition
G.S. 131E-184 (a) (7) Exemptions from review to provide replacement equipment
10A NCAC 14C.0303 Replacement Equipment Administrative Rules

Overview

The existing PET/CT scanner requires replacement for several reasons:

- 1) The existing PET/ CT 44 has required frequent repairs due to the age and condition of the unit.
- 2) Service to the existing host sites will be disrupted if a replacement mobile PET/ CT unit cannot be provided.
- 3) Patient diagnosis and treatment at the host sites will be seriously disrupted without access to PET/ CT.
- 4) Alliance does not have available capacity on other PET/ CT units in North Carolina to provide coverage for the unit that needs to be repaired.

Alliance Imaging recognizes the need to provide high quality, cost effective, and reliable mobile PET/ CT scanner service.

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 1 which shows that the temporary replacement scanner has an actual cost of less than \$2,000,000.

No additional shipping or installation costs are expected. The fair market value for the PET/ CT scanner will be the same as the purchase price of the equipment as reflected in the attached quotes.

The replacement PET/ CT equipment will be used for the same diagnostic purposes as the existing equipment.

In addition, Alliance Imaging is providing prior written notice to the Department in accordance with G.S. 131E-184 (a) (7) Exemption from Review to provide replacement equipment.

Applicability and Conformance with Administrative Rule 10A NCAC 14C.0303 Replacement Equipment

The temporary replacement equipment conforms to the rules as follows:

10A NCAC 14C.0303 Replacement Equipment

(a) The purpose of this Rule is to define the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a).

Alliance Imaging Inc. has reviewed this rule definition.

(b) "Activities essential to acquiring and making operational the replacement equipment" means those activities which are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.

Alliance Imaging Inc. has reviewed this rule definition.

(c) "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

Alliance Imaging Inc. has reviewed this rule definition.

(d) Replacement equipment is comparable to the equipment being replaced if:

(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and

The replacement PET/ CT scanner is comparable to the equipment being replaced because the temporary replacement equipment will also obtain PET/ CT images and data. The proposed replacement mobile PET/ CT scanner is used to acquire the same type of PET/ CT images and data.

(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment in use and is not used to provide a new health service; and

Alliance Imaging Inc. certifies that the replacement mobile PET/ CT equipment will be used for the same diagnostic purposes as the existing unit.

(3) The acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The host sites will utilize the replacement PET/ CT scanner and shall be notified by Alliance Imaging that no increases in costs or patient charges will result from the replacement.

(e) Replacement equipment is not comparable to the equipment being replaced if:

(1) the replacement equipment is new or reconditioned, the existing equipment was purchased second hand and the replacement equipment is purchased less than three years after the acquisition of the existing equipment.

Not applicable. The replacement equipment is functionally similar to the existing equipment and will be used for the same diagnostic procedures as the existing equipment. The replacement equipment is new and will be owned by Alliance more than ten years after the acquisition of the existing equipment.

(2) The replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or

Not applicable. The existing equipment was new when it was acquired in 2006 and the replacement equipment to be purchased and owned by Alliance.

(3) The replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment; or

Not applicable. The replacement equipment is functionally similar to the existing equipment and will be used for the same diagnostic procedures as the existing equipment.

(4) The replacement equipment is purchased and the existing equipment is leased, unless the lease is a capital lease;

Not applicable. Both the existing and the replacement equipment are owned by Alliance.

(5) The replacement equipment is a dedicated PET scanner and the existing equipment is:

(A) a gamma camera with coincidence capability; or

(B) nuclear medicine equipment that was designed, built, modified to detect only the single photon emitted from nuclear events other than positron annihilation.

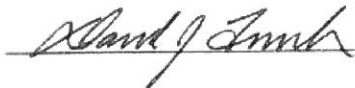
Not applicable. The existing equipment is not a gamma camera or nuclear medicine equipment.

EQUIPMENT COMPARISON

| | EXISTING EQUIPMENT (To be temporarily removed from NC for repairs.) | REPLACEMENT EQUIPMENT |
|--|--|--|
| Type of Equipment (List Each Component) | PET CT | PET CT |
| Manufacturer of Equipment | Siemens | GE |
| Tesla Rating for MRIs | NA | NA |
| Model Number | Siemens Biograph | GE Discovery IQ |
| Serial Number | 1M9A6A8256H022243 | 1S9SC4826FS834422 |
| Provider's Method of Identifying Equipment | PETCT44 | PETCT171 |
| Specify if Mobile or Fixed | Mobile | Mobile |
| Mobile Trailer Serial Number/VIN # | 1M9A6A8256H022243 | 1S9SC4826FS834422 |
| Mobile Tractor Serial Number/VIN # | NA - No changes | NA - No changes |
| Date of Acquisition of Each Component | 2006 | 11/18/2016 |
| Does Provider Hold Title to Equipment or Have a Capital Lease? | Holds Title | Will Hold Title |
| Specify if Equipment Was/Is New or Used When Acquired | New when acquired | New when acquired |
| Total Capital Cost of Project (no construction involved) | NA | \$1,531,790 |
| Total Cost of Equipment | NA | \$1,531,790 |
| Fair Market Value of Equipment | NA | See below |
| Net Purchase Price of Equipment | NA | \$1,531,790 |
| Locations Where Operated | See attached 2017 PET CT 44 inventory form | Same sites as 2017 PET CT 44 |
| Number Days in Use/To be Used in N.C. Per Year | 365 | Specified days for temporary replacement |
| Percent of Change in Patient Charges (by Procedure) | NA | No increase will result |
| Percent of Change in Per Procedure Operating Expenses (by Procedure) | NA | No increase will result |
| Type of Procedures Currently Performed on Existing Equipment | PET CT Procedures | PET CT Procedures |
| Type of Procedures New Equipment is Capable of Performing | NA | PET CT procedures |

Thank you for your review and consideration of this information. Please call me at the office at 336 349-6250 or 336 432-8308 (cell phone) if you have any questions.

Sincerely,



David French
Consultant to Alliance Imaging Inc.
P.O. Box 2154
Reidsville, NC 27323
djfrench45@gmail.com

Attachments:

Letter from Melissa VanOostrom
2017 PETCT 44 Inventory Form

Cc:

Rodney Skelding
Manger of Operations
Alliance Healthcare Services
8390 Hunting Court
Stokesdale, NC 27357

Melissa VanOostrom
Manager of Operations
Alliance Healthcare Services
Phone: 910-340-1494

Andre' D. Kellogg, Sr., MPA
Director of Operations
Alliance Healthcare Services
Phone: 404-317-7800

ALLIANCE HEALTHCARE SERVICES

c/o Rodney Skelding
8390 Hunting Court
Stokesdale, NC 27357

March 6, 2017

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

RE: Equipment Replacement PET CT Unit 44, Serial Number 1M9A6A8256H022243
Replacement PETCT 17, Serial Number 11S9SC4826FS834422

Dear Ms. Frisone,

Alliance Imaging intends to replace its existing mobile PETCT 44, serial number 1M9A6A8256H022243 which was acquired in 2005, with a similar unit that is already owned by Alliance Healthcare Services. The replacement PETCT scanner will be used for the same diagnostic purposes as the existing unit.

In accordance with 10A NCAC 14C.030 Replacement Equipment Administrative Rules, we agree that the replacement MRI equipment will not result in more than a 10 percent increase in charges to any of the PETCT host sites within the first twelve months after the equipment is acquired.

Thank you for your consideration. Please call me at (910) 340-1494 if you have any questions.

Sincerely,

Melissa Van Oostrom

Melissa VanOostrom, Manager of Operations
Alliance HealthCare Radiology
Mobile: (910) 340-1494
Email: mvanoostrom@allianceradiology-us.com



**Registration and Inventory of Medical Equipment
Mobile Positron Emission Tomography Scanners
Friday, January 27, 2017 PET CT 44**

Instructions

This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for mobile positron emission tomography scanners. Please complete all sections of this form and return to Healthcare Planning by **Friday, January 27, 2017**.

1. Complete and sign the form
2. Return the form by one of two methods:
 - a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov
 - b. Mail the form to Patrick Curry, Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Patrick Curry in Healthcare Planning at (919) 855-3865 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Section 1: Contact Information

1. Full legal name of corporation, partnership, individual, or other legal entity that acquired the equipment by purchase, donation, lease, transfer, or comparable arrangement:

Alliance Healthcare Services
(Legal Name)

2. Address of the corporation, partnership, individual, or other legal entity that acquired the equipment:

100 Bayview Circle, Suite 400
(Street and Number)

Newport Beach CA 92660 **(800) 544-321**
(City) (State) (Zip) (Phone Number)

3. Chief Executive Officer or approved designee who is certifying the information in this registration form:

Melissa VanOostrom **Manager Operations**
(Name) (Title)

1233 Front Street Suite A Raleigh, NC 27612
(Street and Number) (City) (State) (Zip)

910-340-1494 **mvanostrom@allianceimaging.com**
(Phone Number) (Email)

4. Information Compiled or Prepared by: **David French**
(Name)

(336) 349-6250
(Phone Number)

difrench45@gmail.com
(Email)

Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2015 – 9/30/2016 Other time period:

(Please make additional copies of pages of this form as needed.)

| Mobile Scanner Information (one scanner per page) | | |
|---|---|--|
| Manufacturer | Siemens | |
| Model Number | PET/CT | |
| Serial or I.D. Number | 1M9A6A8256H022243 PET CT Unit 44 | |
| Date of purchase | 2006 (Replacement Exemption Obtained) | |
| Purchase price | \$1,902,817 | |
| Certificate of Need Project ID | F-6706-02 | |
| Certificate Holder, as listed on Certificate of Need | Alliance HealthCare | |
| | Service Site Number <u>1</u> | Service Site Number <u>2</u> |
| Service Site Information: Please include all of the information requested for each location. | Albemarle Hospital 1144 North Road Street Elizabeth City, NC 27909 Pasquotank | Duke Raleigh Hospital 3400 Executive Drive Raleigh, NC 27609 Wake |
| <u>Procedures* – Inpatient</u> | Inpatient 0 | Inpatient 4 |
| <u>Procedures* – Outpatient</u> | Outpatient 154 | Outpatient 1006 |
| Total # of procedures* for report period | <u>Total 154</u> | <u>Total 1010</u> |
| Put a check by the days per week, and write in the hours per day, the scanner is in operation. | 154 hrs 10/01/2015 – 9/30/2016 | 1010 hrs 10/01/2015 – 9/30/2016 |
| Total number of hours in operation by site for report period. | 154 hrs | 1010 hrs |

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2015 – 9/30/2016 Other time period:

(Please make additional copies of pages of this form as needed.)

| Mobile Scanner Information (one scanner per page) | | |
|---|---|---|
| Manufacturer | Siemens | |
| Model Number | PET/CT | |
| Serial or I.D. Number | 1M9A6A8256H022243 PET CT Unit 44 | |
| Date of purchase | 2006 (Replacement Exemption Obtained) | |
| Purchase price | \$1,902,817 | |
| Certificate of Need Project ID | F-6605-02 | |
| Certificate Holder, as listed on Certificate of Need | Alliance HealthCare | |
| | Service Site Number <u>3</u> | Service Site Number <u>4</u> |
| Service Site Information: Please include all of the information requested for each location. | Johnston Memorial Hospital Auth 509 N. Bright Leaf Blvd. Smithfield, NC 27577 Johnston | Lenoir Memorial Hospital 100 Airport Road Kinston, NC 28501 Lenoir |
| <u>Procedures* – Inpatient</u> | Inpatient 1 | Inpatient 0 |
| <u>Procedures* – Outpatient</u> | Outpatient 198 | Outpatient 151 |
| Total # of procedures* for report period | <u>Total 199</u> | <u>Total 151</u> |
| Put a check by the days per week, and write in the hours per day, the scanner is in operation. | 199 hrs 10/01/2015 – 9/30/2016 | 151 hrs 10/01/2015 – 9/30/2016 |
| Total number of hours in operation by site for report period. | 199 hrs | 151 hrs |

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2015 – 9/30/2016 Other time period:

(Please make additional copies of pages of this form as needed.)

| Mobile Scanner Information (one scanner per page) | | |
|---|---|--|
| Manufacturer | Siemens | |
| Model Number | PET/CT | |
| Serial or I.D. Number | 1M9A6A8256H022243 PET CT Unit 44 | |
| Date of purchase | 2006 (Replacement Exemption Obtained) | |
| Purchase price | \$1,902,817 | |
| Certificate of Need Project ID | F-6605-02 | |
| Certificate Holder, as listed on Certificate of Need | Alliance HealthCare | |
| | Service Site Number <u>5</u> | Service Site Number <u>6</u> |
| Service Site Information: Please include all of the information requested for each location. | Outer Banks Hospital 4800 S. Croatan Highway Nags Head, NC 27959 Dare | Scotland Memorial Hospital, Inc 500 Lauchwood Drive Laurinburg, NC 28352 Scotland |
| <u>Procedures* – Inpatient</u> | Inpatient 9 | Inpatient 5 |
| <u>Procedures* – Outpatient</u> | Outpatient 126 | Outpatient 88 |
| Total # of procedures* for report period | <u>Total 135</u> | <u>Total 93</u> |
| Put a check by the days per week, and write in the hours per day, the scanner is in operation. | 135 hrs 10/01/2015 – 9/30/2016 | 93 hrs 10/01/2015 – 9/30/2016 |
| Total number of hours in operation by site for report period. | 135 hrs | 93 hrs |

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2015 – 9/30/2016 Other time period:

(Please make additional copies of pages of this form as needed.)

| Mobile Scanner Information (one scanner per page) | | |
|---|--|--|
| Manufacturer | Siemens | |
| Model Number | PET/CT | |
| Serial or I.D. Number | 1M9A6A8256H022243 PET CT Unit 44 | |
| Date of purchase | 2006 (Replacement Exemption Obtained) | |
| Purchase price | \$1,902,817 | |
| Certificate of Need Project ID | F-6605-02 | |
| Certificate Holder, as listed on Certificate of Need | Alliance HealthCare | |
| | Service Site Number <u>7</u> | Service Site Number <u>8</u> |
| Service Site Information: Please include all of the information requested for each location. | Southeastern Regional Medical 300 West 27th St. Lumberton, NC 28358 Robeson | Wayne Memorial Hospital 2700 Wayne Memorial Dr. Goldsboro, NC 27534 Wayne |
| <u>Procedures* – Inpatient</u> | Inpatient 9 | Inpatient 0 |
| <u>Procedures* – Outpatient</u> | Outpatient 246 | Outpatient 348 |
| Total # of procedures* for report period | <u>Total 255</u> | <u>Total 348</u> |
| Put a check by the days per week, and write in the hours per day, the scanner is in operation. | 255 hrs 10/01/2015 – 9/30/2016 | 348 hrs 10/01/2015 – 9/30/2016 |
| Total number of hours in operation by site for report period. | 255 hrs | 348 hrs |

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2015 – 9/30/2016 Other time period:

(Please make additional copies of pages of this form as needed.)

| Mobile Scanner Information (one scanner per page) | | |
|---|---|---|
| Manufacturer | Siemens | |
| Model Number | PET/CT | |
| Serial or I.D. Number | 1M9A6A8256H022243 PET CT Unit 44 | |
| Date of purchase | 2006 (Replacement Exemption Obtained) | |
| Purchase price | \$1,902,817 | |
| Certificate of Need Project ID | F-6605-02 | |
| Certificate Holder, as listed on Certificate of Need | Alliance HealthCare | |
| | Service Site Number <u>9</u> | Service Site Number <u>10</u> |
| Service Site Information: Please include all of the information requested for each location. | LifePoint Wilson Medical Center 1705 South Tarboro St. Wilson, NC 27893 Wilson | Carteret General Hospital 3402 Arendell St. Morehead City, NC 28557 Carteret |
| <u>Procedures* – Inpatient</u> | Inpatient 15 | Inpatient 7 |
| <u>Procedures* – Outpatient</u> | Outpatient 421 | Outpatient 211 |
| Total # of procedures* for report period | <u>Total 436</u> | <u>Total 218</u> |
| Put a check by the days per week, and write in the hours per day, the scanner is in operation. | 436 hrs 10/01/2015– 9/30/2016 | 218 hrs 10/01/2015 – 9/30/2016 |
| Total number of hours in operation by site for report period. | 436 hrs | 218 hrs |

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2015 – 9/30/2016 Other time period:

(Please make additional copies of pages of this form as needed.)

| Mobile Scanner Information (one scanner per page) | | |
|---|--|---|
| Manufacturer | Siemens | |
| Model Number | PET/CT | |
| Serial or I.D. Number | 1M9A6A8256H022243 PET CT Unit 44 | |
| Date of purchase | 2006 (Replacement Exemption Obtained) | |
| Purchase price | \$1,902,817 | |
| Certificate of Need Project ID | F-6605-02 | |
| Certificate Holder, as listed on Certificate of Need | Alliance HealthCare | |
| | Service Site Number <u>11</u> | Service Site Number 12 |
| Service Site Information: Please include all of the information requested for each location. | Onslow Memorial Hospital 317 Western Blvd Jacksonville, NC 28546 Onslow | Maria Parham Medical Center 556 Ruin Creek Rd. Henderson, NC 27536 Vance |
| <u>Procedures* – Inpatient</u> | Inpatient 12 | Inpatient 3 |
| <u>Procedures* – Outpatient</u> | Outpatient 452 | Outpatient 85 |
| Total # of procedures* for report period | <u>Total 464</u> | <u>Total 88</u> |
| Put a check by the days per week, and write in the hours per day, the scanner is in operation. | 464 hrs 10/01/2015 – 9/30/2016 | 88 hrs 12/1/2015 – 9/30/2016 |
| Total number of hours in operation by site for report period. | 464 hrs | 88 hrs |

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 3: PET Procedures by CPT Code

Please write the number of procedures provided by CPT Code during the time period of this report.

| CPT Code | CPT Description | Number of Procedures |
|--|---|-----------------------------|
| 78608 | Brain imaging – metabolic evaluation | 2 |
| 78609 | Brain imaging – perfusion evaluation | |
| 78459 | Myocardial imaging - metabolic evaluation | |
| 78491 | Myocardial imaging – perfusion; single study at rest or stress | |
| 78492 | Myocardial imaging – perfusion; multiple studies at rest and/or stress | |
| 78811 | Tumor imaging – limited area (e.g., chest, head/neck) | 3 |
| 78812 | Tumor imaging – skull base to mid-thigh | |
| 78813 | Tumor imaging – whole body | |
| 78814 | Tumor imaging – with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (e.g., chest, head/neck) | 2 |
| 78815 | Tumor imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh | 3342 |
| 78816 | Tumor imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body | 195 |
| Please list other CPT codes and number of procedures billed for (make a copy of this page if needed) | | |
| 78708 | Renal scan | 7 |
| | | |
| Total Number of Procedures | | 3,551 |

Section 4: Patient Origin Data by Service Site

Please provide the county of residence for each patient who received PET scanner services during the time period of this report. Provide patient origin data separately for each service site. Make additional copies of this page as needed. The total number of patients receiving services should be the same as the total number of procedures reported on page 2 of this form.

Service Site Name: No patient origin data is collected by Alliance

County in which service was provided: Not applicable

| Patient County | Number of Patients | Patient County | Number of Patients | Patient County | Number of Patients |
|----------------|--------------------|-----------------|--------------------|----------------------|--------------------|
| 1. Alamance | | 37. Gates | | 73. Person | |
| 2. Alexander | | 38. Graham | | 74. Pitt | |
| 3. Alleghany | | 39. Granville | | 75. Polk | |
| 4. Anson | | 40. Greene | | 76. Randolph | |
| 5. Ashe | | 41. Guilford | | 77. Richmond | |
| 6. Avery | | 42. Halifax | | 78. Robeson | |
| 7. Beaufort | | 43. Harnett | | 79. Rockingham | |
| 8. Bertie | | 44. Haywood | | 80. Rowan | |
| 9. Bladen | | 45. Henderson | | 81. Rutherford | |
| 10. Brunswick | | 46. Hertford | | 82. Sampson | |
| 11. Buncombe | | 47. Hoke | | 83. Scotland | |
| 12. Burke | | 48. Hyde | | 84. Stanly | |
| 13. Cabarrus | | 49. Iredell | | 85. Stokes | |
| 14. Caldwell | | 50. Jackson | | 86. Surry | |
| 15. Camden | | 51. Johnston | | 87. Swain | |
| 16. Carteret | | 52. Jones | | 88. Transylvania | |
| 17. Caswell | | 53. Lee | | 89. Tyrrell | |
| 18. Catawba | | 54. Lenoir | | 90. Union | |
| 19. Chatham | | 55. Lincoln | | 91. Vance | |
| 20. Cherokee | | 56. Macon | | 92. Wake | |
| 21. Chowan | | 57. Madison | | 93. Warren | |
| 22. Clay | | 58. Martin | | 94. Washington | |
| 23. Cleveland | | 59. McDowell | | 95. Watauga | |
| 24. Columbus | | 60. Mecklenburg | | 96. Wayne | |
| 25. Craven | | 61. Mitchell | | 97. Wilkes | |
| 26. Cumberland | | 62. Montgomery | | 98. Wilson | |
| 27. Currituck | | 63. Moore | | 99. Yadkin | |
| 28. Dare | | 64. Nash | | 100. Yancey | |
| 29. Davidson | | 65. New Hanover | | | |
| 30. Davie | | 66. Northampton | | 101. Georgia | |
| 31. Duplin | | 67. Onslow | | 102. South Carolina | |
| 32. Durham | | 68. Orange | | 103. Tennessee | |
| 33. Edgecombe | | 69. Pamlico | | 104. Virginia | |
| 34. Forsyth | | 70. Pasquotank | | 105. Other (specify) | |
| 35. Franklin | | 71. Pender | | | |

| | | | | | |
|------------|--|----------------|--|---------------------------------|--------------|
| 36. Gaston | | 72. Perquimans | | Total Number of Patients | 3,551 |
|------------|--|----------------|--|---------------------------------|--------------|

Section 5: Certification and Signature

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Signature *Melissa Van Oostrom*

Print Name **Melissa VanOostrom**

Date signed **January 22, 2017**

Please complete all sections of this form and return to Healthcare Planning by **Friday, January 27, 2017**.

1. Complete and sign the form
2. Return the form by one of two methods:
 - a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov
 - b. Mail the form to Patrick Curry in Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Patrick Curry in Healthcare Planning at (919) 855-3865 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Attachment 3

All responses should pertain to ~~October 1, 2015 through September 30, 2016~~

10g. Computed Tomography (CT) continued

Scans Performed on Mobile CT Scanners (*Multiply # scans by Conversion Factor to get HECT Units*)

| | Type of CT Scan | # of Scans | | Conversion Factor | | HECT Units |
|---|--|------------|---|-------------------|---|------------|
| 1 | Head without contrast | 0 | X | 1.00 | = | 0 |
| 2 | Head with contrast | 0 | X | 1.25 | = | 0 |
| 3 | Head without and with contrast | 0 | X | 1.75 | = | 0 |
| 4 | Body without contrast | 0 | X | 1.50 | = | 0 |
| 5 | Body with contrast | 0 | X | 1.75 | = | 0 |
| 6 | Body without and with contrast | 0 | X | 2.75 | = | 0 |
| 7 | Biopsy in addition to body scan with or without contrast | 0 | X | 2.75 | = | 0 |
| 8 | Abscess drainage in addition to body scan with or without contrast | 0 | X | 4.00 | = | 0 |
| | Total | 0 | | | | 0 |

10h. Positron Emission Tomography (PET)

| | Number of Units | Number of Procedures* | | |
|---|-----------------|-----------------------|------------|-------|
| | | Inpatient | Outpatient | Total |
| Dedicated Fixed PET Scanner | 0 | 0 | 0 | 0 |
| Mobile PET Scanner | 1 | 4 | 947 | 951 |
| PET pursuant to Policy AC-3 | 0 | 0 | 0 | 0 |
| Other PET Scanners used for Human Research only | 0 | 0 | 0 | 0 |

* PET procedure means a single discrete study of one patient involving one or more PET scans. PET scan means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. **The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 35.**

Name of Mobile Provider: Alliance Healthcare Services

10i. Other Imaging Equipment

| | Number of Units | Number of Procedures | | |
|---|-----------------|----------------------|------------|--------|
| | | Inpatient | Outpatient | Total |
| Ultrasound equipment | 3 | 1,205 | 9,131 | 10,336 |
| Mammography equipment | 2 | 5 | 5,383 | 5,388 |
| Bone Density Equipment | 1 | 2 | 1,295 | 1,297 |
| Fixed X-ray Equipment (excluding fluoroscopic) | 3 | 13,358 | 23,256 | 36,614 |
| Fixed Fluoroscopic X-ray Equipment | 2 | 1,414 | 2,118 | 3,532 |
| Special Procedures/ Angiography Equipment (neuro & vascular, but not including cardiac cath.) | 1 | 679 | 1,359 | 2,038 |
| Coincidence Camera | 0 | 0 | 0 | 0 |
| Mobile Coincidence Camera. Vendor: | 0 | 0 | 0 | 0 |
| SPECT | 0 | 0 | 0 | 0 |
| Mobile SPECT. Vendor: | 0 | 0 | 0 | 0 |
| Gamma Camera | 2 | 335 | 1,676 | 2,011 |
| Mobile Gamma Camera. Vendor: | 0 | 0 | 0 | 0 |

July 1, 2015 thru June 30, 2016

All responses should pertain to **October 1, 2015 through September 30, 2016.**

Patient Origin – PET Scanner

Facility County: Wake

In an effort to document patterns of utilization of PET Scanners in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. This data should only reflect the number of patients, not number of scans and should not include other radiopharmaceutical or supply charge codes. **Please count each patient only once. The number of patients in this table should match the number of PET procedures reported in Table 10h on page 20.**

| County | No. of Patients | County | No. of Patients | County | No. of Patients |
|----------------|-----------------|-----------------|-----------------|------------------------------|-----------------|
| 1. Alamance | 1 | 37. Gates | 0 | 73. Person | 0 |
| 2. Alexander | 0 | 38. Graham | 0 | 74. Pitt | 1 |
| 3. Alleghany | 1 | 39. Granville | 4 | 75. Polk | 0 |
| 4. Anson | 0 | 40. Greene | 0 | 76. Randolph | 2 |
| 5. Ashe | 1 | 41. Guilford | 1 | 77. Richmond | 0 |
| 6. Avery | 0 | 42. Halifax | 5 | 78. Robeson | 3 |
| 7. Beaufort | 1 | 43. Harnett | 39 | 79. Rockingham | 0 |
| 8. Bertie | 0 | 44. Haywood | 0 | 80. Rowan | 0 |
| 9. Bladen | 1 | 45. Henderson | 0 | 81. Rutherford | 0 |
| 10. Brunswick | 2 | 46. Hertford | 0 | 82. Sampson | 9 |
| 11. Buncombe | 0 | 47. Hoke | 0 | 83. Scotland | 0 |
| 12. Burke | 0 | 48. Hyde | 0 | 84. Stanly | 0 |
| 13. Cabarrus | 0 | 49. Iredell | 1 | 85. Stokes | 0 |
| 14. Caldwell | 0 | 50. Jackson | 0 | 86. Surry | 0 |
| 15. Camden | 0 | 51. Johnston | 78 | 87. Swain | 0 |
| 16. Carteret | 2 | 52. Jones | 0 | 88. Transylvania | 0 |
| 17. Caswell | 0 | 53. Lee | 5 | 89. Tyrrell | 0 |
| 18. Catawba | 0 | 54. Lenoir | 0 | 90. Union | 0 |
| 19. Chatham | 2 | 55. Lincoln | 0 | 91. Vance | 4 |
| 20. Cherokee | 0 | 56. Macon | 0 | 92. Wake | 496 |
| 21. Chowan | 1 | 57. Madison | 0 | 93. Warren | 3 |
| 22. Clay | 0 | 58. Martin | 0 | 94. Washington | 0 |
| 23. Cleveland | 0 | 59. McDowell | 0 | 95. Watauga | 0 |
| 24. Columbus | 1 | 60. Mecklenburg | 1 | 96. Wayne | 8 |
| 25. Craven | 1 | 61. Mitchell | 0 | 97. Wilkes | 0 |
| 26. Cumberland | 6 | 62. Montgomery | 0 | 98. Wilson | 9 |
| 27. Currituck | 0 | 63. Moore | 1 | 99. Yadkin | 0 |
| 28. Dare | 0 | 64. Nash | 24 | 100. Yancey | 0 |
| 29. Davidson | 0 | 65. New Hanover | 2 | | |
| 30. Davie | 0 | 66. Northampton | 1 | 101. Georgia | 1 |
| 31. Duplin | 1 | 67. Onslow | 0 | 102. South Carolina | 3 |
| 32. Durham | 8 | 68. Orange | 2 | 103. Tennessee | 0 |
| 33. Edgecombe | 3 | 69. Pamlico | 0 | 104. Virginia | 8 |
| 34. Forsyth | 0 | 70. Pasquotank | 0 | 105. Other States | 3 |
| 35. Franklin | 38 | 71. Pender | 0 | 106. Other | 0 |
| 36. Gaston | 0 | 72. Perquimans | 0 | Total No. of Patients | 784 |

Note: Total number of patients does not equal number of PET procedures reported on Page 20. Patients may receive multiple scans during same visit.

July 01, 2015 June 30, 2016

All responses should pertain to **October 1, 2015 through September 30, 2016.**

10g. Computed Tomography (CT) continued

Scans Performed on Mobile CT Scanners (Multiply # scans by Conversion Factor to get HECT Units)

| | Type of CT Scan | # of Scans | | Conversion Factor | | HECT Units |
|---|--|------------|---|-------------------|---|------------|
| 1 | Head without contrast | — | X | 1.00 | = | — |
| 2 | Head with contrast | — | X | 1.25 | = | — |
| 3 | Head without and with contrast | — | X | 1.75 | = | — |
| 4 | Body without contrast | — | X | 1.50 | = | — |
| 5 | Body with contrast | — | X | 1.75 | = | — |
| 6 | Body without and with contrast | — | X | 2.75 | = | — |
| 7 | Biopsy in addition to body scan with or without contrast | — | X | 2.75 | = | — |
| 8 | Abscess drainage in addition to body scan with or without contrast | — | X | 4.00 | = | — |
| | Total | — | | | | — |

10h. Positron Emission Tomography (PET) See Footnotes (1), (2) for Page 20

| | Number of Units | Number of Procedures* | | |
|---|-----------------|-----------------------|------------|-------|
| | | Inpatient | Outpatient | Total |
| Dedicated Fixed PET Scanner (1) | 2 | 440 | 4,203 | 4,643 |
| Mobile PET Scanner | — | — | — | — |
| PET pursuant to Policy AC-3 (1) | — | — | — | — |
| Other PET Scanners used for Human Research only (3) | 2 | — | — | — |

* PET procedure means a single discrete study of one patient involving one or more PET scans. PET scan means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. **The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 35.**

Name of Mobile Provider: _____

10i. Other Imaging Equipment See Footnotes (2), (3), (4), (5), (6) for Page 20

| | Number of Units | Number of Procedures | | |
|---|-----------------|----------------------|------------|---------|
| | | Inpatient | Outpatient | Total |
| Ultrasound equipment (3) | 18 | 13,548 | 28,292 | 41,840 |
| Mammography equipment | 8 | 33 | 25,262 | 25,235 |
| Bone Density Equipment | 4 | 3 | 4,974 | 4,974 |
| Fixed X-ray Equipment (excluding fluoroscopic) (4) | 49 | 45,941 | 168,016 | 114,077 |
| Fixed Fluoroscopic X-ray Equipment (5) | 9 | 3,712 | 3,699 | 7,411 |
| Special Procedures/ Angiography Equipment (neuro & vascular, but not including cardiac cath.) | 5 | 4,945 | 5,626 | 10,571 |
| Coincidence Camera (2) | — | — | — | — |
| Mobile Coincidence Camera. Vendor: | — | — | — | — |
| SPECT | — | — | — | — |
| Mobile SPECT. Vendor: | — | — | — | — |
| Gamma Camera (6) | 10 | 1,521 | 9,459 | 10,980 |
| Mobile Gamma Camera. Vendor: | — | — | — | — |

July 01, 2015 June 30, 2016

All responses should pertain to **October 1, 2015 through September 30, 2016.**

Patient Origin – PET Scanner

Facility County: Durham

In an effort to document patterns of utilization of PET Scanners in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. This data should only reflect the number of patients, not number of scans and should not include other radiopharmaceutical or supply charge codes. **Please count each patient only once. The number of patients in this table should match the number of PET procedures reported in Table 10h on page 20.**

| County | No. of Patients | County | No. of Patients | County | No. of Patients |
|----------------|-----------------|-----------------|-----------------|------------------------------|-----------------|
| 1. Alamance | 90 | 37. Gates | 1 | 73. Person | 149 |
| 2. Alexander | 6 | 38. Graham | 1 | 74. Pitt | 22 |
| 3. Alleghany | — | 39. Granville | 118 | 75. Polk | 4 |
| 4. Anson | — | 40. Greene | — | 76. Randolph | 16 |
| 5. Ashe | 6 | 41. Guilford | 69 | 77. Richmond | 9 |
| 6. Avery | 1 | 42. Halifax | 15 | 78. Robeson | 48 |
| 7. Beaufort | 3 | 43. Harnett | 33 | 79. Rockingham | 33 |
| 8. Bertie | 3 | 44. Haywood | 3 | 80. Rowan | 16 |
| 9. Bladen | 8 | 45. Henderson | 16 | 81. Rutherford | 6 |
| 10. Brunswick | 48 | 46. Hertford | 4 | 82. Sampson | 17 |
| 11. Buncombe | 13 | 47. Hoke | 9 | 83. Scotland | 12 |
| 12. Burke | 14 | 48. Hyde | 1 | 84. Stanly | 8 |
| 13. Cabarrus | 7 | 49. Iredell | 13 | 85. Stokes | 3 |
| 14. Caldwell | 10 | 50. Jackson | 2 | 86. Surry | 4 |
| 15. Camden | 2 | 51. Johnston | 50 | 87. Swain | 1 |
| 16. Carteret | 26 | 52. Jones | 2 | 88. Transylvania | — |
| 17. Caswell | 13 | 53. Lee | 15 | 89. Tyrrell | 1 |
| 18. Catawba | 17 | 54. Lenoir | 7 | 90. Union | 6 |
| 19. Chatham | 25 | 55. Lincoln | 4 | 91. Vance | 79 |
| 20. Cherokee | — | 56. Macon | 5 | 92. Wake | 375 |
| 21. Chowan | 3 | 57. Madison | 1 | 93. Warren | 20 |
| 22. Clay | — | 58. Martin | 3 | 94. Washington | 3 |
| 23. Cleveland | 5 | 59. McDowell | 4 | 95. Watauga | 4 |
| 24. Columbus | 11 | 60. Mecklenburg | 28 | 96. Wayne | 21 |
| 25. Craven | 19 | 61. Mitchell | 3 | 97. Wilkes | 5 |
| 26. Cumberland | 84 | 62. Montgomery | — | 98. Wilson | 21 |
| 27. Currituck | 7 | 63. Moore | 24 | 99. Yadkin | — |
| 28. Dare | 9 | 64. Nash | 43 | 100. Yancey | 4 |
| 29. Davidson | 7 | 65. New Hanover | 51 | | |
| 30. Davie | 5 | 66. Northampton | 5 | 101. Georgia | 22 |
| 31. Duplin | 16 | 67. Onslow | 21 | 102. South Carolina | 168 |
| 32. Durham | 601 | 68. Orange | 136 | 103. Tennessee | 21 |
| 33. Edgecombe | 6 | 69. Pamlico | 3 | 104. Virginia | 306 |
| 34. Forsyth | 17 | 70. Pasquotank | 6 | 105. Other States | 129 |
| 35. Franklin | 25 | 71. Pender | 14 | 106. Other | — |
| 36. Gaston | 8 | 72. Perquimans | 3 | Total No. of Patients | 3,351 |

Duke University Hospital License Renewal Application 2017
Footnote for Page 35

- (1) PET Scanner patients by zip code do not tie to section 10d. as patients may receive more than one PET scan.