



**Comments on Duke University Health System, Inc.'s
PET-CT Scanner Certificate of Need Application,
Project ID # J-12083-21**

August 2, 2021

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), the University of North Carolina Hospitals at Chapel Hill (UNC Health) submits the following comments related to Duke University Health System, Inc.'s (Duke's) application to develop one additional fixed PET-CT scanner at Duke University Hospital (DUH) for a total of three clinical PET-CT scanners at DUH. UNC Health's comments on this application 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). To facilitate the Agency's review of these comments, UNC Health has organized its discussion by issue, noting the general Certificate of Need (CON) statutory review criteria and specific regulatory criteria relative to each issue, as they relate to the following application:

- **Duke University Health System, Inc. (Duke), Develop one additional fixed PET-CT scanner, Project ID # J-12083-21**

UNC Health's detailed comments include general comments on the Duke application as well as application-specific comments related to its competing application to develop an additional fixed PET scanner in Health Service Area (HSA) IV and a comparative analysis related to its application:

- **The University of North Carolina Hospitals at Chapel Hill (UNC Health), Develop one additional fixed PET scanner, Project ID # J-12089-21**

Based on the following comments, it is clear that Duke's application should be denied and UNC Health's application should be approved.

GENERAL COMMENTS

The 2021 SMFP identifies a need for one additional fixed PET scanner in HSA IV. As noted above, two applications were submitted in response to the need identified for one additional fixed PET scanner in HSA IV – one application was submitted by Duke and the other was submitted by UNC Health. Given the competitive nature of this review, UNC Health understands that the Agency will conduct a comparative analysis of the applications.

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

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

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

Given the analysis of the competing application to follow, as well as the comparative factors, UNC Health believes it has presented the most compelling application to develop additional PET scanner capacity in this review.

DUKE ISSUE-SPECIFIC COMMENTS

1. **The Duke application fails to adequately demonstrate the need for the proposed project.**

While the need determination in the 2021 SMFP was generated based on DUH's utilization, that does not mean that Duke should be awarded the CON – Duke must nonetheless demonstrate the need of patients for its proposed project as well as conformity with all applicable statutory and regulatory review criteria.

Duke argues that its historical utilization demonstrates the need for additional capacity. However, UNC Health believes that Duke's historical utilization data indicates that its existing capacity is more than adequate. On page 33 of its application, Duke notes that, "*Current utilization levels are leading to significant capacity constraints at Duke University Hospital. As a result, the average time from order to appointment is currently 2.5 weeks.*" Notwithstanding the prior statement, Duke projects to increase procedures at DUH from 5,255 procedures in Fiscal Year (FY) 2021 to 6,165 procedures in FY 2022, an increase of more than 1,000 procedures and 17.3 percent. Duke fails to provide any explanation as to why and how – if it already has capacity constraints and long wait times – it will increase volumes beyond its current utilization for PET procedures.

Moreover, while Duke appears to apply only a modest three percent growth rate to its historical volume, its methodology results in procedure growth of 17.3 percent, 13.0 percent, and 4.3 percent for FYs 2022 through 2024, respectively. These growth rates well exceed Duke's historical averages and, absent any rational basis for them, are unreasonable and unsupported.

Based on the discussion above, Duke fails to adequately demonstrate the need the population proposed to be served has for the proposed fixed PET scanner. **As such, Duke's application is non-conforming with Criteria 3, 4, 5, and 6.**

2. **The Duke application fails to meet performance standards.**

The Hospital License Renewal Application (HLRA) form clearly states that a PET procedure is "a single discrete study of one patient involving one or more PET scans" (emphasis added). 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 31." In other words, the HLRA expects the number of PET procedures to equal the number of PET patients.

As shown in excerpts from their 2021 HLRA's, attached hereto as Exhibit 1, DUH and Duke Raleigh have historically reported a higher number of PET procedures, as reported on Table 10g, than PET patients, as reported on the PET Patient Origin Table. In fact, DUH and Duke Raleigh report 1.23 to 1.26 times as many PET procedures as PET patients, as summarized below.

Duke Health PET Procedures and Patients

<i>Hospital</i>	<i>PET Procedures per Table 10g</i>	<i>PET Patients</i>	<i>Ratio</i>
DUH	1,259	1,027	1.23
Duke Raleigh	4,670	3,697	1.26

Source: 2021 HLRAs.

In the footnote provided by DUH for the PET Patient Origin Table, it states “PET Scanner patients by zip code do not tie to section 10d (sic. 10g.) as individual patients may receive more than one PET procedure” (emphasis added). Based on this statement, it is obvious that DUH and Duke Raleigh have historically reported PET scans, rather than adhering to the definition of a PET procedure (which encompasses all scans on a single patient), when reporting their total utilization on Table 10g. Importantly, the *SMFP* uses the PET utilization data reported on Table 10g 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 the Duke application, it appears that the Duke application also provides PET scans as its utilization statistic, rather than PET procedures or patients. As demonstrated below, the Duke application provides PET utilization that is identical to its historical reporting of PET scans at those facilities on its HLRAs.

DUH PET Utilization Comparison

	<i>FY 18</i>	<i>FY 19</i>	<i>FY 20</i>
DUH Form C	4,785	4,947	4,670
DUH HLRA	4,785	4,947	4,670

Duke Raleigh PET Utilization Comparison

	<i>FY 18</i>	<i>FY 19</i>	<i>FY 20</i>
Duke Raleigh Form C	1,170	1,255	1,259
Duke Raleigh HLRA	1,170	1,255	1,259

Given this comparison, it is clear that the utilization projections included in the Duke application are inflated and unreliable because they are based on PET scans and not PET procedures or patients. Therefore, they do not conform with the CON rules as discussed below.

As stated in the HLRA form, a single PET procedure may include more than one PET scan. However, the *SMFP* 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 DUHS states in its application that it is reporting PET procedures, the historical discrepancy between its PET procedures and patients suggests that it has instead reported PET scans based on the definitions in the administrative rules. If so, DUHS representations about its PET procedure utilization are overstated. Specifically, the historical

utilization data provided for DUH and Duke Raleigh appears to be overstated by presenting PET scans rather than procedures (based on the 1 procedure/patient to 1.23 or 1.26 scan ratio indicated in its HLRA).

In its application, Duke provides its utilization projections in an attempt to demonstrate conformity with the performance standards for PET scanners. However, as it appears that DUH and Duke Raleigh’s utilization data is, in fact, PET scans, and not PET procedures as defined by the regulations, then each of these historical and projected utilization statistics is overstated. In order to convert DUH and Duke Raleigh PET scan utilization data to PET procedures, UNC Health divided by each facility’s historical ratio of PET scans to PET procedures or 1.23 and 1.26, respectively. As shown below, when corrected to comply with the definitions in the CON rules, both DUH and Duke Raleigh 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

	<i>DUH FY 20</i>	<i>Duke Raleigh FY 20</i>
PET Scans as reported in Application	4,670	1,259
<u>Divide</u> by Ratio of PET Scans to PET Procedures	1.26	1.23
PET Procedures	3,697	1,027
# of Fixed PET Scanners	2	1
FY20 PET Procedures per Scanner	1,848	1,027

Non-Conformity with Projected Performance Standard

	<i>DUH</i>	<i>Duke Raleigh</i>	<i>Combined Total</i>
FY26 PET Scans as reported in Application	7,375	2,175	9,550
<u>Divide</u> by Ratio of PET Scans to PET Procedures	1.26	1.23	
FY26 PET Procedures	5,853	1,768	7,621
PET Units	3	1	4
FY22 PET Procedures per Unit	1,951	1,768	1,905

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

3. The Duke application fails to adequately demonstrate the reasonableness of its utilization projections.

The Duke application relies on unreasonable and unsupported growth rates to project utilization. Specifically, for non-cardiac PET, Duke calculates a compound annual growth rate (CAGR) from 2018 to 2021 of 3.2 percent for DUH and 6.2 percent for Duke Raleigh. To project total non-cardiac PET utilization for DUH and Duke Raleigh combined, Duke assumes a 3.0 percent annual growth rate applied to historical utilization and then assigns 25 percent of the 3.0 percent annual growth to DUH and 75 percent to Duke Raleigh. This methodology results in assumed annual

growth rates for Duke Raleigh non-cardiac PET ranging from 8.2 percent (from 2025 to 2026) to 10.5 percent (from 2021 to 2022). In other words, Duke's methodology results in annual growth rates for Duke Raleigh non-cardiac PET that exceed historical annual growth by 2.1 to 4.4 percentage points, without providing any reasonable basis for this assumption.

On top of the projected non-cardiac PET utilization for DUH and Duke Raleigh discussed above, Duke projects additional cardiac PET and PSMA-PET procedures (for patients diagnosed with prostate cancer) for DUH. Duke assumes growth in cardiac PET at DUH from 20 procedures in 2018 to 750 procedures in 2023 through 2026. To achieve 750 cardiac procedures per year in the out years, Duke assumes a total of three cardiac PET patients per day x five days per week x 50 weeks per year. UNC Health believes it is questionable that Duke's cardiac PET projections of 750 procedures per year will materialize. It is not clear that Duke has the capability of performing myocardial perfusion imaging (MPI) as UNC Health does, which is now considered to be a gold standard in diagnostic cardiac imaging and definitive CAD diagnosis and requires the radioisotope Rubidium-82. If Duke does not have the capability of performing cardiac perfusion with Rubidium, UNC Health questions whether the "cardiac PET" procedures Duke projects are merely cardiac viability PET studies using the more commonly available radioisotope, FDG, which is performed in a small subset of patients with cardiac conditions.

Duke also projects to begin providing PSMA-PET procedures for prostate cancer patients at DUH beginning with 500 procedures in 2022 increasing to 1,250 per year in 2024 through 2026. As the basis for this projected volume, Duke identifies five providers with a combined 2,000 patients diagnosed with prostate cancer and assumes a total of five PSMA-PET patients per day x five days per week x 50 weeks. The volume for PSMA is projected at 1,250 based on five patients per day x five days per week x 50 weeks, stating that it is "conservatively projecting utilization to reach five such procedures per day."

While Duke's utilization methodology begins with a seemingly modest three percent growth rate applied to total DUH and Duke Raleigh historical PET volume, its methodology overall results in assumed annual growth rates for DUH total PET procedures of 13.0 percent (from 2022 to 2023) and 17.3 percent (from 2021 to 2022). In other words, Duke's methodology results in annual growth rates for DUH total PET procedures in the first two projection years that exceed historical annual growth ranging from 9.8 to 14.1 percentage points. As noted above, Duke's methodology also results in unreasonable annual growth rates for Duke Raleigh non-cardiac PET that exceed historical annual growth by 2.1 to 4.4 percentage points.

Also of note, Duke states on page 33 of its application, "*Current utilization levels are leading to significant capacity constraints at Duke University Hospital. As a result, the average time from order to appointment is currently 2.5 weeks.*" However, as indicated above, Duke's methodology results in 17 percent growth in DUH PET procedures from 2021 to 2022. With the capacity constraints and long wait times Duke asserts, it is questionable how DUH will be able to accommodate 17 percent growth from 2021 to 2022 prior to the development of any additional PET capacity.

Based on the discussion above, it is clear that Duke's projected utilization is unsupported and unreasonable. As such, **the Duke application is non-conforming with Criteria 3, 4, 5, 6, and 18a, and the performance standards for Positron Emission Tomography Scanners (10A NCAC 14C .3700).**

COMPARATIVE ANALYSIS

The UNC Health PET application (Project ID # J-12089-21) and the Duke PET application (Project ID # J-12083-21) each propose to develop an additional PET scanner in response to the 2021 SMFP need determination for HSA IV. Given that two applicants propose to meet the need for the one additional PET scanner in HSA IV, both cannot be approved. To determine the comparative factors that are applicable in this review, UNC Health examined recent Agency findings for competitive PET scanner reviews. Based on that examination and the facts and circumstances of the competing applications in this review, UNC Health considered the following comparative factors:

- Conformity with Applicable Review Criteria
- Geographic Distribution
- Patient Access to Alternative Providers
- Populations to be Served
- Demonstration of Need
- Access by Underserved Groups
- Revenues
- Operating Expenses

UNC Health believes that the factors presented above and discussed in turn below should be used by the Project Analyst in reviewing the competing applications.

Conformity with Applicable Statutory and Regulatory Review Criteria

As noted in the application-specific comments above, the Duke application is not conforming with multiple statutory and regulatory review criteria and as such, cannot be approved. The UNC Health application, however, is conforming with all applicable statutory and regulatory review criteria and therefore is the most effective alternative with regard to conformity with review criteria.

Geographic Distribution

The 2021 SMFP identifies the need for one fixed PET scanner in HSA IV, which includes Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, and Warren counties. There are seven existing fixed PET scanners in HSA IV, all of which are located in Wake, Durham, and Orange counties. There are no existing or approved fixed PET scanners in any of the other counties in HSA IV. UNC Health proposes to locate the fixed PET scanner in Orange County while Duke proposes to locate the fixed PET scanner in Durham County. Therefore, with regard to geographic distribution, both applications are comparable.

Patient Access to Alternative Providers

Duke proposes to develop the fixed PET scanner at DUH. UNC Health proposes to develop the fixed PET scanner at UNC Hospitals. DUH and UNC Hospitals each currently operate two existing fixed PET scanners. Therefore, with regard to patient access to alternative providers, both applications are comparable.

Populations to be Served

The following table shows the projected number of patients to be served in the third project year (Fiscal Year 2026) based on the information provided in applicants' response to Section C.3.(b).

Projected Patients by County – FY 2026

	<i>Duke</i>	<i>UNC Health</i>
Orange	223	880
Durham	1,126	364
Chatham	46	377
Franklin	66	*
Granville	212	*
Johnston	101	*
Lee	43	237
Person	196	*
Vance	106	*
Wake	742	818
Warren	57	*
Alamance	152	417
Caswell	41	*
Cumberland	166	391
Guilford	133	*
Harnett	46	*
Nash	44	*
Robeson	106	*
Wilson	32	*
Other States/Other	2,203	2,865*
Total	5,838	6,349

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

*Included in Other.

Both applicants project to serve patients in all counties in HSA IV. In total, UNC Health projects to serve 89 counties in North Carolina. By comparison, Duke projects to serve the 11 counties in HSA IV as well as eight additional identified counties in North Carolina, for a total of 19 counties (note: while Duke's application does include an Other category, it does not identify any of the Other counties in North Carolina). Therefore, with regard to populations to be served, UNC Health is the more effective applicant.

Demonstration of Need

As discussed above in the issue specific comments, Duke fails to adequately demonstrate that the projected number of PET procedures to be performed was based on reasonable, credible, or supported assumptions. Therefore, with regard to demonstration of need, UNC Health is the more effective applicant.

Access by Underserved Groups

Projected Charity Care

Neither application includes charity care as a payor source for patients. Rather, both combine self-pay and charity care; therefore, it is not possible to determine how much of this payor source is actually attributable to charity care particularly as a comparison between the applicants.

Projected Access by Medicare Recipients

For the applicants in this review, the following table compares Project Year 3 projections for the total number of procedures, the projected number of Medicare procedures, and Medicare procedures as a percentage of total procedures. Generally, the application proposing either the higher percentage or number of Medicare procedures is the more effective alternative with regard to this comparative factor.

<i>Applicant</i>	<i># of Fixed PET Scanners</i>	<i>Total Number of Procedures</i>	<i>Projected Number of Medicare Procedures</i>	<i>Medicare Procedures as a Percentage of Total</i>
DUH	3	7,375	4,385	59.5%
UNC Health	3	6,349	3,130	49.3%

Source: Section L and Section Q of the applications.

As shown above, based on the information provided in Duke's application, Duke has proposed the higher percentage and higher number of Medicare procedures. However, as discussed in the application-specific comments above, Duke overstated its utilization statistics by erroneously presenting PET scans throughout its application rather than PET procedures (defined as all scans for a single patient). Therefore, the figures included in the table above do not provide a meaningful or accurate comparison with regard to access by Medicare recipients. However, as noted in the application-specific comments above, the Duke application is not conforming with multiple statutory and regulatory review criteria and as such, cannot be approved. The UNC Health application, however, is conforming with all applicable statutory and regulatory review criteria and therefore is the most effective alternative with regard to access to Medicare recipients.

Projected Access by Medicaid Recipients

For the applicants in this review, the following table compares Project Year 3 projections for the total number of procedures, the projected number of Medicaid procedures, and Medicaid procedures as a percentage of total procedures. Generally, the application proposing either the higher percentage or number of Medicaid procedures is the more effective alternative with regard to this comparative factor.

<i>Applicant</i>	<i># of Fixed PET Scanners</i>	<i>Total Number of Procedures</i>	<i>Projected Number of Medicaid Procedures</i>	<i>Medicaid Procedures as a Percentage of Total</i>
DUH	3	7,375	291	3.9%
UNC Health	3	6,349	514	8.1%

Source: Section L and Section Q of the applications.

As shown above, UNC Health has proposed the higher percentage and higher number of Medicaid procedures. Further, as discussed in the application-specific comments above, Duke erroneously presented PET scans throughout its application rather than PET procedures and its application is not conforming with multiple statutory and regulatory review criteria and as such, cannot be approved. The UNC Health application, however, is conforming with all applicable statutory and regulatory review criteria and therefore is the most effective alternative with regard to access to Medicaid recipients.

Revenues

Projected Average Net Revenue per PET Procedure

The following table shows the projected net revenue per procedure in Project Year 3 for each of the applicants, based on the information provided in the applicants’ pro forma financial statements in Section Q. Generally, the application proposing the lowest average net revenue per procedure is the more effective alternative with regard to this comparative factor.

<i>Applicant</i>	<i>Net Revenue</i>	<i>Procedures</i>	<i>Net Revenue per Procedure</i>
DUH	\$21,882,814	7,375	\$2,967
UNC Health	\$14,848,700	6,349	\$2,339

Source: Section Q of the applications.

As shown above, UNC Health has proposed the lowest average net revenue per procedure. Further, as discussed in the application-specific comments above, Duke erroneously presented PET scans throughout its application rather than PET procedures and its application is not conforming with multiple statutory and regulatory review criteria and as such, cannot be approved. The UNC Health application, however, is conforming with all applicable statutory and regulatory review criteria and therefore is the most effective alternative with regard to average net revenue per PET procedure.

Operating Expenses

Projected Average Operating Expense per Procedure

The following table shows the projected average operating expense per procedure in Project Year 3 for each of the applicants, based on the information provided in the applicants’ pro forma financial statements in Section Q. Generally, the application proposing the lowest average operating expense per procedure is the more effective alternative with regard to this comparative factor.

<i>Applicant</i>	<i>Total Operating Expenses</i>	<i>Procedures</i>	<i>Operating Expense per Procedure</i>
DUH	\$13,328,890	7,375	\$1,807
UNC Health	\$13,667,807	6,349	\$2,153

Source: Section Q of the applications.

A key difference between the two applications is the assignment of corporate overhead to the projects. UNC Health included projected overhead, another indirect expense, in the amount of 65 percent of all other expenses based on its cost accounting for the service. DUH included Corporate Expense Allocations in other expenses but did not discuss the calculation. To adjust for the difference in the treatment of indirect expenses, adjusted operating expense per procedure was calculated below.

<i>Applicant</i>	<i>Total Operating Expenses</i>	<i>Corporate Allocation</i>	<i>Adjusted Operating Expenses</i>	<i>Procedures</i>	<i>Adjusted Operating Expense per Procedure</i>
DUH	\$13,328,890	\$948,107	\$12,380,783	7,375	\$1,679
UNC Health	\$13,667,807	\$5,384,288	\$8,283,519	6,349	\$1,305

As shown in the table above, UNC Health projects the lowest total expense per fixed PET procedure when operating costs are adjusted to provide a reasonable comparison. Further, as discussed in the application-specific comments above, Duke erroneously presented PET scans throughout its application rather than PET procedures and its application is not conforming with multiple statutory and regulatory review criteria and as such, cannot be approved. The UNC Health application, however, is conforming with all applicable statutory and regulatory review criteria and therefore is the most effective alternative with regard to operating expenses per procedure.

SUMMARY

As noted previously, UNC Health maintains that the Duke application cannot be approved as proposed. As such, UNC Health 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 Health believes that its application represents the most effective alternative for meeting the need identified in the 2021 SMFP for an additional fixed PET scanner in HSA IV. As such, the CON Section can and should approve the UNC Health application.

Please note that in no way does UNC Health intend for these comments to change or amend its application filed on June 15, 2021. If the Agency considers any of these comments to be amending UNC Health’s application, those responses should not be considered.

EXHIBIT 1

All responses should pertain to ~~October 1, 2019 through September 30, 2020.~~ **July 1, 2019 through June 30, 2020**

g. Positron Emission Tomography (PET). Campus – if multiple sites: DUH Campus
see footnote (1) for 10g-10i

	Number of Units	Number of Procedures*		
		Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	2	402	4,268	4,670
Mobile PET Scanner	0	0	0	0
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 31.

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

CON Project ID numbers for all non-grandfathered fixed PET scanners on this campus: J-6420-01 (Duke has an additional PET scanner originally acquired in 1991)

Does the hospital own a mobile PET scanner that performed procedures on this campus? ___ Yes X No

If Yes, enter the CON Project ID number(s) for the mobile scanner(s): N/A

If No, name of Mobile PET Provider, if any: N/A

h. Other Imaging Equipment. Campus – if multiple sites: DUH Campus *see footnotes (2,4,5,6,7,8 &9) for 10g-10i*

	Number of Units	Number of Procedures		
		Inpatient	Outpatient	Total
Ultrasound equipment	21	15,237	26,082	41,319
Mammography equipment	8	58	17,218	17,276
Bone Density Equipment	0	0	0	0
Fixed X-ray Equipment (excluding fluoroscopic)	49	117,853	72,194	190,047
Fixed Fluoroscopic X-ray Equipment	9	19,492	3,514	23,006
Special Procedures/ Angiography Equipment (neuro & vascular, but not including cardiac cath.)	5	11,075	10,193	21,268
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	3	927	8,089	9,016
Mobile Gamma Camera. Vendor:	0	0	0	0
Proton Therapy equipment	0	0	0	0

i. Lithotripsy. Campus – if multiple sites: DUH Campus *see footnotes (3) for 10g-10i*

	Number of Units	Number of Procedures			Lithotripsy Vendor/Owner
		Inpatient	Outpatient	Total	
Fixed	N/A	N/A	N/A	N/A	
Mobile	N/A	N/A	N/A	N/A	

All responses should pertain to ~~October 1, 2019 through September 30, 2020.~~ July 1, 2019 through June 30, 2020

Patient Origin – PET Scanner *see footnote for page 43*

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. Submit one record for the licensed hospital. **DO NOT SUBMIT SEPARATE RECORDS FOR EACH CAMPUS.**

Please count each patient only once. The number of patients in this table should match the number of PET procedures reported in the “Positron Emission Tomography (PET)” table on page 19.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance	96	37. Gates	2	73. Person	124
2. Alexander	5	38. Graham	1	74. Pitt	20
3. Alleghany	0	39. Granville	134	75. Polk	1
4. Anson	0	40. Greene	2	76. Randolph	25
5. Ashe	5	41. Guilford	84	77. Richmond	6
6. Avery	1	42. Halifax	25	78. Robeson	67
7. Beaufort	10	43. Harnett	29	79. Rockingham	13
8. Bertie	6	44. Haywood	7	80. Rowan	5
9. Bladen	9	45. Henderson	8	81. Rutherford	6
10. Brunswick	56	46. Hertford	1	82. Sampson	20
11. Buncombe	25	47. Hoke	12	83. Scotland	10
12. Burke	9	48. Hyde	1	84. Stanly	3
13. Cabarrus	13	49. Iredell	13	85. Stokes	5
14. Caldwell	3	50. Jackson	0	86. Surry	7
15. Camden	4	51. Johnston	64	87. Swain	2
16. Carteret	23	52. Jones	2	88. Transylvania	3
17. Caswell	26	53. Lee	27	89. Tyrrell	0
18. Catawba	18	54. Lenoir	11	90. Union	11
19. Chatham	29	55. Lincoln	3	91. Vance	67
20. Cherokee	0	56. Macon	2	92. Wake	470
21. Chowan	4	57. Madison	2	93. Warren	36
22. Clay	0	58. Martin	6	94. Washington	4
23. Cleveland	2	59. McDowell	3	95. Watauga	11
24. Columbus	18	60. Mecklenburg	32	96. Wayne	26
25. Craven	27	61. Mitchell	2	97. Wilkes	1
26. Cumberland	105	62. Montgomery	0	98. Wilson	20
27. Currituck	5	63. Moore	35	99. Yadkin	2
28. Dare	12	64. Nash	28	100. Yancey	0
29. Davidson	8	65. New Hanover	46		
30. Davie	3	66. Northampton	9	101. Georgia	16
31. Duplin	13	67. Onslow	23	102. South Carolina	130
32. Durham	713	68. Orange	141	103. Tennessee	25
33. Edgecombe	13	69. Pamlico	7	104. Virginia	305
34. Forsyth	29	70. Pasquotank	3	105. Other States	90
35. Franklin	42	71. Pender	22	106. Other	26
36. Gaston	16	72. Perquimans	5	Total No. of Patients	3,697

Duke University Hospital License Renewal Application 2021
Footnote for Page 43

PET Scanner patients by zip code do not tie to section 10d. as individual patients may receive more than one PET procedure.

All responses should pertain to July 1, 2019 through June 30, 2020.

f. Computed Tomography (CT). Campus – if multiple sites: Duke Women’s Cancer Care Raleigh

How many fixed CT scanners does the hospital have? 1
 Does the hospital contract for mobile CT scanner services? Yes No
 If yes, identify the mobile CT vendor _____

Complete the following table for fixed and mobile CT scanners.

	Type of CT Scan	FIXED CT Scanner # of Scans	MOBILE CT Scanner # of Scans
1	Head without contrast	24	0
2	Head with contrast	66	0
3	Head without and with contrast	37	0
4	Body without contrast	271	0
5	Body with contrast	2,155	0
6	Body without contrast and with contrast	134	0
7	Biopsy in addition to body scan with or without contrast	0	0
8	Abscess drainage in addition to body scan with or without contrast	0	0
	Total	2,687	0

g. Positron Emission Tomography (PET). Campus – if multiple sites: _____

	Number of Units	Number of Procedures*		
		Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	0	0	0	0
Mobile PET Scanner	1	18	1,241	1,259
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 31.

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

CON Project ID numbers for all non-grandfathered fixed PET scanners on this campus: _____

Does the hospital own a mobile PET scanner that performed procedures on this campus? Yes No

If Yes, enter the CON Project ID number(s) for the mobile scanner(s): _____

If No, name of Mobile PET Provider, if any: Alliance

All responses should pertain to July 1, 2019 through June 30, 2020.

Patient Origin – PET Scanner

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. Submit one record for the licensed hospital. **DO NOT SUBMIT SEPARATE RECORDS FOR EACH CAMPUS.**

Please count each patient only once. The number of patients in this table should match the number of PET procedures reported in the “Positron Emission Tomography (PET)” table on page 19.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance	5	37. Gates	-	73. Person	7
2. Alexander	-	38. Graham	-	74. Pitt	3
3. Alleghany	-	39. Granville	5	75. Polk	-
4. Anson	-	40. Greene	-	76. Randolph	1
5. Ashe	-	41. Guilford	3	77. Richmond	-
6. Avery	-	42. Halifax	10	78. Robeson	3
7. Beaufort	-	43. Harnett	45	79. Rockingham	-
8. Bertie	-	44. Haywood	-	80. Rowan	1
9. Bladen	2	45. Henderson	-	81. Rutherford	-
10. Brunswick	5	46. Hertford	-	82. Sampson	10
11. Buncombe	2	47. Hoke	-	83. Scotland	1
12. Burke	1	48. Hyde	-	84. Stanly	-
13. Cabarrus	-	49. Iredell	1	85. Stokes	-
14. Caldwell	-	50. Jackson	-	86. Surry	-
15. Camden	-	51. Johnston	58	87. Swain	-
16. Carteret	4	52. Jones	-	88. Transylvania	-
17. Caswell	-	53. Lee	7	89. Tyrrell	-
18. Catawba	2	54. Lenoir	3	90. Union	-
19. Chatham	2	55. Lincoln	-	91. Vance	7
20. Cherokee	1	56. Macon	-	92. Wake	614
21. Chowan	-	57. Madison	-	93. Warren	4
22. Clay	-	58. Martin	-	94. Washington	-
23. Cleveland	-	59. McDowell	-	95. Watauga	-
24. Columbus	1	60. Mecklenburg	1	96. Wayne	14
25. Craven	-	61. Mitchell	-	97. Wilkes	-
26. Cumberland	24	62. Montgomery	2	98. Wilson	12
27. Currituck	1	63. Moore	6	99. Yadkin	-
28. Dare	4	64. Nash	31	100. Yancey	-
29. Davidson	1	65. New Hanover	7		
30. Davie	-	66. Northampton	4	101. Georgia	1
31. Duplin	7	67. Onslow	3	102. South Carolina	2
32. Durham	17	68. Orange	2	103. Tennessee	1
33. Edgecombe	5	69. Pamlico	-	104. Virginia	15
34. Forsyth	-	70. Pasquotank	-	105. Other States	6
35. Franklin	52	71. Pender	1	106. Other	-
36. Gaston	-	72. Perquimans	-	Total No. of Patients	1,027

Note: Total number of unique patients does not equal number of PET procedures reported in table 10b. Patients may receive multiple scans throughout reporting period.