



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

July 28, 2016

Via Email

Paige Bennett
Assistant Chief, Healthcare Planning
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Comments Regarding PET Scanner Need Determination

Dear Ms. Bennett:

Enclosed please find comments in support of the need determination included in the draft 2017 State Medical Facilities Plan for an additional PET scanner in Health Service Area IV. For the reasons set forth in those comments, the Duke University Health System strongly supports this need determination. Please let me know if you have any questions about these comments. Thank you.

Sincerely,

A handwritten signature in black ink that reads 'Catharine W. Cummer'.

Catharine W. Cummer

Enclosure

**COMMENTS IN SUPPORT OF NEED DETERMINATION
FOR ADDITIONAL PET SCANNER IN HSA IV**

Duke University Health System, Inc. d/b/a Duke Raleigh Hospital hereby submits these comments in support of the need determination for an additional PET scanner in HSA IV that appears in the draft 2017 State Medical Facilities Plan. This determination reflects a genuine and growing demand for essential cancer services in the service area, and Duke strongly supports the inclusion of this determination pursuant to the existing methodology in the final plan.

Need Methodology

The need methodology for PET scanners includes two parts, the first based on the total inventory and utilization of equipment in the service area, and the second based on the need for coordination of care at major cancer centers:

Methodology Part 2:

Step 6: Identify each major cancer treatment facility, program or provider in the state, i.e., providers that operate two linear accelerators and performed over 12,500 ESTV procedures in the 12-month period reflected on the Hospital License Renewal Application or Equipment Registration and Inventory Form.

Step 7: A need is determined for one additional fixed PET scanner if a major cancer treatment facility, program or provider identified in Step 6 is hospital-based and does not own or operate a fixed dedicated PET scanner, except as provided in Step 8 for both parts of the methodology combined.

This second part of the methodology reflects the essential and integral use PET scanning in cancer care. PET scanning is used not only for the initial diagnosis of a condition, but may be used throughout a patient's treatment for monitoring and managing chemotherapy, radiation, and other care. A 2014 article in the journal Cancers found the following:

During the last 20 years the continuous technological progress has revolutionized the role of PET scan in Oncology. Moving from its original role for tumor staging and restaging PET/CT has become a seminal tool for tumor prognostication: as a new metrics for tumor volume and spread measurement at baseline and as a compass for treatment tailoring both in lymphoma and solid tumors like esophageal carcinoma, inoperable non-small cell lung carcinoma and metastatic breast cancer.

Gallamini A, Zwarthoed C, Borra A. Positron Emission Tomography (PET) in Oncology. *Cancers*. 2014;6(4):1821-1889. doi:10.3390/cancers6041821.

Need in HSA IV

Duke Raleigh Hospital is a hospital-based major cancer treatment facility that now operates four linear accelerators (two at the hospital campus and an additional two in outpatient departments off campus), and performed well over 12,500 ESTVs on its linear accelerators in the applicable reporting period. It does not have a fixed PET scanner. As evidence of the need for access to PET scanning capacity for patient care, however, Duke Raleigh was the second most highly utilized mobile PET site in the state in 2014-15, at 675 procedures per year, based on one day per week of mobile PET access.

This utilization was not an aberration: in November 2015, Duke Raleigh was able to add an additional half day per week plus a half day every other week of mobile services. This additional capacity was filled almost immediately. As a result, from July 2015 through June 2016, Duke Raleigh performed 951 mobile PET procedures, with only 1.75 days/week of mobile access – an increase of 40% over the previous year.

Duke Raleigh Hospital Mobile PET Procedures

<u>July</u> <u>15</u>	<u>Aug</u> <u>15</u>	<u>Sept</u> <u>15</u>	<u>Oct</u> <u>15</u>	<u>Nov</u> <u>15*</u>	<u>Dec</u> <u>15</u>	<u>Jan</u> <u>16</u>	<u>Feb</u> <u>16</u>	<u>March</u> <u>16</u>	<u>April</u> <u>16</u>	<u>May</u> <u>16</u>	<u>June</u> <u>16</u>	<u>Total</u>
70	61	66	63	78	90	79	89	90	75	87	103	951

To try to meet this growing need, Duke Raleigh has requested additional mobile time, which is not currently available.

Duke University Hospital in Durham has also shown utilization growth over the past year, performing 4643 procedures from July 2015 to June 2016, a 10% increase over the previous year. The draft 2017 State Medical Facilities Plan similarly documents growing utilization statewide. Moreover, according to data from the North Carolina Office of State Budget and Management, the population of Wake County is projected to increase by nearly 10%, more than 100,000 people, over the next 10 years. Duke Raleigh Hospital accordingly anticipates that the need for comprehensive cancer care, including PET scanning services, will only increase in this area. Therefore, the need determination generated by the existing methodology accurately reflects a need for additional fixed PET capacity in the service area.

We would note that the new Policy TE-1, which was promulgated to expand the availability of mobile PET capacity in rural areas in the state, is not anticipated to have any effect on the Wake County market. Policy TE-1 provides that any converted mobile scanner “shall not serve any mobile host site that is not owned by the PET certificate holder or an entity related to the PET certificate holder such as a parent or subsidiary that is located in the county where any existing or approved fixed PET scanner is located,” except for the original fixed scanner location. Because there are PET scanners located in Wake County, any new mobile scanner is not eligible to be deployed in the county. Duke University Hospital, moreover, cannot practically convert one of its existing fixed scanners to mobile use, as both fixed scanners there highly utilized already and have no excess capacity.

In conclusion, Duke Raleigh Hospital strongly supports the need determination for an additional fixed PET scanner in HSA IV, as accurately reflecting a need for coordinated comprehensive cancer services in this area.