

**COMPETITIVE COMMENTS ON**  
**2021 HSA IV PET NEED DETERMINATION**  
**SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.**

Duke University Health System, Inc. (“Duke”) presents these comments regarding the application filed by UNC Hospitals (UNC) for an additional fixed PET scanner in HSA IV (J-012089-21). For the reasons set forth herein, that application does not meet the need established by the State Health Coordinating Council and should be denied.

UNC’s application depends on two key factors to make its case: resolutely ignoring available PET capacity in the UNC system, and relying on vague and unwarranted volume projections and patient origin projections. Both flaws are fundamental and render the applicable nonconforming with several criteria. These issues and other deficiencies in the application are discussed at length below.

***Duplication of existing and approved services***

**Criterion 3, Criterion 4 and Criterion 6**

UNC Healthcare has significant available PET capacity in the health service area that it fails to address in its application. This omission negates any claimed need for the project; ignores more effective available alternatives; and reflects a glaring unnecessary duplication of UNC’s own existing and approved services in its system.

**1) Undeveloped PET scanner at Rex Hospital**

First, UNC fails to mention anywhere in its application the PET scanner that has been approved, but not yet developed, at UNC Rex Hospital in Raleigh (Project J-11659-19). UNC cannot dispute that Rex is part of the UNC system. Rex Hospital, Inc. is wholly owned by Rex Healthcare, Inc. Rex Healthcare, Inc. is wholly owned by the University of North Carolina Healthcare System, which similarly owns and operates UNC Hospitals. Rex is located in Wake County, which is in the same HSA and PET service area as UNC Hospitals in Orange County. In reading the application, it would appear that UNC and UNC Rex have no connection, and moreover that Rex is not already sitting on a CON that it is choosing not to develop.

UNC Rex was approved for Project J-11659-19 for a second PET scanner effective June 1, 2019. In its July 1, 2021, progress report for this project (attached), UNC Rex stated:

As explained in previous progress reports, the COVID-19 pandemic has imposed some delays on this project. Based on the diversion of resources to the COVID-19 response and recovery efforts, development of this additional fixed PET scanner has been delayed. Although a purchase order has already been issued and Rex remains committed to acquisition of the scanner and development of the project, Rex anticipates further delays of up to a year. Rex has reassessed the project and has tentative plans to resume the project later this summer.

These vague assurances of its intent to restart the project “later” notwithstanding, UNC Rex does not actually provide any updated timetable, stating that “[a]n updated timetable will be proposed as soon as possible after more certainty and reliability surrounding the timeline can be obtained.” Despite this lack of “certainty and reliability” in executing on an existing project for PET capacity in the same system in the same HSA, UNC purports to need yet an additional scanner in the HSA. The proposed project thus unnecessarily duplicates capacity that UNC Healthcare has readily available to it.

Moreover, if UNC Healthcare is not planning to implement that project, it calls into question any claims of capacity constraints on its existing equipment at UNC Hospitals or need for additional capacity. It also renders any commitment to pursue the project it proposes in the current application questionable. If UNC Healthcare is choosing not to develop the additional PET scanner already approved at UNC Rex, why would it develop such equipment at UNC Hospitals in Chapel Hill now?

If it is planning on implementing the UNC Rex project, UNC fails to address the effect of that additional available capacity on its projections for the hospital in Chapel Hill. This problem is especially apparent when the patient origin for the UNC’s PET services are examined. The following reflects UNC’s actual historical patient origin as reported in its annual license renewal applications.

Year	UNC Wake PET Origin	UNC Orange PET Origin
2020	685	578
2019	594	535
2018	509	441
2017	617	546
2016	462	326

*Source: UNC annual license renewal applications, 2017-2021*

Note that UNC mentions in the Assumptions to Form C that these data reported in the license renewal applications actually includes patients who may have only received CT procedures instead of PET-only or combined PET-CT procedures. Therefore, UNC’s historical patient origin at page 43 of the Application does not match the PET patient origin numbers provided on its license renewal applications. Regardless, this license renewal data demonstrates that each

year, UNC provides more procedures to Wake County patients than to Orange County patients on its PET equipment. A significant number of patients from Wake County and other counties more proximate to Rex could reasonably be anticipated to obtain procedures at Rex rather than in Chapel Hill when an additional PET scanner is put into service there.

In addition to undermining any demonstration of need and volume projections at UNC in Chapel Hill under Criterion 3 and Criterion 6, this approved scanner at Rex Hospital is not addressed by UNC as an alternative under Criterion 4. If UNC has now determined that it needs additional PET capacity in Orange County more than in Wake County – which it appears it has, by filing this application for additional equipment in Chapel Hill while indefinitely delaying the development of its approved scanner in Wake County – it could seek a material compliance determination or a change in scope application to develop the system’s approved scanner to Orange County.

## 2) Available PET-MR capacity at UNC Hospitals

In addition to resolutely ignoring the approved scanner not yet put into service at UNC Rex, UNC also omits any mention of another source of capacity to address its purported needs for PET scanning, namely, the existing PET-MR scanner approved for clinical use (see Project J-10016-12). As set forth in its original application for that project, a PET-MR scanning provides an alternative to PET-CT for certain patients and clinical conditions. Specifically, PET-MR may be especially appropriate for pediatric patients needing PET scans, as well as the cardiac and PSMA/prostate patients described in UNC’s application. UNC fails to address the extent to which this equipment is not an available alternative to meet patient needs.

## ***Unreasonable volume projections***

### **Criterion 3 and Criterion 5**

UNC’s utilization is also fundamentally flawed, relying on a variety of assumptions that are, in fact, at odds with its documented existing experience.

#### 1) Unsupported reliance on HSA growth rate

Without any basis, UNC projects that going forward its PET volume will grow at a rate equal to 75% of the HSA’s historical growth rate. However, the HSA growth rate relied upon in UNC’s utilization projections has no connection to UNC’s own proposed patient origin. As set forth at page 46, more than 50% of patients are projected to come from Alamance, Cumberland, and unspecified “other” counties or states potentially outside of the HSA, based on its existing patient origin patterns, and therefore UNC’s historical and projected utilization is not, in fact, significantly tied to the overall HSA utilization or growth.

In fact, UNC’s own experience with patients from the HSA is uneven at best:

	Total UNC patients (patient origin reports)	UNC patients from HSA (patient origin reports)	HSA total (UNC application Form C assumption)	UNC utilization as percentage of total HSA volume
2019	4939	2383	9016	26.4%
2018	4278	1735	8452	20.5%
2017	4199	2123	7564	28.1%
2016	2968	1392	6659	20.9%

*Source: DHSR Patient origin reports 2017-2020, UNC application Form C*

(It is notable that the patient origin reports which draw from the license renewal applications appear to overstate UNC’s actual PET utilization as UNC now acknowledges those applications include some CT-only volume performed on the PET scanner. The patient origin reports that UNC relies upon for its projections include UNC’s inflated volumes, for example reporting a total of 4939 PET procedures at UNC Hospitals in the 2019 patient origin report while UNC’s application now states that it performed only 4450 PET procedures for that year (Form C Assumptions p. 1). Presumably the difference is CT-only procedures. If such procedures are subtracted out from the patient origin report, UNC’s share of actual PET procedures in the HSA each year is even lower.)

Having never attracted more than 30% of the total PET procedures for patients from the HSA, and with such variable utilization for patients from the HSA, it is not reasonable for UNC to base its growth assumptions on the HSA growth rate.

Furthermore, the primary engine of growth in PET utilization in the HSA is Wake County. As set forth in the table on page 3 of UNC’s Assumptions, between 2016 and 2019 more than half of the incremental growth in the HSA reflected Wake County patients alone (1239 out of 2357).

As set forth above, UNC’s Wake County patient volumes between 2016 and 2019 increased more slowly than the overall growth rates for the county and the HSA presented in the UNC application. While all Wake County patient procedures (performed at any location) increased by a CAGR of 11.0%, UNC’s own Wake County patient volumes increased by a CAGR of less than 9% over the same timeframe. In fact, focusing on the more recent experience of UNC’s own experience between FY 2017 and FY 2019 is even more striking:

	<u>FY 2017</u>	<u>FY 2019</u>	<u>2 year-CAGR</u>
Total Wake County patients <i>Source: Form C Assumptions p. 3</i>	3784	4615	10.44%
Wake County patients at UNC <i>Source: 2018 and 2020 UNC LRAs – note, apparently includes CT-only procedures</i>	617	594	-1.88%

Moreover, it does not appear that UNC made any great strides in Wake County utilization in SFY 2020, documenting a total of 514 patients from Wake County out of a total of 3991 (UNC Application, p. 43). If this figure is to be “normalized” at the same rate that UNC used for its total PET volumes, UNC served a “normalized” number of 561 Wake County patients (based on the ratio of actual utilization to “normalized” utilization for SFY 2020 from 3991 to 4357 as set forth in the Assumptions pp. 1 and 4). This reflects a continued decrease in Wake County patients, and further undercuts any assumption that the HSA’s historical growth rate has any bearing on UNC’s anticipated utilization.<sup>1</sup>

2) Growth rate at odds with actual 2020-2021 experience

UNC also wrongly states that its volume growth between SFY 2020 and SFY 2021 supports the application’s projected 8% growth rate for future years. Specifically, UNC “assumes” that its total PET procedures grew 8.4% from 3991 procedures in SFY 2020, to 4327 procedures in SFY 2021 (UNC Form C Assumptions, p. 4). This “assumption” incorrectly compares apples to oranges. 3991 reflects UNC’s actual volume in SFY 2020 and 4327 reflects its normalized volume in SFY 2021. In fact, the “normalized” volumes UNC presents in its Assumptions show that its total utilization decreased from SFY 2020 to SFY 2021:

	<u>SFY 2020</u>	<u>SFY 2021</u>	<u>Growth Rate</u>
Actual PET volumes (p.4)	3991	unknown	unknown
“Normalized” PET volumes (p.1)	4357	4327	-.7%

*Source: UNC Form C Assumptions*

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<sup>1</sup> Duke acknowledges that the 514 patients does not match the license renewal application data, and it is impossible to tell what UNC’s actual historical PET volume for Wake County patients is. This simply further underscores the unreasonableness of UNC’s reliance on the HSA growth to support its projected utilization.

Thus, if UNC relies on the difference between SFY 2020 and SFY 2021 as the basis for future growth, it would have less volume in the future than now. It appears, instead, to have simply lit upon 8% as the necessary growth rate to get it past the regulatory performance threshold of 2080 procedures/machine. Nothing in the UNC's own experience supports that rate.

### 3) Unsupported baseline for SFY 2021

Finally, the volume projections are unreliable given that UNC calculates future utilization by applying the unsupported 8% growth rate going forward to a "normalized" SFY 2021 baseline that is nowhere explained. While it could be appropriate to annualize recent utilization data in light of the effects of COVID-19 to analyze growth trends, UNC appears to provide variable approaches to annualizing each year. For example, for FY 20, it states that it excluded the months of March, April and May and "adjusted for those months based on the same proportion of volume from 2019." (See UNC Application p. 66 and Form C Assumptions p. 1). For 2021, however, UNC states that "2021 data was seasonalized utilizing July 2020 through April 2021 data as a percentage of total procedures based on 2020 internal data." (Form C Assumptions p. 1). Frankly, it is impossible to determine what this sentence means. Having stated that SFY 2020 data was itself "normalized," it is unclear how UNC derived its "normalized" 2021 data based on 2020 volumes. UNC is therefore applying an unreasonable growth rate to an unsupported baseline volume. The resulting volume projections and financial pro formas are unreasonable.

## ***Patient Origin***

### **Criterion 3 and Criterion 9**

As discussed above, on p. 46 in Section C, UNC projects that 45% of its patients will come from "other counties," without any specificity as to the county or HSA. Simply lumping nearly half of all patients into "other" fails to adequately identify the population to be served.

Despite this lack of specificity in Section C, in Section J UNC states, without supporting data, that only 3.1% of patients will be from outside the same or adjacent HSAs. There is no basis for this representation provided in the application. Accordingly, UNC has failed to provide information sufficient to evaluate conformity with Criterion 9.

## ***Financial Feasibility***

### **Criterion 5**

For all the reasons set forth above, UNC's volume projections are unsupported and undermine any analysis of financial feasibility.

In addition, UNC acknowledges that it performs CT procedures on one of its PET scanners for which patients receive "two distinct billable procedures." (Form C Assumptions, p. 2). It does not make clear whether it will also use the proposed equipment to perform CT-only scans. Either way, the financial pro formas apparently ignore the expenses and revenues for the CT procedures performed on the existing and proposed equipment.

## ***Regulatory Criteria***

UNC fails to meet the performance thresholds for PET scanners appear at 10A NCAC 14C.3703.

UNC attempts to demonstrate conformity with the required historical threshold by relying on "normalized" data rather than actual data for the year prior to submission of the application as required by the applicable regulation. There is a brief mention at page 3 of the Form C Assumptions that UNC actually provided only 3991 PET procedures in FY 20, falling short of the required 2080 procedures per machine (based on 2 machines). Duke is not aware that UNC sought a declaratory ruling or other amendment to this regulation to excuse it from having to meet its express requirements as to historical utilization.

UNC also failed to document the historical and projected utilization on its PET-MR scanner. The performance standard applies to "existing dedicated PET scanners, excluding those used exclusively for research." There is no exclusion for PET-MR scanners as opposed to PET-CT scanners; both are, in fact "dedicated PET scanners." Moreover, as set forth above, UNC applied for, and obtained, CON approval to use the PET-MR equipment for clinical PET procedures, and UNC reports such procedures on its annual license renewal applications. Even using UNC's "normalized" data demonstrates that it did not meet the historical performance threshold for all of its PET scanners.

## ***Comparative Analysis***

For all the reasons set forth above, UNC's application is nonconforming with several review criteria. Similarly, UNC's application should not prevail in any comparison with Duke's own application for a PET-CT scanner at Duke University Hospital in the same review. While each facility already has 2 fixed PET-CT scanners, Duke's fixed PET-CT scanners are more highly utilized, and UNC also has a fixed PET-MR scanner on the same campus available to provide PET

capacity. In addition, Durham County is more populous and faster growing than Orange County. Therefore, Duke's Durham County location provides increased access to more patients. In addition, as discussed above, the UNC system already has additional capacity available in a previously approved, but undeveloped, PET-CT scanner, making the Duke project comparatively superior in terms of improving access and increasing patient choice for patients throughout the health service area. Finally, UNC's costs and revenues per procedure and payor mix are unreliable due to unsupported volume projections and lack of specificity about PET v. CT procedures performed on its equipment.



**Certificate of Need  
Progress Report Form**

County: Wake \_\_\_\_\_ Date of Progress Report: 7/1/2021 \_\_\_\_\_  
Facility: Rex Hospital, Inc. \_\_\_\_\_ Facility ID #: 953429 \_\_\_\_\_  
Project ID #: J-11659-19 \_\_\_\_\_ Effective Date of Certificate: 6/1/2019 \_\_\_\_\_

Project Description: Acquire a second fixed dedicated PET scanner pursuant to the need determination in the 2019 SMFP.

**A. Status of the Project**

1. Describe in **detail** the **steps taken** to complete the project since the CON was issued or since the last progress report was submitted. **Inadequate responses to this question will result in the certificate holder being asked to redo the progress report.**

As explained in previous progress reports, the COVID-19 pandemic has imposed some delays on this project. Based on the diversion of resources to the COVID-19 response and recovery efforts, development of this additional fixed PET scanner has been delayed. Although a purchase order has already been issued and Rex remains committed to acquisition of the scanner and development of the project, Rex anticipates further delays of up to a year. Rex has reassessed the project and has tentative plans to resume the project later this summer.

2. Identify all changes to this project approved after the issuance of the certificate, including:
  - a. Cost Overruns and/or Changes of Scope (Include the Project ID #s);
  - b. Material Compliance determinations; and
  - c. Declaratory Rulings

Not applicable.

3. If the project is not going to be developed exactly as approved (including the previously approved changes identified in #2 above), describe all differences between the project as approved and the project as currently proposed. Such changes include, but are not limited to, changes in the:
  - a. Site;
  - b. Design of the facility;
  - c. Number or type of beds to be developed;
  - d. Medical equipment to be acquired;
  - e. Proposed charges; and
  - f. Capital cost of the project.

Not applicable.

4. Pursuant to N.C. Gen. Stat. § 131E-181(d), the Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) cannot determine that a project is complete until “the health service or the health service facility for which the certificate of need was issued is licensed and certified and is in material compliance with the representations made in the certificate of need application.” To document that new or replacement facilities, new or additional beds or dialysis stations, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate sections within the Agency and the Centers for Medicare and Medicaid Services (CMS).

**B. Timetable**

1. Complete **the following table**. The first column **must** include the timetable dates found on the certificate of need. If the Agency has previously authorized an extension of the timetable in writing, you may substitute the dates from that letter in the first column.
2. **Are you requesting a timetable extension?**  Yes  No If the answer is **yes**, enter your proposed completion dates in the third column of the table below. **Proposed completion dates are contingent upon Agency approval.**
3. Explain **the reason(s) for the delay in development**: See response to A. 1. Above. Rex has not changed the dates in this table from the previous progress report. An updated timetable will be proposed as soon as possible after more certainty and reliability surrounding the timeline can be obtained.

Project Milestones	Projected Completion Date from Certificate	Actual Completion Date	Proposed Completion Date*
	mm/dd/yyyy	mm/dd/yyyy	mm/dd/yyyy
Drawings Completed	10/25/2019		
25% of Construction / Renovation Completed (25% of the cost is in place)	1/13/2020		
Construction / Renovation Completed	6/1/2020		
<b>Services Offered (Required)</b>	7/1/2020		
Final Annual Report Due	10/1/2023		

\*Proposed completion dates are contingent upon Agency approval.

**C. Medical Equipment Projects** – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in N.C. Gen. Stat. § 131E-176(14o); 2) the specific equipment listed in G.S. 131-176(16); or 3) equipment that creates a diagnostic center as defined in N.C. Gen. Stat. § 131E-176(7a), provide the following information for each piece or unit of equipment:

- 1) Manufacturer
- 2) Model
- 3) Date Acquired

Purchase Order has been issued and has already been provided as an exhibit in a previous progress report.

**D. Capital Expenditure**

1. What is the total approved capital cost of the project indicated on the certificate of need?  
\$4,206,352
2. Complete the table below and provide supporting documentation, which may include:
  - a. Copies of executed purchase orders for major medical equipment (as defined in N.C. Gen. Stat. 131E-176(14o)), MRIs, PET scanners, Cath equipment, linacs or simulators, etc. If you previously provided them, you do not need to provide another copy.
  - b. If applicable, copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Purchase Price of Land		
Closing Costs		
Site Preparation		
Construction/Renovation Contract(s)		
Landscaping		
Architect / Engineering Fees		
Medical Equipment		\$2,352,850
Non-Medical Equipment		
Furniture		
Consultant Fees (specify)		
Financing Costs		
Interest during Construction		
Other (specify)		
<b>Total Capital Cost</b>	\$0	\$2,352,850

3. What is the projected remaining capital expenditure required to complete the project? \$1,853,502
4. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference.  
The total cost is not projected to exceed 115% of the CON approved capital expenditure.

**E. Certification** – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief. In addition, I acknowledge that incomplete progress report forms **will not** be accepted and **must** be resubmitted upon notification from the Agency Project Analyst.

Signature:

*Elizabeth Runyon*

Name and Title

Elizabeth Runyon, System Director of Regulatory Affairs, UNC HCS

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